



The Roadmap for
European CAM Research

A pan-European research network for Complementary and Alternative Medicine (CAM)

Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebø)

Legal status and regulation of CAM in Europe

Part I - CAM regulations in the European countries

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Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebo)

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CAMbrella – A pan-European research network for Complementary and Alternative Medicine (CAM)

The goal of this collaboration project was to look into the present situation of CAM in Europe in all its relevant aspects and to create a sustained network of researchers in the field that can assist and carry through scientific endeavours in the future. Research into CAM – like any research in health issues – must be appropriate for the health care needs of EU citizens, and acceptable to the European institutions as well as to national research funders and health care providers. It was CAMbrella's intention to enable meaningful, reliable comparative research and communication within Europe and to create a sustainable structure and policy.

The CAMbrella network consists of academic research groups which do not advocate specific treatments. The specific objectives were

- To develop a consensus-based terminology widely accepted in Europe to describe CAM interventions
- To create a knowledge base that facilitates our understanding of patient demand for CAM and its prevalence
- To review the current legal status and policies governing CAM provision in the EU
- To explore the needs and attitudes of EU citizens with respect to CAM
- To develop an EU network involving centres of research excellence for collaborative research.

Based on this information, the project created a roadmap for research in CAM in Europe. The roadmap sums up and streamlines the findings of the whole project in one document that aims to outline the most important features of consistent CAM research at European level.

For other reports of the CAMbrella project which are also available on <https://phaidra.univie.ac.at/> see the additional information on the description data (meta-data) of this report.

Foreword

CAMbrella Work Package 2 (WP2) - Legal Status and regulation of CAM in Europe

This report is developed by WP2 in the CAMbrella consortium in the period January 1, 2010 to April 30, 2012, and has been updated in the period from May to October 2012. The present report represents the updated version from November 5, 2012.

The aim of this work package was to review and describe in all 27 EU member states as well as 10 associated states (later expanded with two additional countries):

- The legal status of CAM
- The regulatory status of CAM practices
- The governmental supervision of CAM practices
- The reimbursement status of CAM practices and medicinal products
- The regulation of CAM medicinal products

An additional aim was to review at the EU level:

- The status of EU-wide regulation of CAM practices and medicinal products
- The potential obstacles for EU-wide regulation of CAM practices and medicinal products

The country-specific status has been described on the basis of publicly available legal and regulatory documents supplemented by personal visits to a purposive sample of countries. The status with regard to regulation of CAM medicinal products and the EU-wide regulation of CAM has been described on the basis of publicly available legal and regulatory documents only.

The work of WP2 **Legal status and regulation of CAM in Europe** is presented in **three separate reports**:

1. **Part I - CAM regulations in the European countries** ([present report](#))
2. Part II - Herbal and homeopathic medicinal products
3. Part III - CAM regulations in EU/EFTA/EEA

All reports are available on <https://phaidra.univie.ac.at/>.

Tromsø, Norway, November 5, 2012

On behalf of WP2 in CAMbrella,

Solveig Wiesener and Vinjar Fønnebø

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Summary

This report describes in 27 EU member states and 12 associated states the legal and regulatory status of complementary and alternative medicine (CAM), the governmental supervision of CAM practices as well as the reimbursement status of CAM practices.

The European Parliament (Resolution A4-0075/97) and The Parliamentary Assembly of the Council of Europe (Resolution 1206(1999)) have both passed resolutions recommending a stronger harmonization of, what they call, non-conventional medicine in Europe.

The EU has, however, repeatedly confirmed that it is up to each member state to organize and regulate their health care system. This will, of course, also apply to CAM. Despite this, the recent Cross-border Healthcare Directive 2011/24/EU together with other Directives indirectly encourage some degree of harmonization, and can limit how diverse European health care can be. CAM practitioners can be registered in the European Commission database of regulated professions, and patients will probably have certain rights according to the Cross-border Healthcare Directive.

Data underlying this report were collected from the 39 countries by communicating with the Ministries of Health, Law or Education, governmental representatives, and members of national CAM associations. A search was performed in the national web sites/databases to identify official law documents. The scientific as well as the non-scientific literature were also searched for documents and websites describing CAM regulation in each of the 39 countries. We also collected information from European CAM associations/coalitions, CAMbrella members and stakeholders. In addition a search was performed in the websites/databases EUROPA and EUR-lex to identify European Union official legal documents. Personal visits, including meetings with the Ministries of Health and CAM practitioners representing organizations, were made to four countries. Health authorities (if possible both legal and regulatory) were asked to verify the situation described for their specific country.

To compare the 39 countries we have classified CAM legislation and regulations into the following categories:

1. CAM general legislation.
2. Specific CAM legislation (name of treatment/practice).
3. EU title (registered in the EU regulated professions database, Directive 2005/36/EC)(7).
4. National protected title.
5. Statutory register.

Twelve common treatment modalities have been described in detail in each country.

CAM treatment is in general either unregulated or regulated within the framework of the public health system. The only common factor we have found across all 39 nations is the

amazing ability they have demonstrated of structuring legislation and regulation differently in every single country, no matter how small the size of the population.

Nineteen of 39 countries have a general CAM legislation, 11 of these have a specific CAM law and 6 countries have sections on CAM included in their health laws (like “Law on health care” or “Law on health professionals”). In addition to the general CAM legislation some countries have regulations on specific CAM treatments.

The twelve treatment modalities vary considerably with regard to how many countries regulate the profession or practice in some way or another. Acupuncture is regulated in 26 countries, anthroposophic medicine in 7 countries, ayurveda in 5 countries, chiropractic in 26 countries, herbal medicine/phytotherapy in 10 countries, homeopathy in 24 countries, massage in 20 countries, naprapathy in 2 countries, naturopathy in 8 countries, neural therapy in 3 countries, osteopathy in 15 countries, and finally traditional Chinese medicine in 10 countries. This regulatory diversity will influence patients, practitioners and researchers when crossing European borders.

When patients cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers working under a completely different reimbursement system. Every aspect of the current situation can thus be a threat to patient safety. In post-modern Europe where patient choice in health care is seen as a core value, this confusing European market makes any informed treatment-seeking very challenging.

When practitioners cross borders they will encounter a substantial variety of CAM practice in Europe. This raises serious concerns with regard to the predictability, quality and safety of health care delivery to European citizens. When CAM professions in some countries are tightly regulated while the same professional categories in other countries are totally unregulated, an establishment of collegial common ground is very challenging.

When researchers cross borders they will experience that research on efficacy and effectiveness of CAM is severely hampered by the conglomerate of European regulation. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study will therefore be generalisable only within a narrow national or cultural context.

There are in principle two options that can be chosen to achieve a higher degree of harmonization: legislation and regulation at the EU/EEA level or voluntary harmonization. We do not foresee EU/EEA level legislation/regulation in the foreseeable future since the EU repeatedly has upheld its position of leaving this to the individual country. Voluntary harmonization is, however, possible within current legislation. The successful mutual recognition of physiotherapists across Europe shows how this can be done, and could be a potential template for development of harmonized regulation also of CAM professions in Europe.

1 Introduction

The present report constitutes one part of the CAMbrella Work Package (WP) 2 Reports labelled under the superordinate “Legal status and regulation of CAM in Europe”(1). The present part I provides an overview on “**CAM regulations in the European countries**” and describes the legal, regulatory, supervisory and reimbursement status of CAM in Europe. The report describes how CAM-related issues are regulated in 39 European countries. Regulation of CAM medicinal products will be described in WP2 Report part II - “Herbal and homeopathic medicinal products”(2). The EU/EFTA/EEA regulations are described in WP2 Report part III – “CAM regulations in EU/EFTA/EEA”(3).

2 Aim

The objectives covered in this report are to review in 27 EU member states and 12 associated states:

- The legal and regulatory status of CAM.
- The governmental supervision of CAM practices.
- The reimbursement status of CAM practices.

3 National legislation and adjustments to EU regulations

3.1 Countries included in the report and their legal connection to EU

The report covers 27 EU member states as well as 12 associated states. Each state is influenced by EU legislation and has adjusted national legislation to EU regulations depending on their connection to the EU.

Table 3.1.1 Country membership (X) to EU/EEA/EFTA, Council of Europe and FP7 (Seventh Framework Programme)

| Countries | EU | EEA | EFTA | Schengen | The Council of Europe |
|------------------------|--------------------------|----------------------|-----------------|----------|-----------------------|
| Albania | Potential candidate, FP7 | | Trade agreement | | X |
| Austria | X 1995 | X | | X 1997 | X |
| Belgium | X | X | | X 1995 | Founding member (FM) |
| Bosnia and Herzegovina | Potential candidate, FP7 | | | | X |
| Bulgaria | X 2007 | X | | | X |
| Croatia | Candidate, FP7 | | Trade agreement | | X |
| Cyprus | X 2004 | X | | | X |
| Czech Republic | X 2004 | X | | X 2007 | X |
| Denmark | X | X | | X 2001 | FM |
| Estonia | X 2004 | X | | X 2007 | X |
| Finland | X 1995 | X | | X 2001 | X |
| France | X | X | | X 1995 | FM |
| Germany | X | X | | X 1995 | X |
| Greece | X | X | | X 2000 | X |
| Hungary | X 2004 | X | | X 2008 | X |
| Iceland | Candidate, FP7 | X | X | X 2001 | X |
| Ireland | X | X | | | FM |
| Israel | FP7 | | Trade agreement | | - |
| Italy | X | X | | X 1997 | FM |
| Latvia | X 2004 | X | | X 2007 | X |
| Liechtenstein | FP7 | X | X | | X |
| Lithuania | X 2004 | X | | X 2007 | X |
| Luxembourg | X | X | | X 1995 | X |
| Macedonia | Candidate, FP7 | | Trade agreement | | X |
| Malta | X 2004 | X | | X 2007 | X |
| Montenegro | Candidate, FP7 | | | | X |
| Netherlands | X | X | | X 1995 | FM |
| Norway | FP7 | X | X | X 2001 | FM |
| Poland | X 2004 | X | | X 2007 | X |
| Portugal | X | X | | X 1995 | X |
| Romania | X 2007 | X | | | X |
| Serbia | Potential candidate, FP7 | | Trade agreement | | X |
| Slovakia | X 2004 | X | | X 2007 | X |
| Slovenia | X 2004 | X | | X 2007 | X |
| Spain | X | X | | X 1995 | X |
| Sweden | X 1995 | X | | X 2001 | FM |
| Switzerland | FP7 | bilateral agreements | X | X 2008 | X |
| Turkey | Candidate, FP7 | | Trade agreement | | X |
| United Kingdom | X | X | | | FM |

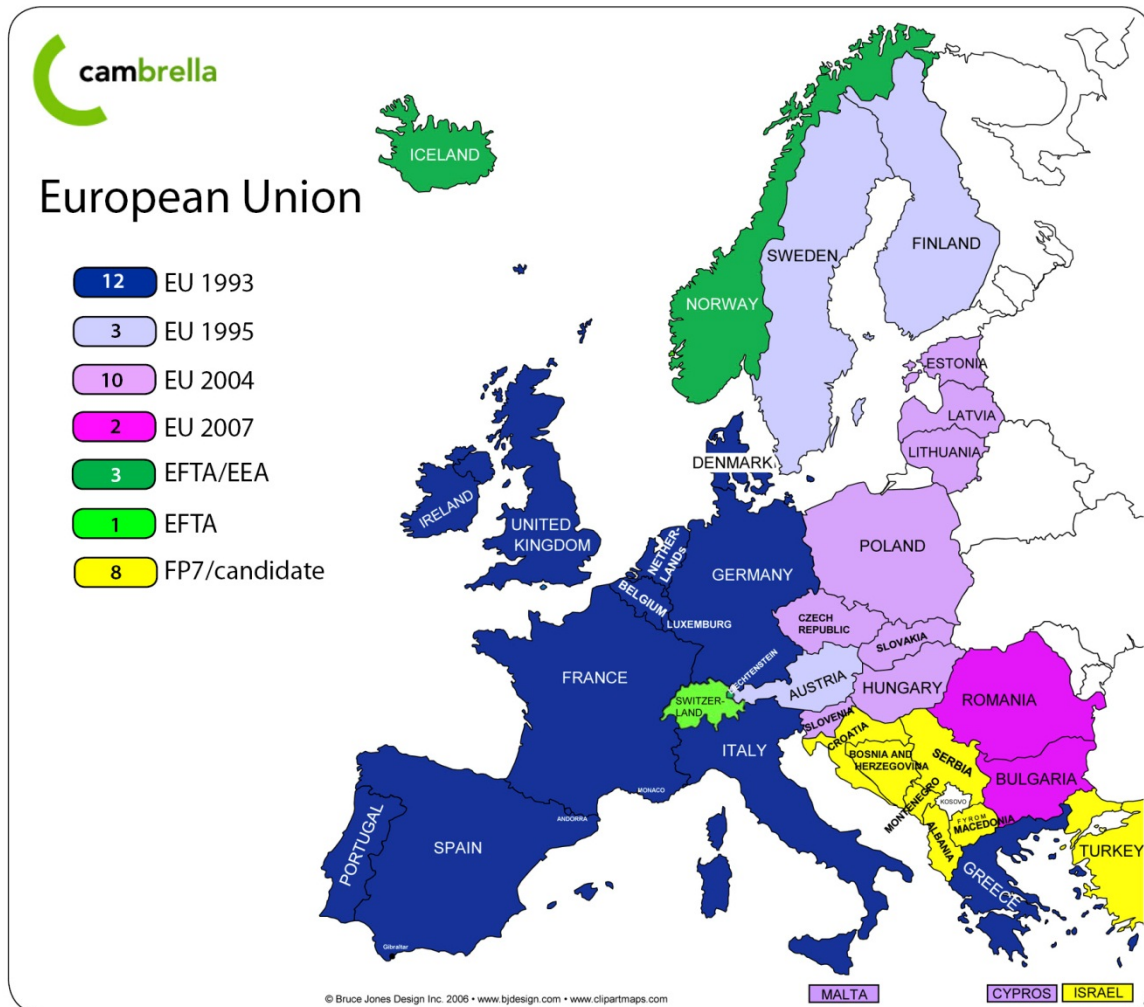


Figure 3.1.1 Country relationship to the European Union map

3.2 How EU legislation influences national CAM legislation

The EU Treaties have repeatedly established that **health policy is a national responsibility** for the member states. This is adjusted and confirmed in the Lisbon Treaty in TITLE XIV Public Health Article 168 number 7(4): ***“7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood”.***

This statement is important to keep in mind when describing national legislation and regulation of CAM. Despite the statement, the following EU Directives and Regulations can potentially influence national legislation regarding CAM practices, treatments and patients’ rights and safety:

- The “Professional qualifications Directive” 2005/36/EC of 7 September 2005, on the recognition of professional qualifications(5).
- The “Patient Rights Directive” 2011/24/EU of 9 March 2011, on the application of patients' rights in cross-border healthcare(6).

3.2.1 Professional qualifications

The Directive 2005/36/EC is the legal basis for free movement of professionals in Europe. A profession is considered regulated when access to it and the exercise of it are subject to the acquisition of a specific professional qualification(5). The Directive 2005/36/EC states that *“it should be laid down that any host Member State in which a profession is regulated must take account of the qualifications obtained in another Member State and assess whether they correspond to those which it requires”*.

The European Commission database of regulated professions in the EU Member States, EEA countries and Switzerland has been established on the basis of Directive 2005/36/EC. The database includes professions falling under the **“General System” of mutual recognition** of professional qualifications, and the **“Sectorial professions”** giving **automatic recognition** on the basis of harmonization of minimum training requirements for: **doctors, nurses, midwives, pharmacists, dentists, veterinary surgeons and architects(7)**. Some states have CAM professions registered in the European Commission database of regulated professions.

3.2.2 “Patients’ rights in cross-border healthcare” Directive 2011/24/EU

This Directive describes the patients’ rights with regard to access safe and good quality treatment and to be reimbursed for it. Patients should experience equal treatment with the citizens of the country in which they are treated and the treatment shall be based on quality and safety standards of healthcare (Memo/11/32 Brussels 19 Jan 2011 Press release)(6).

This Directive can bear influence on CAM practices and CAM patients whether the specific treatment/practitioner is registered as conventional or non-conventional in the country of interest. We have not found that CAM treatment has been an important subject of interest in the cross-border healthcare legislation in the member states.

4 Methods

Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary between the 39 countries included in this report. As an introduction we made a comprehensive overview of matters that may influence CAM in national legislation.

Data were collected from 39 countries by communicating with the Ministries of Health, Law or Education, governmental representatives, and members of national CAM associations. A search was performed in the national web sites/databases to identify official law documents. The scientific as well as the non-scientific literature were also searched for documents and websites describing CAM regulation in each of the 39 countries.

We collected information from European CAM associations/coalitions (Listed in attachment 1) and CAMbrella members and stakeholders with the help of e-mail, telephone conferences as well as meetings/conferences in **Brussels, Berlin, Bologna and Birmingham**.

In addition a search was performed in the websites/databases EUROPA and EUR-lex to identify European Union official legal documents. Details of this process can be found in the WP2 Report part III – “CAM regulations in EU/EFTA/EEA”(3).

A questionnaire developed by the Pecs Tudományegyetem – University of Pecs (Hungary) (PTE) member of the CAMbrella WP2 group was used to gain information from some of the countries in the eastern part of Europe.

Personal visits, including meetings with the Ministries of Health and CAM practitioners representing organizations, were made to the following countries:

- **Bosnia & Herzegovina** (Federation of Bosnia and Herzegovina (FBiH) (Banja Luka) and Republika Srpska (RS) (Sarajevo)),
- **The Czech Republic** (Prague),
- **Hungary** (Budapest),
- **Montenegro** (Podgorica and Igalo).

These countries were selected on the basis of a need to double-check printed information and collecting information in countries where printed information was not readily available.

Health authorities (if possible both legal and regulatory) were asked to verify the situation described for their specific country. For some countries the English phrasing of the legal and regulatory situation can be challenging. The legal regulation of CAM is often a controversial political matter, and some countries have therefore preferred to retain the description of their situation in its presented version.

4.1 The legal and regulatory status of CAM and CAM practices

This report has a focus on the legal and regulatory issues applicable when practitioners provide treatment to individuals with a disease condition. Legal and regulatory issues with regard to health counsellors are not covered unless these groups are inseparable from other practitioners.

We have not reviewed in detail regulations for dentists, veterinary surgeons, pharmacists, midwives and nurses.

4.1.1 CAM legislation

National CAM/health legislation and regulations often include guidelines outlining the conditions for being allowed **to treat patients** with CAM. These can consist of educational and/or training requirements, and systems for **authorizations and licences**. Requirements for **registers** and **self-regulation** are often included when regulating the practices. **Self-regulation** can be required to **be statutory or voluntary**. The level of **education and training** can be **statutory regulated or voluntary**.

The legal status of CAM treatments and practices are regulated through:

- General CAM legislation by law or governmental regulation.
- General laws and governmental regulations on health care (conventional and CAM).
- Regulation of specific CAM practices and treatments.
- No CAM-specific legislation or regulation. In those situations CAM practices and treatments are indirectly regulated through other laws and regulations like the **criminal code, education, social security, finance and health insurance (reimbursement)**.

In the country-specific reviews we have concentrated on:

- **The first legislative level:** laws passed by the national Assembly/Parliament.
- **The secondary legislative level:** bylaws, national/governmental regulations – mostly designed by the Ministries.
- **Supervision** regulations.
- **Reimbursement** regulations.
- **Regulations of professional authorizations, licences and titles** (including when delegated to professional member associations).
- **Regulations of professional registers** – statutory or voluntary.

4.1.2 Practitioners of CAM

Regulation of practice is in general mostly tied to formal education and/or training in conventional or non-conventional medicine.

Regulated professions who practise CAM are often divided into:

4.1.2.1 Health professionals:

A. Medical Doctors (MDs)

We found different classifications: medical doctor, medical doctor with CAM education, medical doctor with CAM licence, medical doctor with CAM authorization, physician, CAM physician, or allopathic doctor.

In this report we will use the term **medical doctor or physician with/without CAM training** to cover these categories. When referring to legislation we will use the terminology found in the documents.

B. Other health professionals

In most cases these are conventional health personnel with an educational level of 3-5 years. Nurses and midwives are the health professions most commonly represented in this category. We also found physiotherapist, chiropractor, manual therapist, osteopath, masseur, naprapath and other titles in national legal documents, in some countries regulated as health personnel, in others as CAM practitioners.

In this report we use the term “(regulated) health personnel” with/without CAM training or the specific profession mentioned by name. Medical doctors will be included in this category if the regulation includes both medical doctors and other health professionals in the same regulatory documents.

4.1.2.2 Other CAM practitioners

This category includes CAM practitioners with a short or no medical education or training. Classifications that we have found in the legislation include medically trained personnel (less than 3 years), non-medical personnel, paramedics, non-professional health worker, acupuncturist, herbalist, homeopath and other CAM practitioners.

Germany, Switzerland and Liechtenstein have established a category called “Heilpraktiker” or “Naturheilpraktiker”. This is a model where non-medical practitioners of CAM need to obtain a legal qualification as “Heilpraktiker” or “Naturheilpraktiker” in order to practice CAM. In Germany a “Heilpraktiker” must pass a public exam in conventional medicine subjects and register in order to get the licence to practise. Iceland has chosen a similar model where these practitioners are called “natural health practitioners”.

To compare the 39 countries we have classified CAM legislation and regulations into the following categories:

1. CAM general legislation.
2. Specific CAM legislation (name of treatment/practice).
3. EU title (registered in the EU regulated professions database, Directive 2005/36/EC)(7).
4. National protected title.
5. Statutory register.

5 Thirty-nine countries – a summary

Each country report includes:

- The legal and regulatory status of CAM and CAM practices.
- The governmental supervision of CAM Practices.
- The reimbursement status of CAM practices.
- 12 specified CAM treatments (plus “other treatments”).

Several countries have established new legislation/regulation or adjusted their old legislation/regulation over the recent decade. There seems to be a pattern where the countries that joined the EU after 2000 to a greater degree have taken the relevant EU directives as guidance when establishing or adjusting their CAM legislation/regulation. The original EU member states have to a lesser extent adjusted their legislation. The regulation of CAM medicinal products is no longer up to each state to decide, and this is now regulated at the EU level as described in WP2 report part II (2).

In this report we have concentrated on CAM legislation in general and the most common CAM treatments and professionals. Treatments of interest except for the 12 chosen are described under “other treatments”.

5.1 General CAM legislation

17 countries have a general CAM legislation, 11 of these countries with a specific CAM law and 6 countries with CAM sections included in their general health care legislation. In addition to the general CAM legislation some countries have regulations on specific CAM treatments.

Of the 15 **original EU member countries** (joined the EU before 1996), **3 (Belgium, Germany and Portugal)** have a general CAM law. **Denmark** has a “law on a self-regulatory registration system for alternative practitioners”. These 4 countries have additional regulations on specific CAM treatments.

10 of the original EU member countries have regulations on **specific CAM treatments**. (Austria, Denmark, Finland, France, Greece, Italy, Luxembourg, Spain, Sweden, UK). **Ireland** does **not have specific regulations** of any CAM treatment.

All **4 EFTA countries (Iceland, Liechtenstein, Norway and Switzerland)** have a general CAM legislation. Iceland, Liechtenstein and Norway have CAM laws and Switzerland has regulated CAM in their general health care legislation.

3 of the 10 countries who joined the EU in 2004 have a general CAM legislation. **Hungary and Slovenia** have a CAM law and **Malta** have general CAM legislation included in their general health care legislation. The other **7 member countries who joined in 2004 (Cyprus, Czech Republic, Estonia, Latvia, Lithuania, Poland and Slovakia)** have regulations on specific CAM treatments.

The **2 new member** countries that joined the **EU in 2007, Bulgaria and Romania**, have a general CAM legislation as well as specific CAM treatment regulations.

The 4 candidate countries have different regulations. **Macedonia** has a general CAM legislation, but no CAM law. **Turkey** has some specific CAM treatment regulations, and **Croatia and Montenegro** have no CAM regulations. **Montenegro** has a CAM law in progress. (Iceland is also a candidate country, but is in this report included in the EFTA section).

All **3 potential candidate countries** have some general CAM regulations. **Serbia** has a CAM law, **Albania and Bosnia & Herzegovina** have some general CAM regulations within their general health care legislation. **Bosnia and Herzegovina** has a CAM law in progress.

The CAM regulations are either very general or very detailed, and we found no more similarities between the countries that have a CAM law or general CAM legislation than between the countries with only specific CAM treatment regulations. Some of the general regulations are only a specification of what CAM is, often to be supported by additional regulations or specifications issued by the Ministry of Health or the professions' associations. In some countries additional specifications have not been made. As an example both Norway and Hungary have a CAM law. In Norway the CAM law is general without describing in detail the treatments or practitioners, in Hungary the CAM legislation is detailed with specifications similar to how they have regulated the conventional health care system. We found few similarities in the regulations of the specific CAM treatments between the countries, and it is challenging to find out "who are allowed to practise" the different treatments.

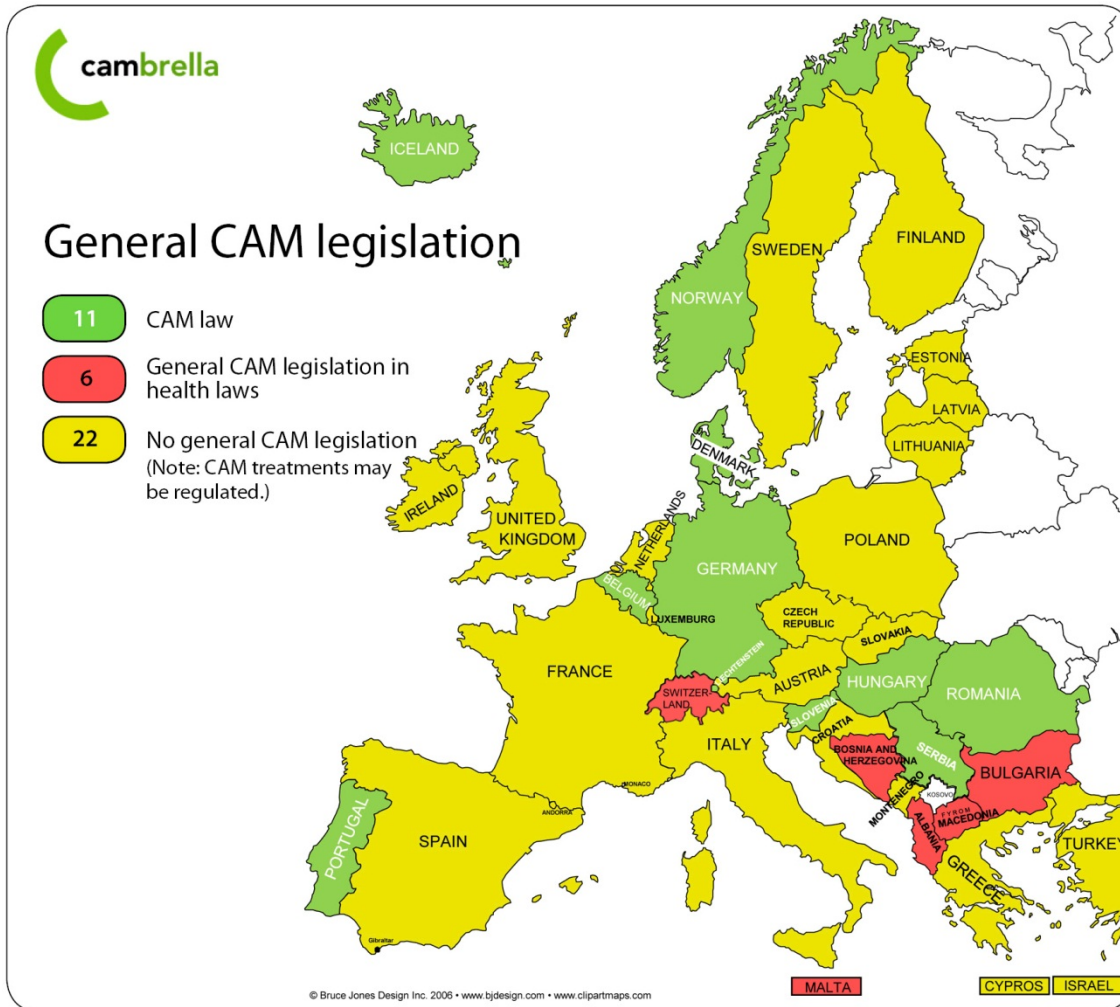


Figure 5.1.1 General CAM legislation map

Table 5.1.1 General CAM legislation - countries

| General CAM legislation | | | |
|-------------------------|--------------------|--|------------------------|
| CAM law (11) | | General CAM legislation in health laws (6) | |
| Belgium | Original EU member | | |
| Denmark | Original EU member | | |
| Germany | Original EU member | | |
| Portugal | Original EU member | | |
| Iceland | EFTA | Switzerland | EFTA |
| Liechtenstein | EFTA | | |
| Norway | EFTA | | |
| Hungary | 2004 EU member | Malta | 2004 EU member |
| Slovenia | 2004 EU member | Bulgaria | 2007 EU member |
| Romania | 2007 EU member | Macedonia | Candidate EU |
| Serbia | Candidate EU | Albania | Potential candidate EU |
| | | Bosnia & Herzegovina | Potential candidate EU |

5.2 Acupuncture

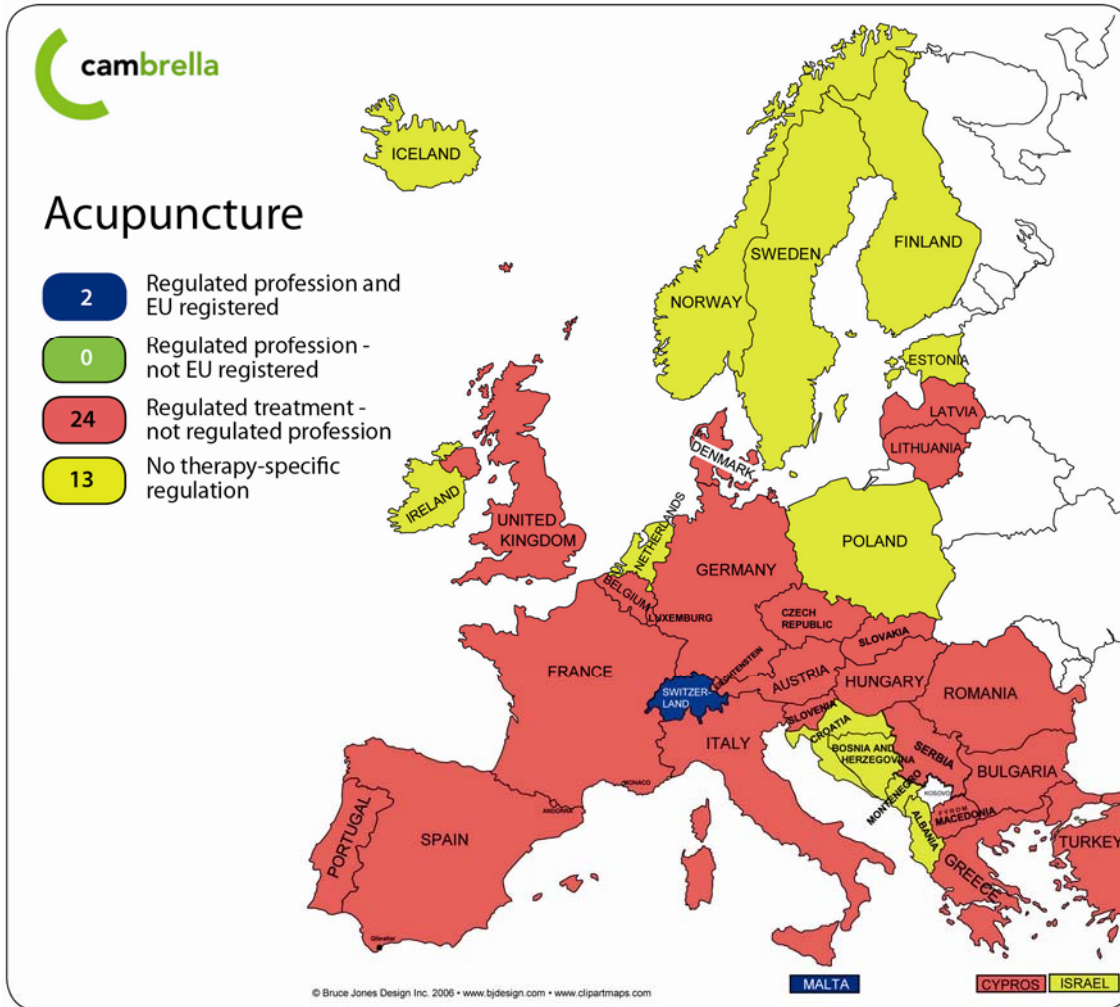


Figure 5.2.1 Acupuncture map

Table 5.2.1 Acupuncture regulations - countries

| Regulated profession and EU registered (2) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (24) | | No regulation (13) |
|--|--|---|------------|--------------------|
| Malta | | Austria | Lithuania | Albania |
| Switzerland | | Belgium | Luxembourg | Bosnia/Herzegovina |
| | | Bulgaria | Macedonia | Croatia |
| | | Cyprus | Portugal | Estonia |
| | | Czech Republic | Romania | Finland |
| | | Denmark | Serbia | Iceland |
| | | France | Slovakia | Ireland |
| | | Germany | Slovenia | Israel |
| | | Greece | Spain | Montenegro |
| | | Hungary | Turkey | Norway |
| | | Italy | UK | Poland |
| | | Latvia | | Sweden |
| | | Liechtenstein | | The Netherlands |

Acupuncture is mostly regulated as a treatment that may or may not be provided by regulated health professionals or other CAM practitioners. 2 countries (**Malta and Switzerland**) have a regulated profession named “**acupuncturist**”, which for both countries is registered in the EU database for regulated professions. In some countries acupuncture treatment may be provided in conventional healthcare (also in hospitals).

24 countries have **acupuncture treatment regulations**. Some countries have clear regulations about who may treat patients with acupuncture and educational minimum standards. Other countries have more general regulations. In about half of the countries only doctors may provide acupuncture treatment. In many of these countries only doctors with specific acupuncture training may practise. In countries with acupuncture regulations there is a mixture of regulations for regulated health professionals and CAM practitioners with or without medical education and CAM training. In some countries regulation is delegated to the professional associations. Some countries use the terminology “**medical acupuncturist**” (Germany) or “**additional medical qualification**” for doctors or other regulated health professionals (like physiotherapists, nurses, midwives). We have listed these as regulations for acupuncture treatment, not as a regulated profession.

13 countries have no specific acupuncture regulations. However, **3 of those countries (Albania, Iceland, Norway)** have CAM general legislation that influences acupuncture treatment. And most of the countries have conventional health regulations that influence the practice of acupuncture (like health professionals act or law on health care).

It is difficult to compare the countries, and hardly any similarities have been found in the regulations or standards of education and training for practitioners providing acupuncture treatment.

5.3 Anthroposophic medicine

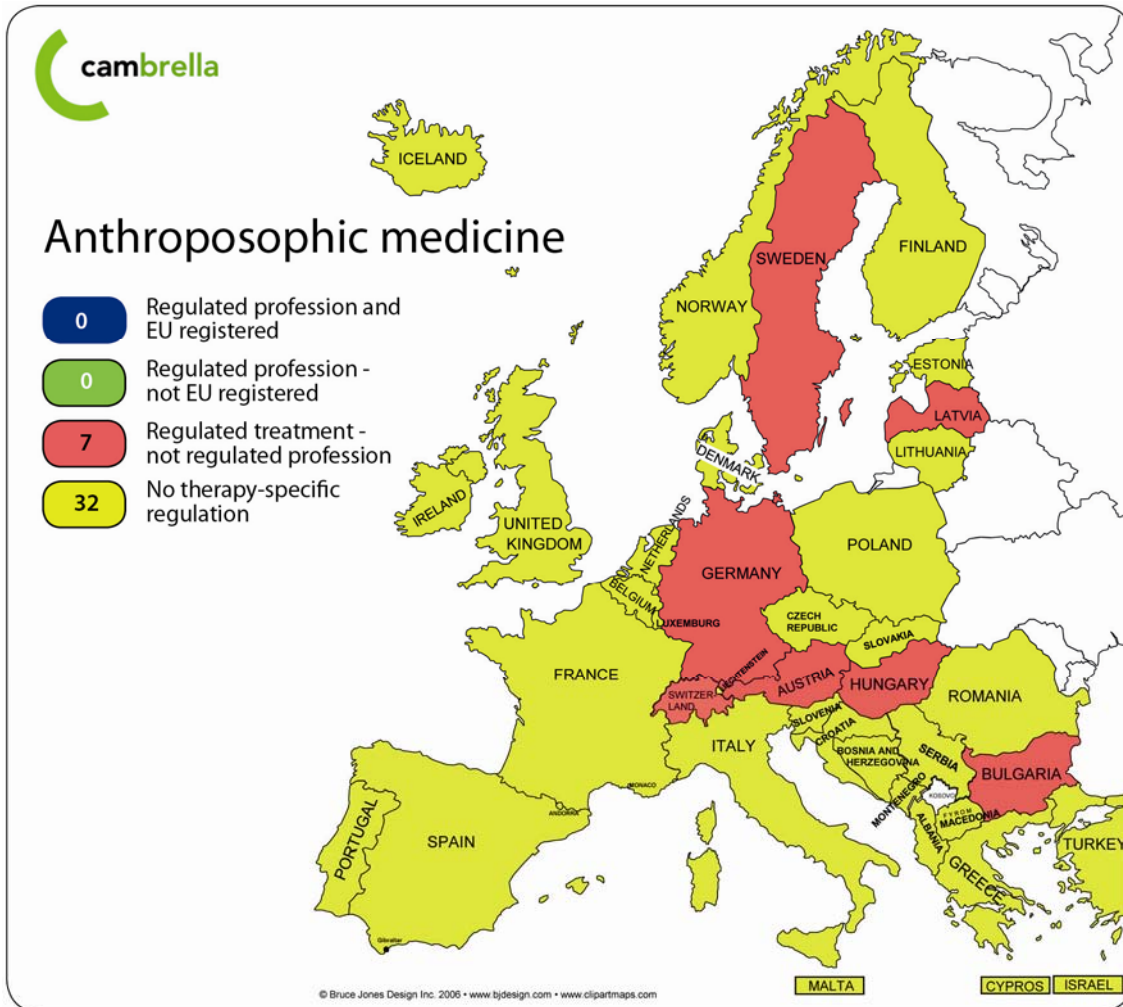


Figure 5.3.1 Antroposophic medicine map

Table 5.3.1 Anthroposophic medicine regulations - countries

| Regulated profession and EU registered (0) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (7) | No regulation (32) |
|--|--|--|--------------------|
| | | Austria | |
| | | Bulgaria | |
| | | Germany | |
| | | Hungary | |
| | | Latvia | |
| | | Sweden | |
| | | Switzerland | |

7 countries have specific regulations on anthroposophic medicine. In **Bulgaria and Latvia** anthroposophic medicine is **statutory registered** as an additional education for medical doctors. In **Austria** diplomas awarded by the Austrian Medical Board **specialise physicians** in anthroposophic medicine. In **Germany** anthroposophic medicine is regulated **by law** as “a

specific therapeutic system”. In **Hungary** medical doctors may provide anthroposophic medicine. In **Sweden** anthroposophy may only be provided at the **Vidar clinic**. In **Switzerland** anthroposophy is recognized as a **specific therapeutic system** and detailed regulations are delegated to **medical and non-medical associations**.

32 countries have no direct regulation of anthroposophic medicine. However, there are probably additional training courses and diplomas awarded by the medical associations in some of these 32 countries. National health regulation influences the practise of anthroposophic medicine in the countries without specific regulation of this treatment.

5.4 Ayurveda

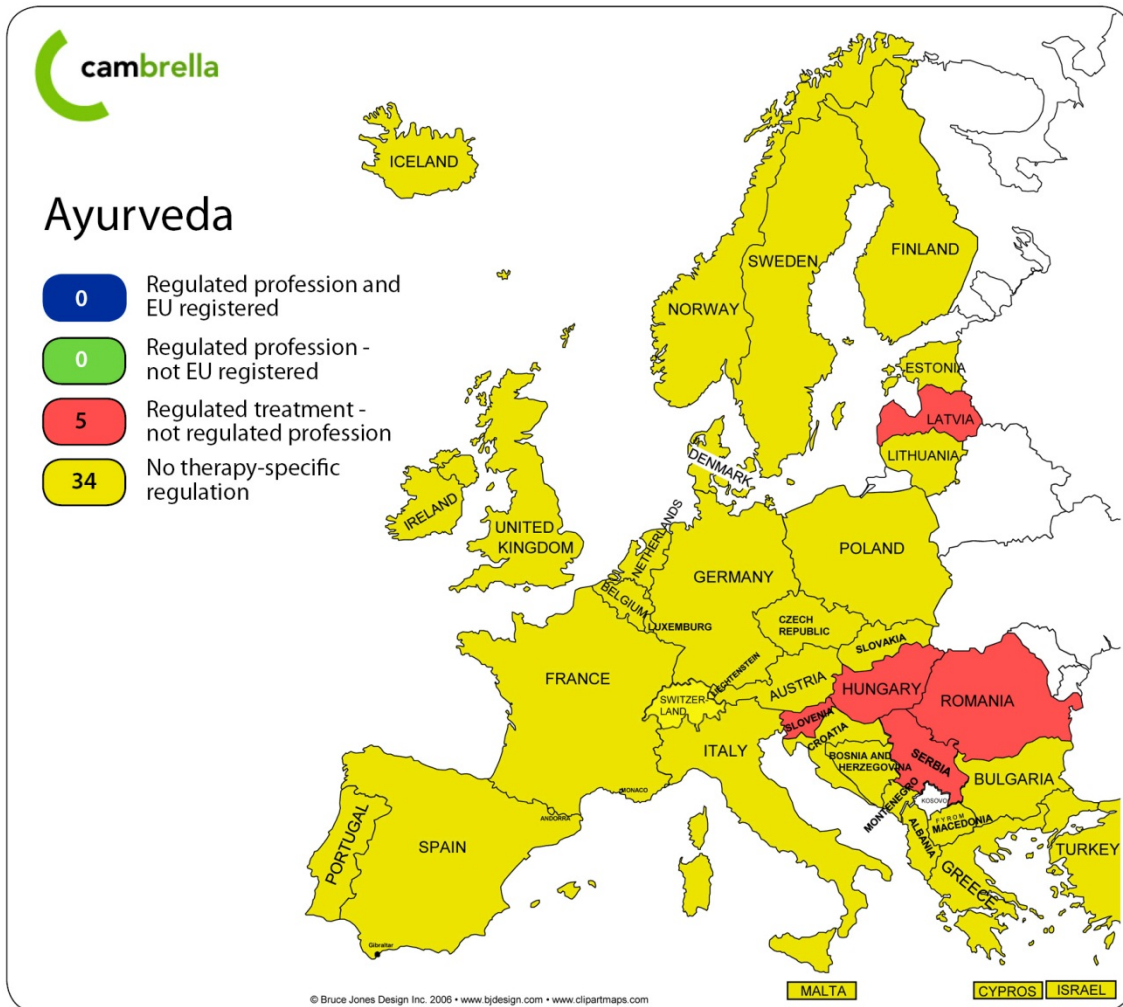


Figure 5.4.1 Ayurveda map

Table 5.4.1 Ayurveda regulations - countries

| Regulated profession and EU registered (0) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (5) | No regulation (34) |
|--|--|--|--------------------|
| | | Hungary | |
| | | Latvia | |
| | | Romania | |
| | | Serbia | |
| | | Slovenia | |

We have found that ayurvedic medicine is directly mentioned in **regulations in 5 out of 39 countries**. In some of the other 34 countries ayurvedic medicine is recognized as a therapeutic system that may be provided by regulated health personnel (often doctors), but not directly mentioned in the regulations.

Hungary has regulated Ayurvedic medicine as “an individual complex medical system” provided only by medical doctors. In **Latvia** ayurvedic medicine has a legal status and was recommended as safe to wide application in the institutions of public health services”. In **Romania** ayurvedic medicine is “legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM”. In **Serbia** the CAM bylaw lists ayurvedic medicine as “a method of treatment suitable for practise”. **Slovenia** has listed ayurvedic medicine in the CAM act as “a CAM system that may be used when carrying out CAM practices”.

5.5 Chiropractic

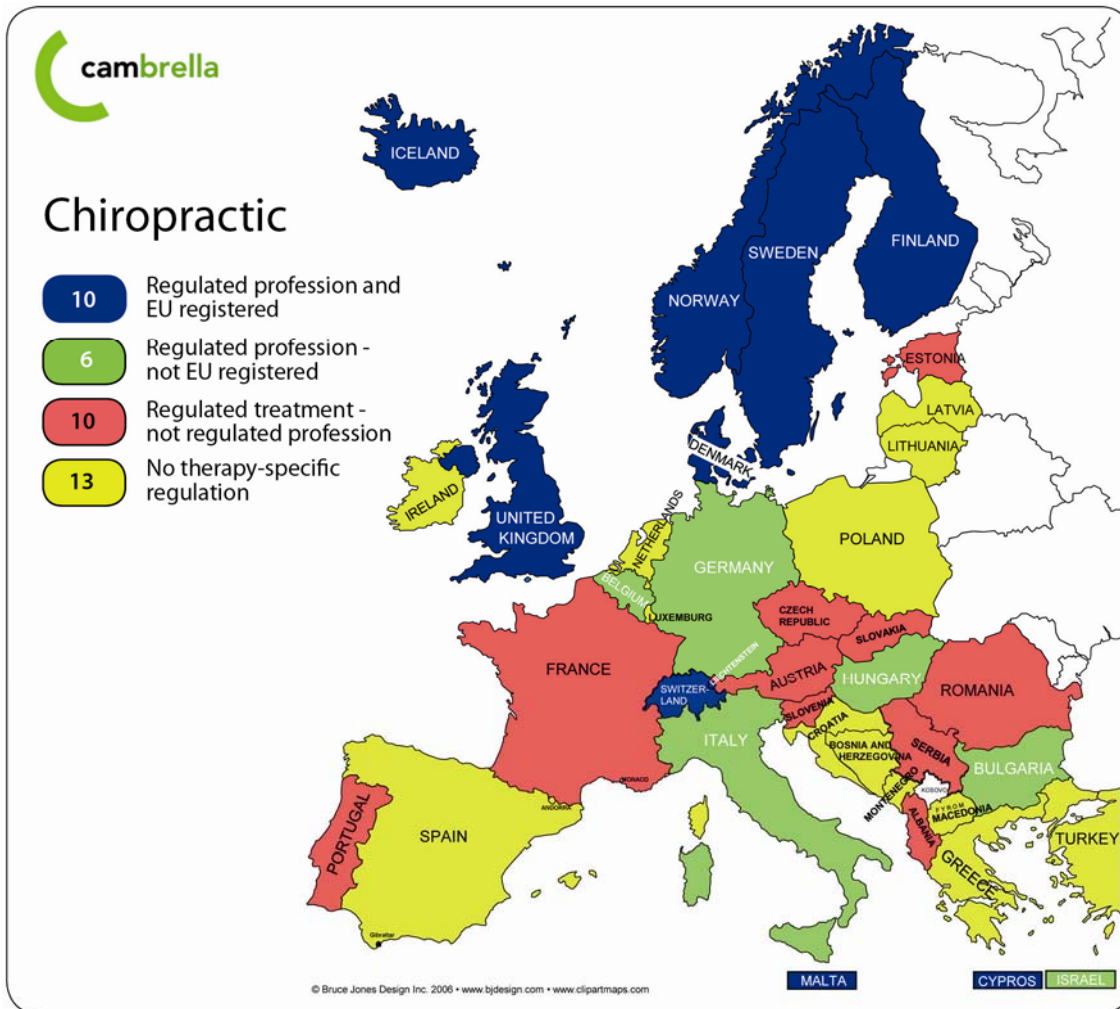


Figure 5.5.1 Chiropractic map

Table 5.5.1 Chiropractic regulations - countries

| Regulated profession and EU registered (10) | Regulated profession Not EU registered (6) | Regulated treatment Not regulated profession (10) | No regulation (13) |
|---|--|---|----------------------|
| Cyprus | Belgium | Albania | Bosnia & Herzegovina |
| Denmark | Bulgaria | Austria | Croatia |
| Finland | Germany | Czech Republic | Greece |
| Iceland | Hungary | Estonia | Ireland |
| Liechtenstein | Israel | France | Latvia |
| Malta | Italy | Portugal | Lithuania |
| Norway | | Romania | Luxembourg |
| Sweden | | Serbia | Macedonia |
| Switzerland | | Slovakia | Montenegro |
| UK | | Slovenia | Poland |
| | | | Spain |
| | | | The Netherlands |
| | | | Turkey |

Chiropractor is a **regulated profession** in **16 of the 39** countries. **10 countries** have also registered chiropractor in **the EU regulated professions database**. Educational and professional regulations differ in these countries, but in most of the 16 countries a chiropractor is recognized as a **conventional health profession**.

10 countries have some regulations on **chiropractic treatment**, but not a regulated profession called chiropractor.

13 countries have **no specific regulation** of chiropractic. However, the treatment may be regulated through CAM general legislation or conventional health legislation.

In some countries chiropractic treatment is regulated as **manual therapies**. In others we found regulations describing that other professionals may treat chiropractic, for example **physiotherapists**.

5.6 Herbal medicine/Phytotherapy

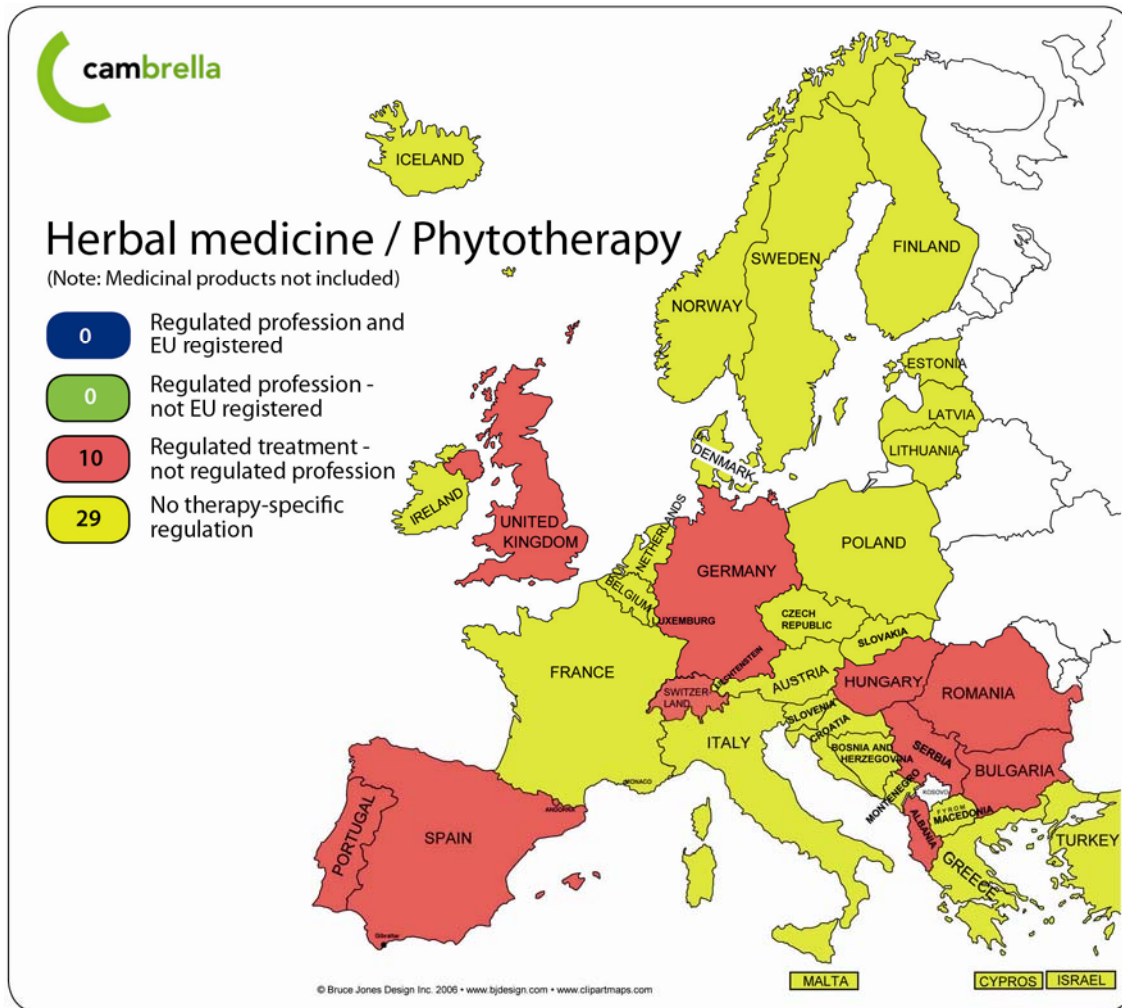


Figure 5.6.1 Herbal medicine/Phytotherapy map

Table 5.6.1 Herbal medicine / Phytotherapy regulations - countries

| Regulated profession and EU registered (0) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (10) | No regulation (29) |
|--|--|---|--------------------|
| | | Albania | |
| | | Bulgaria | |
| | | Germany | |
| | | Hungary | |
| | | Portugal | |
| | | Romania | |
| | | Serbia | |
| | | Spain | |
| | | Switzerland | |
| | | UK | |

Herbal medicine/Phytotherapy as a treatment is directly regulated in **10 of 39 countries**. The regulations of medicinal products are described in the Delivery 9, WP2 Report no. 2. In all 39 countries treatments like Traditional Chinese Medicine (TCM), ayurvedic medicine, homeopathy and others would probably include herbal medicine/phytotherapy treatment regulations.

In **Albania** herbal medicine is regulated in the law on health care as an alternative therapeutic system. **Bulgaria** has educational regulations for herbal medicine providers in the health law. In **Germany** the treatment is common among medical doctors and Heilpraktikers, and regulated by the medicines act as a distinct therapeutic system. In **Hungary** the CAM law regulates Phytotherapy. In **Portugal** phytotherapy is regulated by law on the provision of non-conventional therapies. In **Romania** herbal therapy is recognized as a CAM therapy in the group “herbal practice” in the law on CAM. In **Serbia** the CAM bylaw lists phytotherapy as “a method of treatment suitable for practise”. In **Spain** a new act is in progress, and “nature medicine as a medical act is only allowed to practise by medical doctors”. In **Switzerland** herbal medicine is included in federal laws and detailed regulation is delegated to medical and non-medical associations. In **UK** regulation of herbal medicine practitioners is voluntary. Statutory regulation is in progress.

5.7 Homeopathy

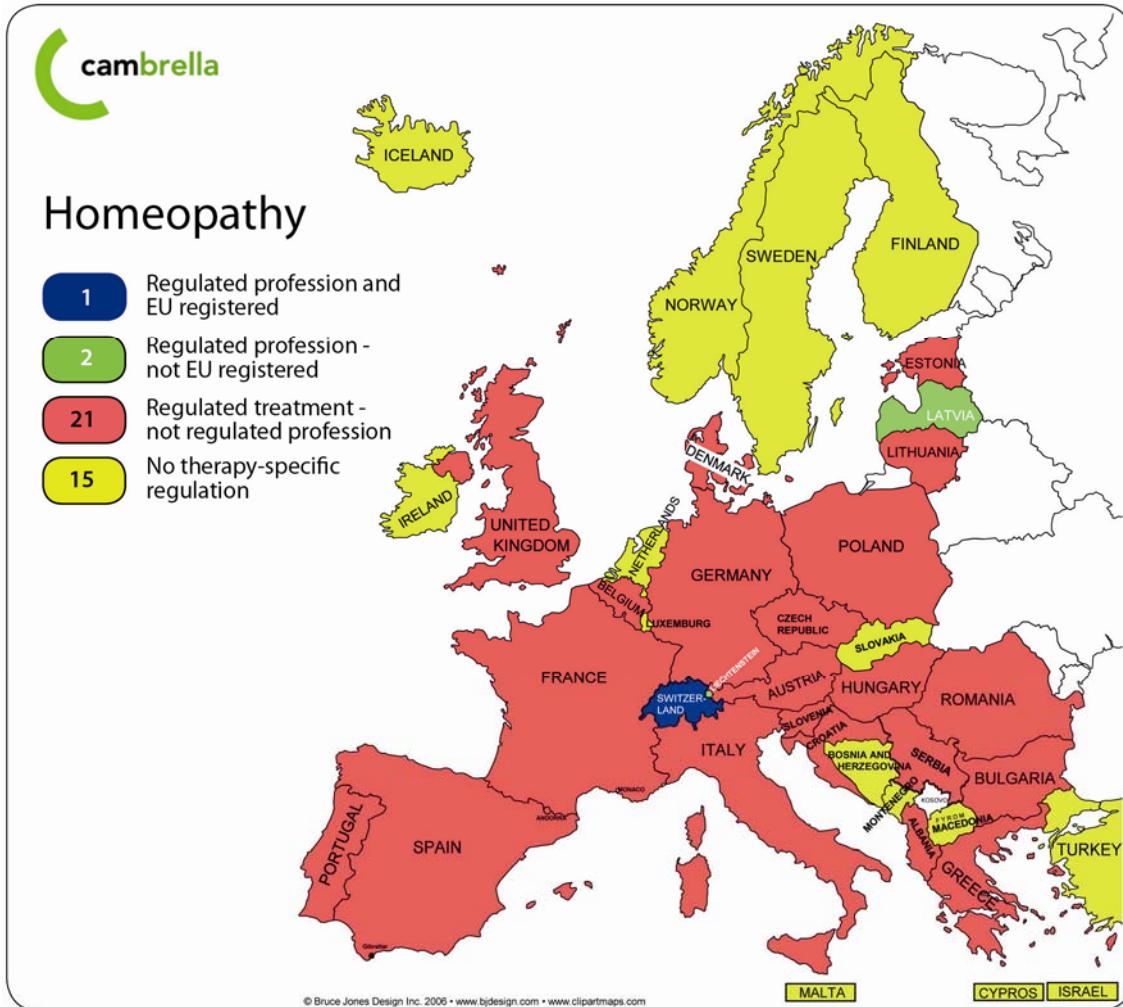


Figure 5.7.1 Homeopathy map

Table 5.7.1 Homeopathy regulations - countries

| Regulated profession and EU registered (1) | Regulated profession Not EU registered (2) | Regulated treatment Not regulated profession (21) | | No regulation (15) |
|--|--|---|-----------|----------------------|
| Switzerland | Latvia | Albania | Hungary | Bosnia & Herzegovina |
| | Liechtenstein | Austria | Lithuania | Cyprus |
| | | Belgium | Italy | Finland |
| | | Bulgaria | Poland | Iceland |
| | | Croatia | Portugal | Ireland |
| | | Czech Republik | Romania | Israel |
| | | Denmark | Serbia | Luxembourg |
| | | Estonia | Slovenia | Macedonia |
| | | France | Spain | Malta |
| | | Germany | UK | Montenegro |
| | | Greece | | Norway |
| | | | | Sweden |
| | | | | Slovakia |
| | | | | The Netherlands |
| | | | | Turkey |

Switzerland has regulated homeopathy and has registered homeopath as a profession in the EU regulated professions database under **“Natural health practitioner”** as **naturopathe/homeopath**.

2 countries (Latvia, Liechtenstein) have regulations that may be seen as **a regulation of a homeopathy profession**. **Latvia** has regulated “homeopathic doctors” **Liechtenstein** has registered “Naturheilpraktiker with a homeopathy specialty”.


21 countries have **regulated homeopathy treatment**. Please read details of country-wide regulations under each country description.

15 countries have **no specific** homeopathic treatment regulations, but general CAM or other health legislation may regulate homeopathic practices.

The table “Homeopathy - Who may practise” is an example of how difficult it can be to understand the consequences of national regulation. We have, to our best knowledge, listed whether the different categories of practitioners in each country are allowed to practise homeopathy. If only medical doctors with CAM additional education are allowed to practise, we have put “No” in the column for medical doctors. This is done in the same way for other health personnel. If the regulation (or absence of regulation) is too unclear for us we have inserted a question mark. The countries with CAM practitioners like Heilpraktiker, Natur heilpraktiker, healer and likewise may not be correctly represented.

We have decided not to introduce this table for other treatments because of the unclear situation.

Table 5.7.2 Homeopathy - Who may practice



Homeopathy - Who may practice

| Country | Specific homeopathy treatment regulation | Medical Doctors (MDs) | Medical Doctors with CAM training | Conventional practitioners (CPs) PS3 ¹ | Conventional health personnel with CAM training | CAM practitioners ² | Other may practice | Other CAM legislation | Notes |
|------------------|--|-----------------------|-----------------------------------|---|---|--------------------------------|--------------------|-----------------------|-----------------------|
| Albania | Yes | ? | ? | ? | ? | ? | ? | Yes | |
| Austria | Yes | Yes | Yes | ? | ? | ? | No | Yes | |
| Belgium | Yes | Yes | Yes | Yes | Yes | ? | No | Yes | |
| Bosnia and Herz. | No | Yes | Yes | ? | ? | ? | No | No | |
| Bulgaria | Yes | Yes | Yes | No | No | No | No | Yes | |
| Croatia | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | |
| Cyprus | No | Yes | Yes | No | No | No | No | Yes | |
| Czech Republic | Yes | No | Yes | No | No | No | No | Yes | |
| Denmark | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Estonia | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | |
| Finland | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| France | Yes | Yes | Yes | Yes | Yes | No | No | Yes | |
| Germany | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Heilpraktiker |
| Greece | Yes | Yes | Yes | Yes | Yes | Yes | ? | Yes | |
| Hungary | Yes | No | Yes | No | No | No | No | Yes | |
| Iceland | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Healer |
| Ireland | No | Yes | Yes | Yes | Yes | Yes | Yes | No | |
| Israel | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Italy | Yes | Yes | Yes | No | No | No | No | Yes | |
| Latvia | Yes | Yes | Yes | No | No | No | No | Yes | |
| Liechtenstein | Yes | Yes | Yes | Yes | Yes | No | No | Yes | |
| Lithuania | Yes | No | Yes | No | No | No | No | Yes | |
| Luxembourg | No | Yes | Yes | ? | ? | No | No | Yes | |
| Macedonia | No | Yes | Yes | ? | ? | ? | ? | Yes | |
| Malta | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Montenegro | No | Yes | Yes | ? | ? | ? | ? | No | |
| Netherlands | No | Yes | Yes | Yes | Yes | Yes | ? | Yes | |
| Norway | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Poland | Yes | Yes | Yes | Yes | Yes | Yes | ? | Yes | |
| Portugal | Yes | Yes | Yes | Yes | Yes | Yes | ? | Yes | |
| Romania | Yes | No | Yes | No | No | No | No | Yes | |
| Serbia | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | |
| Slovakia | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Slovenia | Yes | Yes | Yes | ? | ? | ? | No | Yes | |
| Spain | Yes | Yes | Yes | ? | ? | ? | No | Yes | |
| Sweden | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| Switzerland | Yes * | Yes | Yes | ? | ? | ? | ? | Yes | *Naturopath/homeopath |
| Turkey | No | Yes | Yes | ? | ? | ? | ? | Yes | |
| United Kingdom | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |

1) Conventional practitioners (CPs) (PS3 post-secondary level 3-4 years)
2) CAM practitioner (CAM trained personnel, medical trained, DSE diploma post- secondary education level)

5.8 Massage

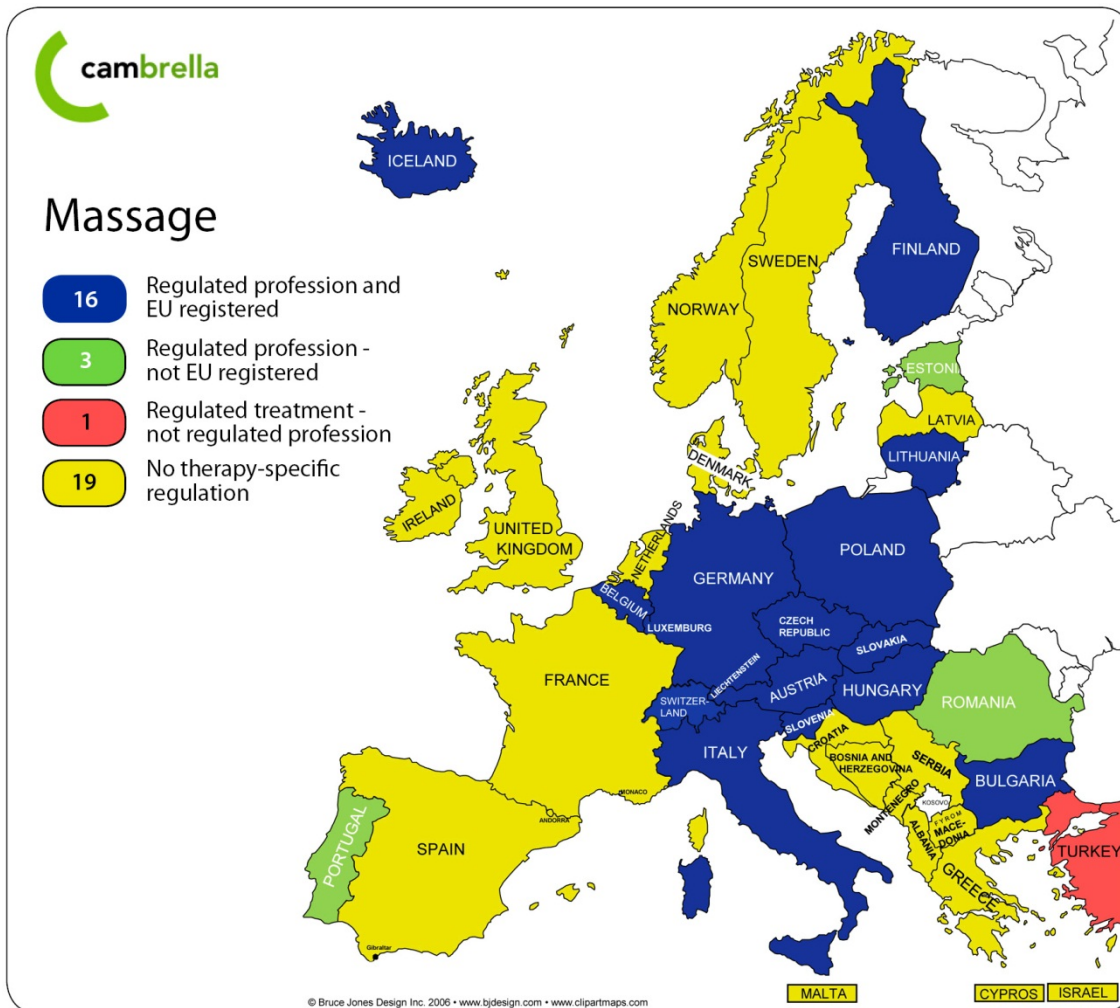


Figure 5.8.1 Massage map

Table 5.8.1 Massage regulations - countries

| Regulated profession and EU registered (16) | | Regulated profession Not EU registered (3) | Regulated treatment Not regulated profession(1) | No regulation (19) | |
|---|---------------|--|---|----------------------|-----------------|
| Austria | Italy | Estonia | Turkey | Albania | Macedonia |
| Belgium | Liechtenstein | Portugal | | Bosnia & Herzegovina | Malta |
| Bulgaria | Lithuania | Romania | | Croatia | Montenegro |
| Czech Republik | Luxembourg | | | Cyprus | Norway |
| Finland | Poland | | | Denmark | Serbia |
| Germany | Slovakia | | | France | Spania |
| Hungary | Slovenia | | | Greece | Sweden |
| Iceland | Switzerland | | | Ireland | The Netherlands |
| | | | | Israel | UK |
| | | | | Latvia | |

16 countries have “**massage**” national regulated as a profession and also registered in the EU regulated professionals database. **The Czech Republic, Estonia and Slovakia** have registered 2 different massage professions, with different educational levels. **Lithuania** has listed **massage** as “**manual therapy**” in the national register, and **masseur** in the EU database. **14 of these 16 countries** have registered masseur in the qualification level DSE-diploma (post-secondary education). **Bulgaria** has a qualification level PS3- diploma of post-secondary level (3-4 years). **Switzerland** has qualification level to be checked.

In 3 countries masseur is a profession, but not registered in the EU database (**Estonia, Portugal, Romania**). The regulations are very dissimilar. Please read the country-wide description for further information.

Turkey has regulated educational requirements for practising massage treatment, but as we understand masseur is not a regulated profession.

19 countries have **no direct regulations** on massage treatment. In some of these countries general CAM or health legislation regulate the practice of massage treatment. Massage is in some countries included in “manual therapy” or “physical therapy”.

5.9 Naprapathy

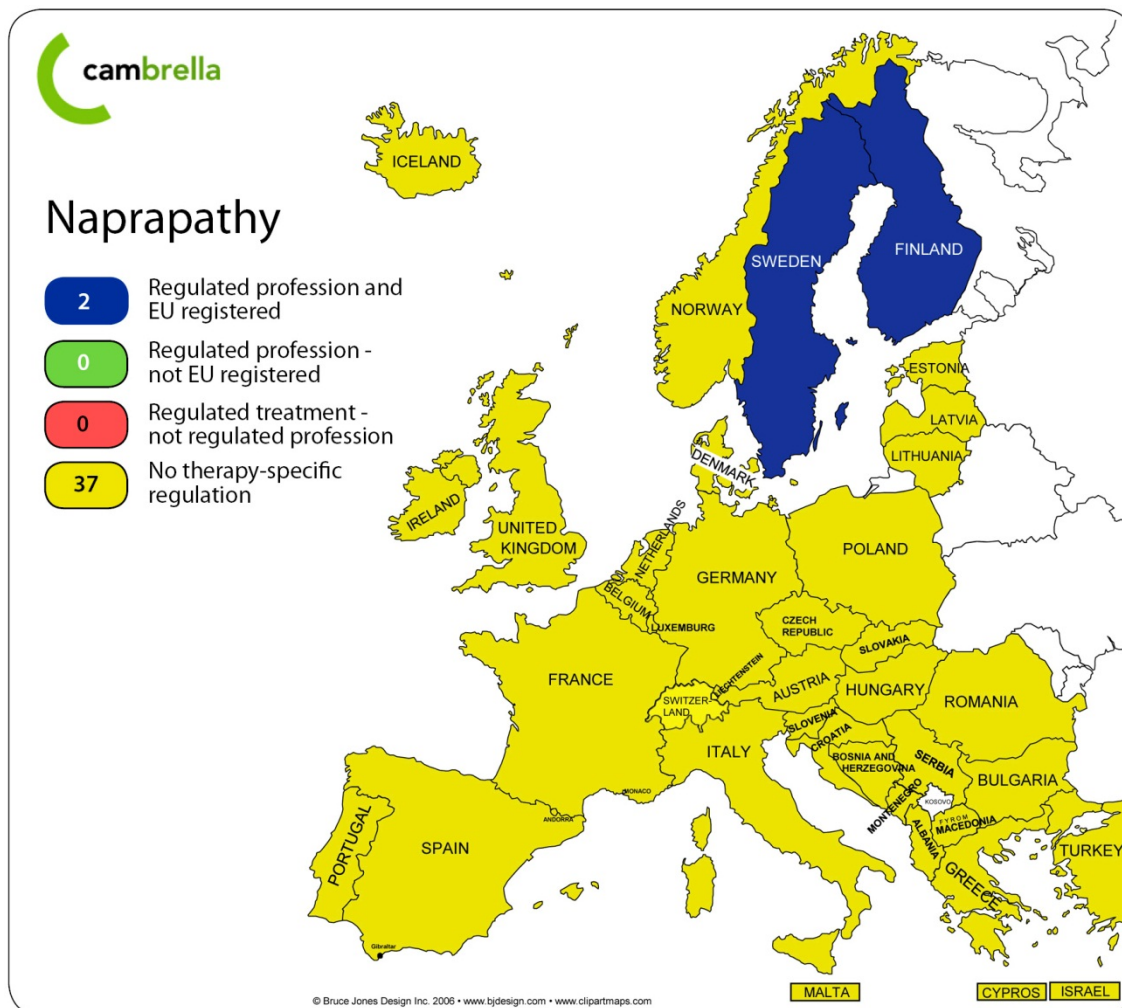


Figure 5.9.1 Naprapathy map

Table 5.9.1 Naprapathy regulations - countries

| Regulated profession and EU registered (2) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession(0) | No regulation (37) |
|--|--|---|--------------------|
| Finland | | | |
| Sweden | | | |

Naprapathy is a regulated and protected profession in Finland and Sweden. Finland has registered their naprapath profession in the EU regulated professions database as **physical therapist** with the title “**Naprapaati/Naprapat**”. **Sweden** has registered their naprapath profession in the EU database as **chiropractor** with the title “**naprapat**”.

We have not found that naprapathy is recognized or practised in the other 37 countries. In some countries “**manual therapy**” or “**physical therapy**” is a common terminology for similar treatments.

5.10 Naturopathy

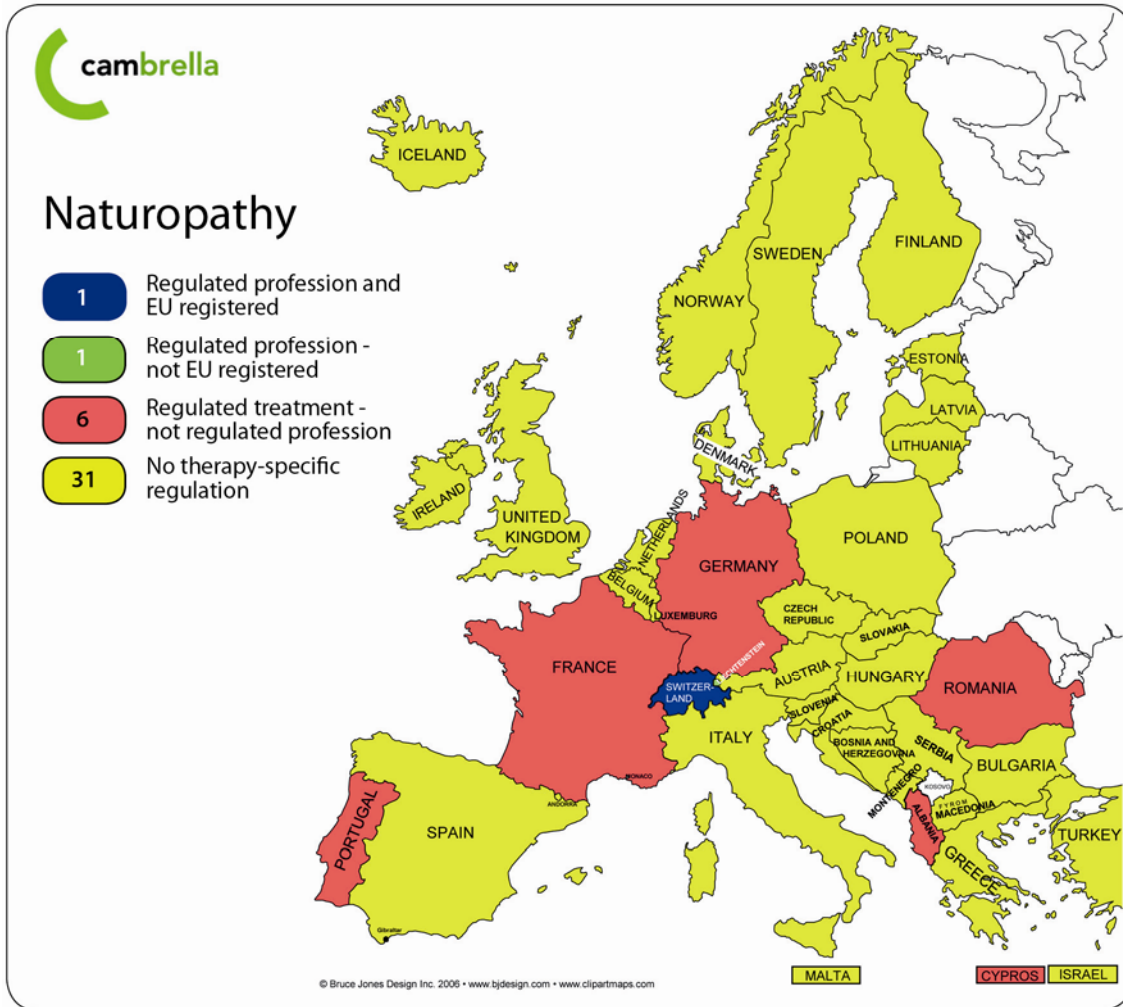


Figure 5.10.1 Naturopathy map

Table 5.10.1 Naturopathy regulations - countries

| Regulated profession and EU registered (1) | Regulated profession Not EU registered (1) | Regulated treatment Not regulated profession (6) | No regulation (31) |
|--|--|--|--------------------|
| Switzerland | Liechtenstein | Albania | |
| | | Cyprus | |
| | | France | |
| | | Germany | |
| | | Portugal | |
| | | Romania | |

Naturopathy is a **regulated profession** in **2 countries (Switzerland, Liechtenstein)**. **Switzerland** has regulated the profession “**natural health practitioner**” and has registered two different professions in the EU regulated professions database, **naturopathe/homéopathe(FR)** and **naturopathe (de tradition Européenne)(FR)**. **Liechtenstein** has not

registered the naturopath in the EU database. In **Liechtenstein** naturopathy is provided by the regulated profession “**Naturheilpraktiker**” with naturopathy specialty.

6 countries have naturopathy treatment regulations (**Albania, Cyprus, France, Germany, Portugal, Romania**). **Albania** has regulated naturopathy by law as “a therapeutic system”. In **Cyprus** alternative practitioners may register in the “Cyprus general council & register of alternative therapists” where the “Cyprus Naturopathic Association” is included. In **France** naturopath is registered under the category “self-employed” under “human health activities not elsewhere classified”. In **Germany** naturopathy is recognized as “a distinct therapeutic system”. **Portugal** has regulated naturopathy by the law “on the provision of non-conventional therapies”. **Romania** has recognized naturopathy as a CAM therapy in the group “alternative therapies” in the CAM law.

In **31 countries** we did not find specific naturopathy regulations. General CAM and health regulations may bear influence on naturopathy treatments.

5.11 Neural therapy

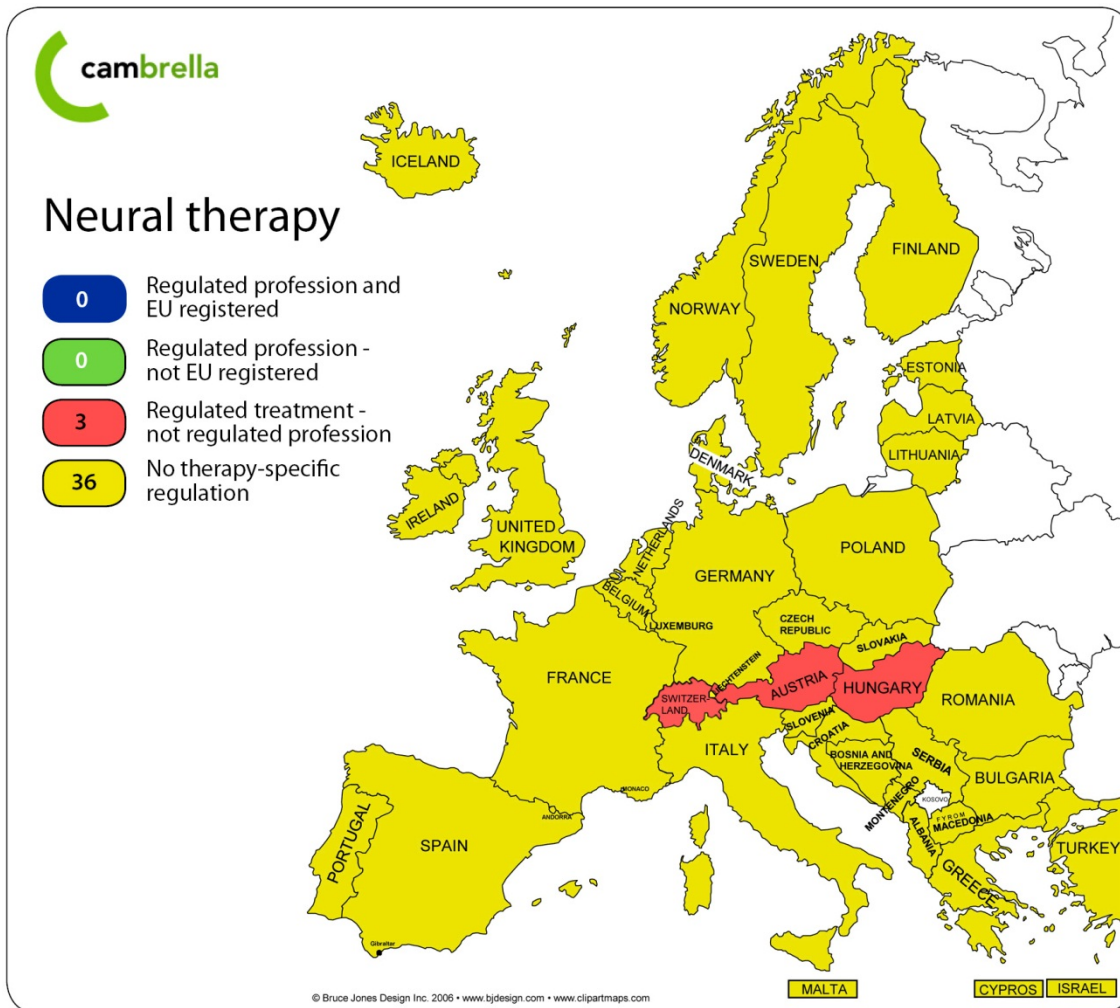


Figure 5.11.1 Neural therapy map

Table 5.11.1 Neural therapy regulations - countries

| Regulated profession and EU registered (0) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (3) | No regulation (36) |
|--|--|--|--------------------|
| | | Austria | |
| | | Hungary | |
| | | Switzerland | |

3 countries (Austria, Hungary, Switzerland) have specific regulation on neural therapy. In **Austria** diplomas awarded by the medical association specialise physicians in neural therapy. In **Hungary** CAM legislation regulates neural therapy. In **Switzerland** neural therapy is included in federal laws.

36 countries have no specific regulation on neural therapy. General CAM and health regulations may influence neural therapy practices.

5.12 Osteopathy

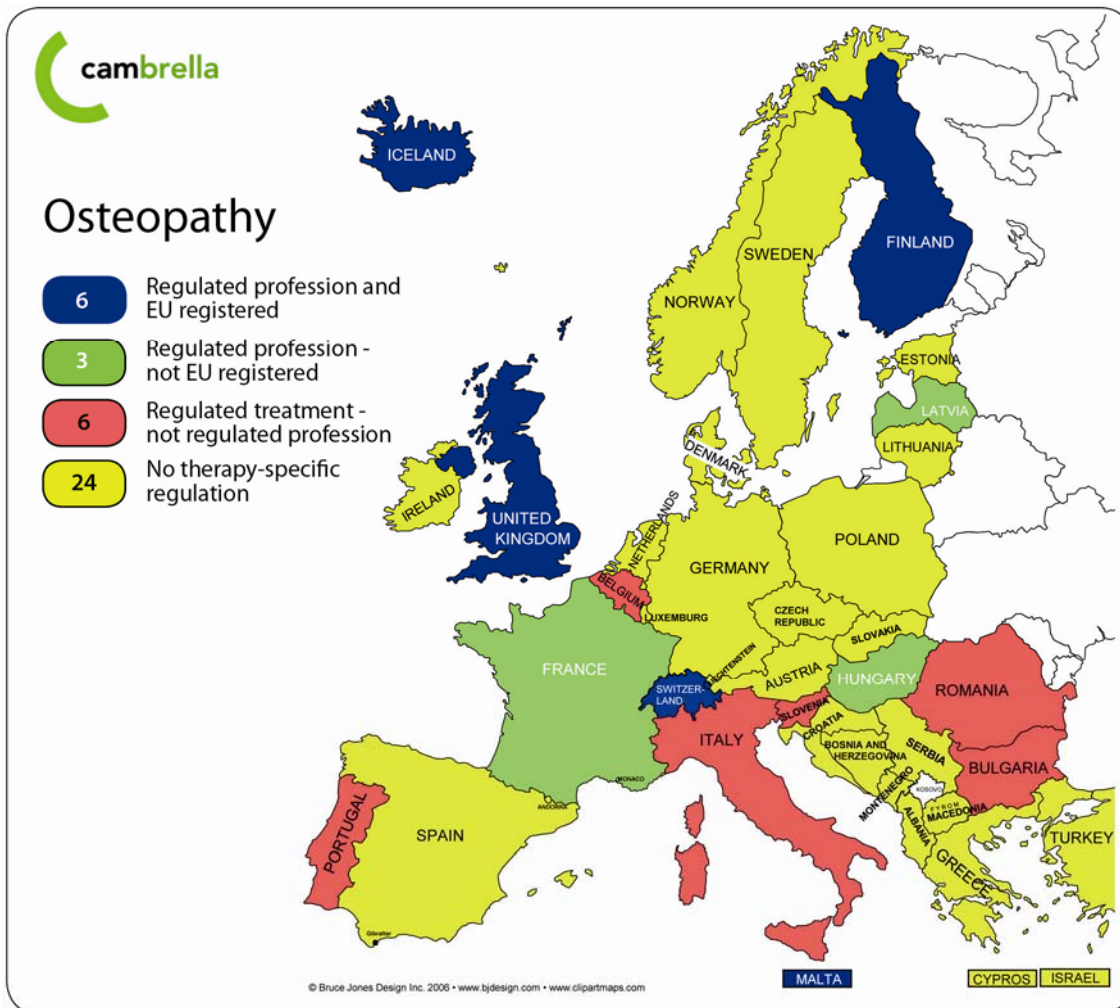


Figure 5.12.1 Osteopathy map

Table 5.12.1 Osteopathy regulations - countries

| Regulated profession and EU registered (6) | Regulated profession Not EU registered (3) | Regulated treatment Not regulated profession (6) | No regulation (24) |
|--|--|--|--------------------|
| Finland | France | Belgium | |
| Iceland | Hungary | Bulgaria | |
| Liechtenstein | Latvia | Italy | |
| Malta | | Portugal | |
| Switzerland | | Romania | |
| UK | | Slovenia | |

In **9 countries** osteopath is a **regulated profession**. 6 countries have registered the profession in the EU regulated professions database. (**Finland, Iceland, Liechtenstein, Malta, Switzerland, UK**). **Finland, Iceland, Liechtenstein, Malta** require a qualification level PS3 – diploma of post-secondary level (3-4 years). In **Switzerland** the qualification level is 5 years

plus 2 years of internship. In **UK** “osteopath” is registered with a qualification level PS4-diploma of post-secondary level (exactly 4 years). In **France, Hungary and Latvia** the osteopath profession is regulated, but not registered in the EU database. In **France** legislation provides a medical qualification to practise osteopathy. A new law on chiropractic and osteopathy is in progress. In **Hungary** only doctors may practise and osteopathy is regulated as “**manual therapy**”. In **Latvia** doctors may have a doctoral degree of osteopathy and a rank as “**doctor of osteopathy**”.

6 countries have regulations on osteopathy treatment, but not regulated the profession (**Belgium, Bulgaria, Italy, Portugal, Romania, Slovenia**). In **Belgium** the CAM law includes a “Chamber of osteopathy”. In “**Bulgaria**” the health law includes “non-conventional physical methods” which may include osteopathy. In **Italy** court rulings and the medical association have acknowledged osteopathic treatment for health professionals with approved international osteopathic education. In **Portugal** the CAM law “on the provision of non-conventional therapies” regulates osteopathy. In **Romania** the CAM law recognizes osteopathy in the group “manual therapies”. In **Slovenia** osteopathy is listed in the CAM law as “other CAM systems”, a method defined within “manipulative and body –based methods”.

In 24 countries we have not found specific osteopathy regulations. General CAM and health regulations may influence osteopathic treatment.

5.13 Traditional Chinese Medicine (TCM)

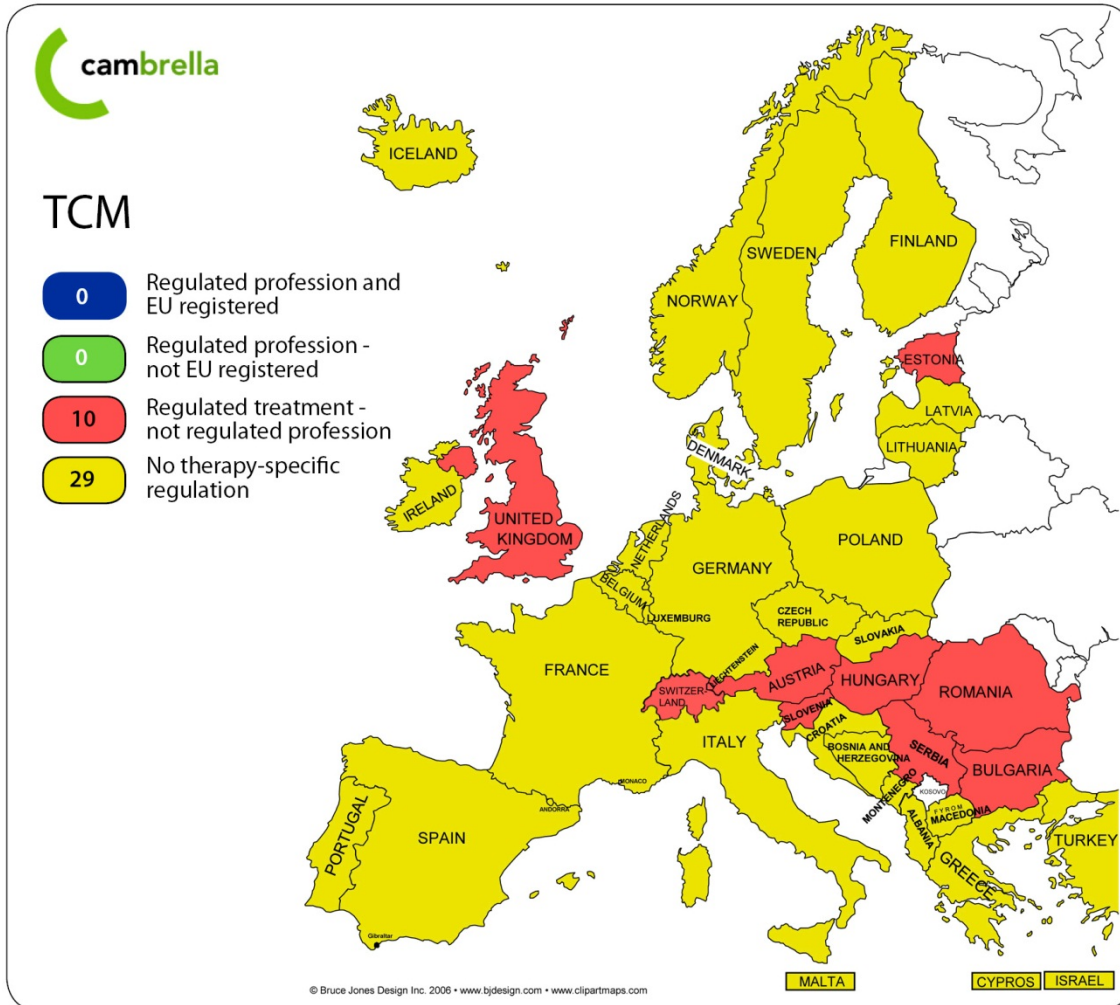


Figure 5.13.1 TCM map

Table 5.13.1 TCM regulations - countries

| Regulated profession and EU registered (0) | Regulated profession Not EU registered (0) | Regulated treatment Not regulated profession (10) | No regulation (29) |
|--|--|---|--------------------|
| | | Austria | |
| | | Bulgaria | |
| | | Estonia | |
| | | Hungary | |
| | | Liechtenstein | |
| | | Romania | |
| | | Serbia | |
| | | Slovenia | |
| | | Switzerland | |
| | | UK | |

Traditional Chinese medicine is a therapeutic system consisting of different treatments. We have not found any professions called TCM practitioner, but some countries regulate TCM as acupuncture.

10 countries out of 39 have specific regulations on TCM (acupuncture is separately described). In **Austria** TCM is only allowed for medical doctors. In **Bulgaria** the health law regulates the use of non-pharmaceutical products of organic or mineral origin. Further, acupuncture and acupressure are regulated. TCM is in **Estonia** regulated as a professional standard according to the Professions act. Certificate as a Chinese natural therapist can be issued. In **Hungary** TCM follows the regulations of acupuncture. **Liechtenstein** has regulated TCM in the health law as a treatment that may be provided by the “Naturheilpraktiker”. In **Romania** the CAM law recognizes Chinese medicine in the group “alternative therapies”. Only doctors, dentists and pharmacists with approved additional qualifications may practise TCM in Romania. In **Serbia** TCM is listed in the CAM bylaw as “a method of treatment suitable for practise”. Regulated health personnel may practise TCM in Serbia. **Slovenia** has listed TCM in the CAM act as “a CAM system that may be used when carrying out CAM practices”. Practitioners with educational level of at least secondary education in healthcare may practise TCM in Slovenia. In **Switzerland** TCM is included in federal laws and detailed regulation delegated to medical and non-medical associations. In the **UK** a TCM practitioner may register voluntarily with a professional body. A statutory regulation on those prescribing Chinese herbal medicines is in progress.

In **29 countries** we have not found specific TCM regulations. General CAM and health regulations may influence TCM treatment. Note also the **acupuncture** regulations for all the 39 countries.

6 Discussion on CAM aspects related to EU/EFTA/EEA legislation and regulations

In this report we have both presented country-specific legal and regulatory issues in 39 European states as well as summaries of the situation for twelve CAM therapies. CAM treatment is in general either unregulated or regulated within the framework of the public health system. Most countries in northern Europe have a more or less unregulated system while many of the countries in southern and Eastern Europe have to a large degree regulated all health practices. The only common factor we have found across all 39 nations is the amazing ability they have demonstrated of structuring legislation and regulation differently in every single country, no matter how small the size of the population.

This country-specific regulation can be seen as a beneficial willingness on behalf of the local government to introduce legislation and regulation that resonates with the local context. The CAM landscape has developed quite differently in various regions of Europe, some treatment modalities that have a long-standing tradition in Central Europe may be virtually unknown in the UK and Scandinavia and vice versa. The cultural attitudes to “freedom of practice” may also differ substantially. It is, of course, impossible to determine which system of regulation that best serves the needs of the population. Stake holders in a country will have different opinions. Some will ask for more tight regulation, even in countries that are thoroughly regulated already, while others will see any government regulation as unnecessary interference in their treatment activities.

The situation is, in principle, the same as in conventional medicine, but the diversity is in reality considerably higher. As long as the local population, treatment providers and researchers remain within their country’s boundaries they will adjust to the current situation. As soon as anyone attempts to initiate cross-border treatment and research activity, they will, however, run into incompatible systems that will be experienced as impossible to navigate.

6.1 Methodological considerations

Collecting the relevant documents and documentation from 39 different states was challenging. Some legislation and regulatory documents could have evaded us in this effort, despite the in-depth literature search and personal contact with the national health authorities, either in person or by phone/e-mail. If this has happened in one or more countries, the information given will be inaccurate, and will be updated in a later online version of this document.

Inaccuracies in the information can also be caused by misunderstandings in the translation of the documents to English. In countries where official English versions were unavailable, we have used local health authorities to assist us with the translation; official translation agencies have not been involved. We foresee that these potential inaccuracies will be rectified when the document has been exposed to the international public.

Legislation and regulations are also constantly under revision, and we can only describe the current situation. In some countries there have been imminent plans for revisions. If this has been the case, we have included the planned changes in the text. Again, a dynamic online document following this report will include regularly updated information for the European and international public.

6.2 Consequences for European patients and citizens

With patients more willing to cross borders in their search for health care (encouraged by the recent Cross-border Health Directive(6)), it is imperative that they are aware of the widely different status of CAM legislation and regulation in culturally similar European nations. When patients cross European borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers. They may also face a completely different reimbursement system, and if the treatment they undergo results in unwanted adverse or side effects they will be differently safeguarded depending on which state they are in.

Although the European Regulations and Directives listed in this document all indirectly influence the practice of CAM in Europe, the intention of the European Parliament outlined in its 1997 Resolution(8) has not been achieved. This document thoroughly documents that a European patient will experience a wide variation in CAM treatment situations depending on country of residence. She will face the following challenges:

1. A wide diversity in which treatments and providers that are available.
2. A wide diversity of available treatments and providers.
3. For similarly labelled treatments; a totally unpredictable level of professional competence.
4. Very differing systems of authority regulation of quality of the services provided.
5. Unpredictable system of reimbursement for services provided.
6. Limited and complex opportunities for complaints.

Every aspect of the current situation can be a threat to patient safety. In post-modern Europe where patient choice in health care is seen as a core value, this confusing European market makes any informed treatment-seeking very challenging. It also indirectly discourages any cross-border treatment-seeking activity. For patients, health insurances and treatment providers there is an unacceptably high level of confusion.

Patient respect and protection are most likely the underlying motives for each state to organize their regulation so differently. It is, however, difficult to understand that small European countries (which represent small population groups) need widely different legislation and regulations tailored to their own uniquely defined safety requirements. Realizing that a substantial proportion of European citizens at any one time are seeking CAM treatment, it seems strange that a culturally homogeneous continent like Europe can accept this unpredictable situation for its citizens.

In conventional medicine there is a relatively high level of predictability with regard to which health professions a patient can gain access to across Europe. The Professional Qualifications Directive established an automatic recognition on the basis of harmonization of minimum training conditions for doctors, nurses, midwives, pharmacists and dentists within the health care system. In the CAM sector there is some mutual recognition according to the “General System” in the Directive, but patients cannot expect to find the provider of their choice as an authorized/licensed treatment provider in all European countries. They might not even find that the treatment modality they are seeking exists at all in another country.

The reimbursement systems of CAM treatments also differ widely between the states. Cross-border CAM treatments are currently, in practice, only available for patients that can afford the cost of treatment and travel with only partial or no reimbursement in the home state. This means that patients must have detailed knowledge on how CAM is regulated in the relevant countries according to the Cross-border healthcare(6) or Social Security Directive (9). However, these two insurance and reimbursement systems are not coherent. The member states can limit reimbursement relating to the quality and safety of the health care provided. CAM treatment is generally less documented than conventional medicine and CAM is in many countries not included in the national health supervision system. This means that reimbursement of CAM treatment can be refused because regulation of CAM in the country of affiliation differs from the country of treatment.

6.3 Consequences for CAM practitioners

When CAM professions in some countries are tightly regulated while the same professional categories in other countries are totally unregulated, an establishment of collegial common ground is very challenging. Despite these challenges, there have been numerous organizations ([Attachment 1](#)) established who have attempted to coordinate international collaboration and facilitate research. Most of these organizations have as one of their goals to attain scientific, legal and regulatory recognition and approval of their CAM treatment modality. The current legal and regulatory landscape would most likely have appeared even more confusing without their efforts.

6.3.1 Authorized/licensed health care providers

For medical doctors the Directive 2005/36/EC facilitates the mutual recognition of conventional medical qualifications (basic training, additional training as general practitioners or medical specialists, if applicable)(5). The system does, however, not easily handle their possible additional qualifications in specific CAM therapies.

The authorized/licensed health care providers with or without a local specialty can practise CAM in another state according to legislation in that specific country. However, such practice is sometimes impossible due to the heterogeneous regulation in Europe.

Obstacles can be:

- Authorizations and licences allowing the practice of CAM differ between states.
- There are differences from state to state with regard to which CAM treatments that can be provided by the authorized/licensed health care providers included in the Directive 2005/36/EC(5).
- Education and training programmes both for health professionals included in Directive 2005/36/EC(5) and for other CAM providers differ from state to state. Consequently a doctor of medicine in one state could have some training in the CAM field included in the curriculum, while CAM training is not included in the curriculum in another state. Both curricula can, however, have been accepted according to the professionals Directive.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practise performed by authorized/licensed health care providers. This ranges from providers with no training in CAM practising in a state where no, or only a select few, CAM modalities are permitted used by these providers, to, at the other extreme, providers practising in states where there is considerable CAM training within the current curriculum, post-graduate accredited CME training courses in several CAM modalities, and authorization/licensing of CAM specialists in the respective professions.

This situation raises concerns with regard to the predictability, quality and safety of health care delivery to European citizens by licensed health care providers practising CAM.

6.3.2 CAM provider without an authorization /license as a health care provider

Directive 2005/36/EC) on the recognition of professional qualifications influences the provision of CAM treatment in Europe also for those CAM providers who are not authorized/licensed as health care personnel(5). A few countries have established separate authorization/licensing systems for some categories of CAM providers (for example acupuncturists and chiropractors), and these are included in the professional groups

regulated by Directive 2005/36/EC. These CAM providers can seek professional recognition within the countries that regulate them. CAM providers share the basic right to work in all European states under the Directive 2004/38/EC (Rights of Union citizens to move and reside freely)(10). However the country-specific nature of member states' recognition of CAM professions means they cannot exercise this right across all member states. They can thus possibly be legally recognized in their own country, but not recognized in other EU or EFTA countries. They are required to follow national legislation/regulations in each state with regard to what treatment they are allowed to give, and relate to the provider and insurance regulations within the state's private or public health systems. This severely hampers the free movement of providers despite the Cross-border Healthcare Directive and Social Security Regulation.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practice performed by providers who are not authorized/licensed health care providers. This ranges from an extreme of being refused to practise at all, because all treatment of people with health conditions is reserved for authorized/licensed health care personnel only, to another extreme in some European countries where anyone can practise CAM without any CAM education or training. Another extreme situation is being allowed to practise CAM as a fully trained provider with an authorization/license on equal terms to an authorized/licenced health care provider.

This diverse situation raises, as in the case of authorized/licensed health care providers, concerns with regard to the predictability, quality and safety of CAM health care delivery to European citizens.

6.4 Consequences for CAM researchers

A third important issue is **clinical research collaboration**. Research on efficacy and effectiveness of CAM is severely hampered by the conglomerate of European regulation. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study will therefore be generalizable only within a narrow national or cultural context. Research should be strengthened on the monitoring and safety aspects on CAM practices. An essential discussion to be initiated is how to develop the current regulatory system in Europe to improve and facilitate cross-border clinical CAM research, and what would the advantages and disadvantages be for researchers if CAM were regulated at an EU/EEA level?

6.5 Possible ways forward

Patients, practitioners (authorized/licensed as well as those without an authorization/licence) and researchers would all benefit if there was a higher degree of harmonization of legislation and regulation of CAM in Europe. The four freedoms form the political platform of the EU/EEA area. These freedoms can only be fully practised if the citizens can enjoy a predictable and safe system of health care. Conventional medicine across Europe is predictable enough through the various directives passed over recent years. CAM has, however, not been given a similar degree of attention despite its widespread use.

There are in principle two options that can be chosen to achieve a higher degree of harmonization: legislation and regulation at the EU/EEA level or voluntary harmonization. We do not foresee EU/EEA level legislation/regulation in the foreseeable future since the EU repeatedly has upheld its position of leaving this to the individual country.

Voluntary harmonization is, however, possible within current legislation. Directive 2005/36/EC outlines how countries can enable mutual professional recognition for categories of professionals (5). The successful mutual recognition of physiotherapists across Europe shows how this can be done. Physiotherapists represent a profession in conventional medicine that is not regulated as one of the “Sectorial professions” giving automatic recognition on the basis of harmonization of minimum training requirements. Physiotherapy has therefore been harmonized according to the “General system” of mutual recognition of professional qualifications, and could serve as a potential template for development of harmonized regulation of CAM professions in Europe. **Physiotherapy is recognized as a conventional regulated health profession** in 38 of the 39 countries we have described, and 29 of 31 EU/EEA members have registered the profession in the EU regulated professions database (Figure 6.5.1). Physiotherapy professionals can thus with few obstacles move from one European country to another, and patients are ensured that, across Europe, they will encounter professionals with similar background and experience.

Chiropractic, massage, osteopathy, naprapathy could be similarly regulated and entered into the common EU regulated professions database. This would establish a situation similar to physiotherapy to which they are fairly closely related. Several countries in the eastern region of Europe have entered their **massage therapist** profession into the database, and have thereby established a “common market” for this profession in the region. This demonstrates that this approach is viable also in the CAM area.

We think a pan-European professional initiative could influence national health authorities to register the relevant profession in the EU regulated professions database. If this is done, EU-level regulation will turn out to be unnecessary.

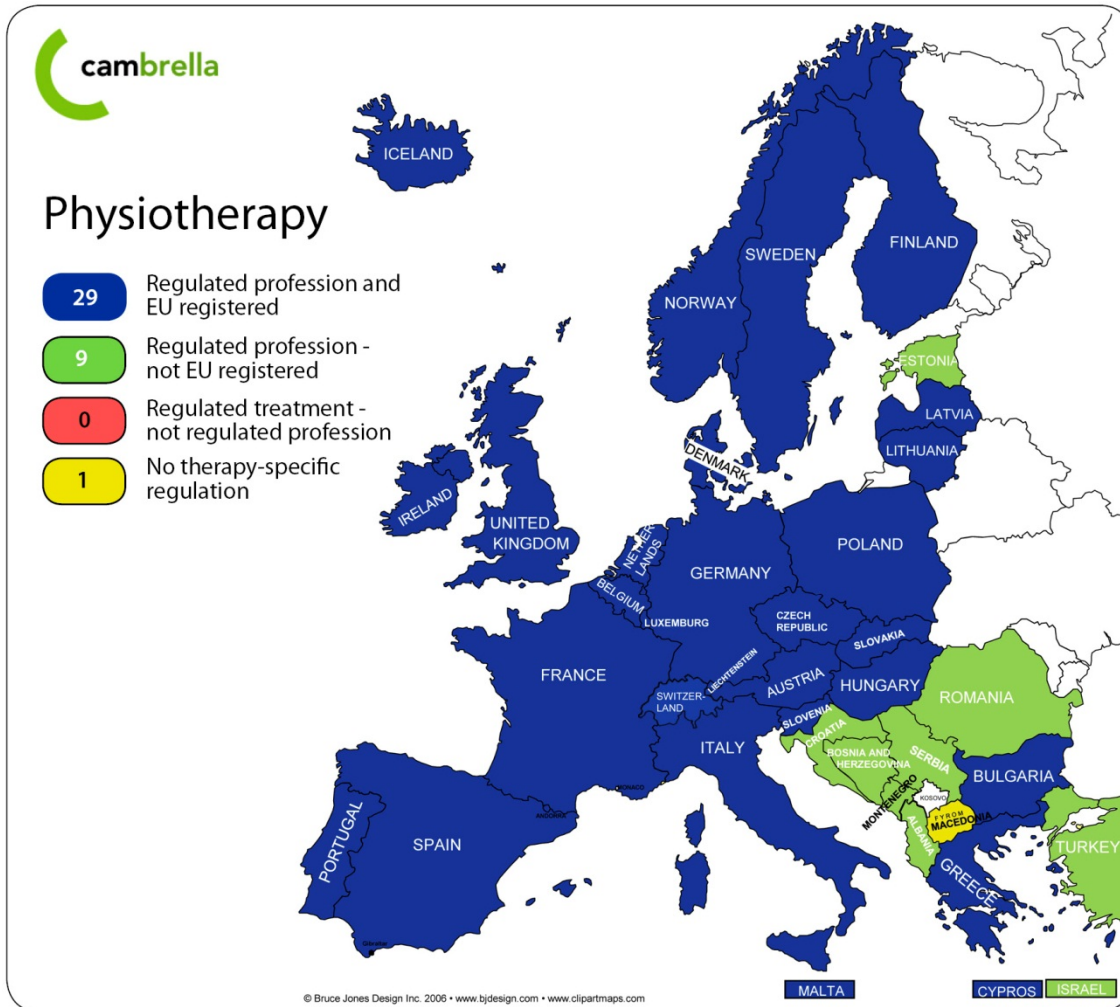


Figure 6.5.1 Physiotherapy map

Table 6.5.1 Physiotherapy regulations - countries

| Regulated profession and EU registered (29) | Regulated profession Not EU registered (9) | Regulated treatment Not regulated profession (0) | No regulation (1) |
|---|--|--|-------------------|
| 29 countries | Albania | | Macedonia |
| | Bosnia & Herzegovina | | |
| | Croatia | | |
| | Estonia | | |
| | Israel | | |
| | Montenegro | | |
| | Romania | | |
| | Serbia | | |
| | Turkey | | |

7 Conclusions

The EU treaties have repeatedly established that health policies are a national responsibility for the member states, and this is clearly reflected in the current situation with regard to CAM legislation and regulation. Despite several EU Directives, Regulations and Resolutions that influence how member states organize their national health policy and services, no two countries described in this report have a common approach to legislation and regulation in this area. The diversity applies to whether the field is regulated at all, what treatments are considered to be CAM, whether CAM treatments should be only practiced by practitioners with education/training in the discipline, whether license to practise should be limited to authorized/licensed health personnel and even whether medical doctors need a several-year specialization to be allowed to practice CAM. There appears to be no predictable pattern with regard to geography, political history, population size or cultural diversity. This diversity will clearly influence patients, practitioners and researchers crossing European borders (encouraged by the recent Cross-border Health Directive).

When patients cross European borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers. They may also face a completely different reimbursement system, and if the treatment they undergo results in unwanted adverse or side effects they will be differently safeguarded depending on which state they are in. Every aspect of the current situation can thus be a threat to patient safety. In post-modern Europe where patient choice in health care is seen as a core value, this confusing European market makes any informed treatment-seeking very challenging.

There is room for a substantial variety of CAM practise in Europe. This ranges from an extreme in some countries where anyone can practise CAM without any CAM education or training to the other extreme where only medical doctors with a specialization in the relevant CAM discipline are allowed to practise. This situation raises serious concerns with regard to the predictability, quality and safety of health care delivery to European citizens. When CAM professions in some countries are tightly regulated while the same professional categories in other countries are totally unregulated, an establishment of collegial common ground is very challenging.

Research on efficacy and effectiveness of CAM is also severely hampered by the conglomerate of European regulation. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study will therefore be generalisable only within a narrow national or cultural context.

There are in principle two options that can be chosen to achieve a higher degree of harmonization: legislation and regulation at the EU/EEA level or voluntary harmonization. We do not foresee EU/EEA level legislation/regulation in the foreseeable future since the EU repeatedly has upheld its position of leaving this to the individual country. Voluntary

harmonization is, however, possible within current legislation. The successful mutual recognition of physiotherapists across Europe shows how this can be done, and could be a potential template for development of harmonized regulation also of CAM professions in Europe.

8 Countries

8.1 Albania

The Republic of Albania (hereafter Albania) applied for European Union (EU) membership on 28. April 2009 and is listed as a potential candidate country to EU (11). Albania is connected to the FP7 research programme through a memorandum of understanding and as such included in the CAMbrella survey of CAM legislation in Europe. Albania has been a member of the Council of Europe since 1995 (12).

8.1.1 The legal and regulatory status of CAM and CAM practices

In Albania alternative medicine is regulated, and some CAM treatments are mentioned in the regulation. Article 20 of "**Law on Health Care** in the Republic of Albania" from 2009 states that (13);

1. **Alternative Medicine** is a set of preventive and curative health practices, such as **homeopatia, naturopatia, chiropractic and herbal medicine**, which does not follow the general medical methods that are accepted and may not have a scientific explanation for their effectiveness.
2. Treatments, conditions and manner of use of unconventional therapeutic methods are **determined by order of the Minister of Health**.
3. **Advertisement and practice** of alternative medicine methods unlicensed by the Ministry of Health are prohibited.

There are **no follow-up regulations** of this activity approved by the Ministry of Health (MOH).

Article 19 of the **health care law of 2009** regulates **sport and rehabilitation medicine**, including **physiotherapy** (see below)(13). **Article 31** states that registration of health professionals is a mandatory process, headed by the Ministry of Health. Operational orders are regulated by separate laws(13). **Article 33** states that the Ministry of Health establishes mandatory programs for continuing education (CME) for health care professionals (13).

Albania has a health care system that is mainly public (14). Private medical practice has been legal since 1992 (15). Private practice licences are no longer issued by the MOH. The private sector includes most of the pharmaceutical services (14).

The Act on regulated professions in Albania from 2009 applies to every person who wants to exercise a regulated profession in the Republic of Albania. The law does not apply for the professions, which, according to the legislation in force, have special requirements, but not necessarily the character of formation or qualification required for regulated professions (16). According to the **professionals act article 5, regulated health professionals** in Albania are **doctor, dentist, pharmacist, nurse, midwife, physiotherapist and veterinarian** (16).

A. To earn the right to exercise a regulated profession, each candidate must:

- a) Perform professional practice.
- b) Perform the state examination.
- c) Be registered in the respective UP (national professional register)(16).

8.1.2 The governmental supervision of CAM Practices

Law on health care 2009 article 4 states that the Health Minister directs the policy, organization and supervision of the health care system (13).

According to the law on Public Health, inspection shall be performed by the State Health Inspectorate as a dependant body to the Minister of Health, and the Chief Inspector of state health, in order to perform his duties, shall technically rely on the Institute of Public Health (17). Regulated health services and regulated health professionals (including CAM licensed professionals) are included in the supervision programme under the State Health Inspectorate.

The Ministry of Health has special attention to “The National Centre of Quality, Safety and Accreditation of Health Institutions” and “The Centre of Continuous Medical Education” to increase their authority (14).

8.1.3 The reimbursement status of CAM practices and medicinal products

The Health insurance scheme in Albania is governed by law Nr. 10 383, dated 24 February 2011 on Compulsory Health Care Insurance (18). “This law defines the legal status, the structure, functions and the activity of the Health Care Insurance Fund which manages the funding of the health care services onto the compulsory health care insurance scheme”(18).

The health care insurance scheme in Albania covers health care services funded by the private and public sector (18). Patient services covered are:

- a) medical examinations and treatment in public health care centres and public hospitals and additional services in public hospitals.
- b) medical examinations and treatment in private medical practices and private hospitals to an extent agreed with the Health Insurance Fund (HIF).
- c) drugs, medical products and treatment by other persons in the medical profession.

The Health Insurance Institute (HII) was established in 1995 as a national statutory body. Reimbursement coverage has been introduced and extended in planned stages. Additional funding comes from patients and foreign aid. Even if patients co-payments is low, it is likely that out-of-pocket payments prevent low-income people from obtaining health care services

and pharmaceuticals (15). Private insurance has been legal in Albania since 1992 (15). Medical doctors are employed by the State, general practitioners (GP's) are paid by the Health Insurance Institute (HII) according to a capitation system, specialists are paid a fixed salary by the MOH (19).

The pharmaceutical services in Albania are mainly private with rigorous monitoring from the MoH and the National Center of Drugs Control (14). The Drug Commission on Drafting and Reviewing the Reimbursement List selects the drugs that are going to be reimbursed (14). In 2009 450 drugs were on the reimbursement list. Albania collaborates with the European Drug Agency to adjust national legislation to the European Union Directives (14).

The health insurance act of 2011, article 10 includes insurance services by defining: “the list of reimbursable drugs and also the measure of coverage from compulsory insurance. The structure of the drug list is defined based on the list of the basic drugs according to classification INN (active principle of drug) as defined by WHO and also to the cheapest alternative” (18).

The Instrument for Pre-accession Assistance (IPA) programme was launched by the European Medicines Agency in late 2009 in order to support and foster links between the European Medicines Agency and the Beneficiaries (including Albania) in order to ensure future co-operation in the Agency's networks and to prepare the countries for integration into the European regulatory network for medicines (www.ema.europa.eu).

8.1.4 Acupuncture

No specific regulation has been found on acupuncture.

8.1.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.1.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.1.7 Chiropractic

Chiropractic is regulated in the “Law on Health Care” from 2009, article 20, Alternative Medicine, as a therapeutic system that does not follow the general medical methods that are accepted and may not have a scientific explanation for their effectiveness (13).

Treatments, conditions and manner of use of chiropractic shall be determined by order of the Minister of Health (13). Advertisement and practice of chiropractic unlicensed by MoH are prohibited (13).

There are no follow up regulations approved by MoH that regulates chiropractic.

8.1.8 Herbal medicine/Phytotherapy

Herbal medicine is regulated in the “Law on Health Care” from 2009, section 20, Alternative medicine, as a therapeutic system that does not follow the general medical methods that are accepted and may not have a scientific explanation for their effectiveness (13).

Treatments, conditions and manner of use of herbal medicine shall be determined by order of the Minister of Health (13). Advertisement and practice of herbal medicine treatment unlicensed by MoH are prohibited (13). There are no follow up regulations approved by MoH that regulates herbal medicine treatment.

8.1.9 Homeopathy

Homeopathy is regulated in the “Law on Health Care” from 2009, section 20, Alternative medicine, as a therapeutic system that does not follow the general medical methods that are accepted and may not have a scientific explanation for their effectiveness (13).

Treatments, conditions and manner of use of homeopathy shall be determined by order of the Minister of Health (13). Advertisement and practice of homeopathy unlicensed by MoH are prohibited (13). There are no follow up regulations approved by MoH that regulates homeopathy treatment.

8.1.10 Massage

No specific regulation has been found on massage.

8.1.11 Naprapathy

No specific regulation has been found on naprapathy.

8.1.12 Naturopathy

Naturopathy is regulated in the “Law on Health Care” from 2009, section 20, Alternative medicine, as a therapeutic system that does not follow the general medical methods that are accepted and may not have a scientific explanation for their effectiveness (13).

Treatments, conditions and manner of use of naturopathy shall be determined by order of the Minister of Health (13). Advertisement and practice of naturopathy unlicensed by MoH are prohibited (13). There are no follow up regulations approved by MoH that regulates naturopathy.

8.1.13 Neural therapy

No specific regulation has been found on neural therapy.

8.1.14 Osteopathy

No specific regulation has been found on osteopathy.

8.1.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.1.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a **regulated health profession** in Albania according to the Act on regulated professions article 5(16) and Act on health care, article 19; Rehabilitation and Sports Medicine (13). Rehabilitation Medicine is provided by a physiotherapist with a university degree. The order of MOH 2011 on professional practise of health professions, point 3, regulates that physiotherapy internship practice is 3 months (20). Sports Medicine is a form of providing health care for active sportsmen, implemented as part of health care services. The Minister of Health determines, by-laws, rules of organization and operation of the Sports Medicine Service (13).

8.2 Austria

Austria became a member of the European Union(EU) in 1995(11) and of the Council of Europe on 16 April 1956 (12).

8.2.1 The legal and regulatory status of CAM and CAM practices

We have found no specific CAM regulations in Austria. Physicians are, however, implicitly permitted to use alternative treatments (21).

The Bundesgesetz über die Gesundheit Österreich GmbH (GÖGG) (the Health Care Act Austria)(22) managed by Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIIIG) regulates the basic health system in Austria (22).

The Ärztegesetz BGBl, I Nr. 169/1998 (Law on physicians)(3) regulates the profession of medical doctors in Austria. The Physiotherapy Act regulates physiotherapy and occupational therapists BGB1. Nr. 460/1992 (23). Different medical massage professions are regulated by the BGBl. I Nr. 169/2002 (24). Midwives are subject to the “Hebammengesetz” BGB1. Nr. 310/1994 (25).

Medical practise is limited to medical doctors. The “Ärztegesetz”(Federal Medical Law) states that practicing as a medical doctor includes every task based on medical-scientific knowledge that is performed directly on a person or for the person (25). All doctors are mandatory members of a medical chamber in their respective province (Landesärztekammer) who jointly constitute the Austrian Medical Chamber (Österreichische Ärztekammer)(26). The “Österreichische Ärztekammer” manages the mandatory list of medical doctors (27).

The Federal Medical Law states in section 1.2; “Only legally qualified and authorized professionals are allowed to practise medicine” (28). Medicine is defined in the Ärztegesetz as: “All activities based on medico-scientific knowledge carried out directly or indirectly on human beings” – “performed for the purposes of diagnosis, treatment, and prophylaxis” (§2, Ärztegesetz).

Many physicians in Austria have a diploma of at least one form of CAM. The training in CAM methods is located in the different scientific/medical CAM societies, which specialize in one of the CAM traditions, like homeopathy (Österreichische Gesellschaft für Homöopathische Medizin-ÖGHM) (www.homöopathie.at), anthroposophic medicine (Gesellschaft für Anthroposophische Medizin in Österreich- GAMÖ) (www.anthromed.at) and others. CAM training courses require certain standards to be achieved before awarding an “Ärztekammerdiplom”.

The diplomas are awarded by the Austrian Medical Board. The most common methods are **acupuncture, anthroposophic medicine chiropractic manipulation, homeopathy, neural therapy and traditional Chinese medicine** (29).

“A fundamental question is if the term “treatment” (“Heilverfahren”) is subject to legal regulation. An explicit legal norm for treatment, in particular regarding osteopathy does not exist in Austria. Who and with which methods and concepts is permitted to “heal” respectively perform treatments on patients, can be gathered from the respective medical fields” (25).

Medical acts that are not provided by authorized health professionals, such as midwives, medical-technical assistants, and nurses, are reserved for physicians (Ärztegesetz (Law on Physicians) of 1984 (173,174) (28).

According to the Law on Health Services, only scientifically recognized medical care can be provided in hospitals. Acupuncture, neuraltherapy, and chiropractic are recognized, but not homeopathy (22).

8.2.2 The governmental supervision of CAM Practices

The ‘Gesundheitsreformgesetz’ (health care reform act) BGBl I No. 179/2004 regulates health quality in Austria (30).

The ‘Bundesinstitut für Qualität im Gesundheitswesen (BIQG)’ (The Federal Institute for Quality in the Health Care System (BIQG)) manages health quality coordination (31, 32). BIQG is a unit of ‘Gesundheit Österreich GmbH’ (32). The legal basis for BIQG is ‘Das Gesundheitsqualitätsgesetz (GQG)’ (The Health Quality Act)(30) and the ‘Gesetz über die Gesundheit Österreich GmbH (GÖGG)’ (The Health Care Act Austria)(31).

“These actors include social security institutions, federal ministries, provinces, professional societies, chambers and professional representations, patient advocacies and patient support groups” (32). “The Austrian Society of Medical Quality Assurance and Quality Management LLC (ÖQMED, www.oeqmed.at), which is fully owned by the Austrian Medical Chamber, periodically publishes a Medical Quality Report in which the results of its evaluation of physician’s practices are given” (32).

Austrian doctors are answerable to courts of law and to their competent local disciplinary commission, which acts under the supervision of the disciplinary council of the Austrian Medical Chamber (26). Article 136 of the Austrian Ärztegesetz (Act on the medical profession) regulates breach of discipline (Disziplinarvergehen)(27).

In the same way physiotherapy is regulated by article 33 “Strafbestimmungen in MTD-Gesetz” (23) and massage professions by article 78 “Strafbestimmungen in MMhm-Gesetz” (23).

The Criminal law; [BGBl Nr. 60/1974](#) (33) draws the boundaries for appropriate conduct by medical professionals (26) (§ 80 and §110 in special)(33).

Unskilled persons who practise medical acts or activities reserved for physicians, risk a fine or imprisonment of up to three months (Article 184 of the Penal Code). The court is tolerant, and the law is enforced only on practitioners that use methods with no scientific support (28).

8.2.3 The reimbursement status of CAM practices and medicinal products

For acupuncture a small reimbursement is provided by the social security services, if the indication is pain. All other possible acupuncture indications are not reimbursed.

Costs for CAM treatments in general are not reimbursed by social security services, but in special cases this is negotiable (cancer patients, children). Patients have to consider that themselves and negotiate reimbursements on their own initiative. Private insurance companies offer packages that include CAM.

8.2.4 Acupuncture

Acupuncture is legally recognized for pain therapy within the limits of conventional medicine and acknowledged by the “Oberster Sanitätsrat” 1986. Diplomas are awarded by the Austrian Medical Board. Acupuncture is perceived as a part of conventional medicine called Integrative medicine. For acupuncture some reimbursement is given in special cases (34).

According to the Law on Health Services, acupuncture is a scientifically recognized treatment that can be provided in hospitals (22).

8.2.5 Anthroposophic medicine

Diplomas awarded by the Austrian Medical Board specialise physicians in anthroposophic medicine.

8.2.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.2.7 Chiropractic

Diplomas awarded by the Austrian Medical Board specialise physicians in chiropractic manipulation.

8.2.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.2.9 Homeopathy

The federal medical Law and Ärztegesetz (Law on Physicians of 1984 (173,174)) states that “only medical professionals are allowed to practise medicine” (28). The “Österreichische Ärztekammer” (ÖÄK - Austrian Medical Council) issues the Complementary medicine Homeopathy diploma – ‘ÖÄK Diplom Komplementäre Medizin Homöopathie’ - to medical doctors who have successfully passed an examination in homeopathy (28).

8.2.10 Massage

The Act “Medizinischer Masseur- und Heilmasseurgesetz – MMHmG”- BGBl. I Nr. 169/2002, regulates massage professions in Austria (24). Different massage titles are registered in the national register for registered professions as well as in the EU regulated professionals database.

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Masseur**” recognized under Directive 2005/36/EC(5), ID 654. General system of recognition - primary application. National legislation: Gewerbeordnung 1994. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C,D). Art.11 c(7). Useful link: nihil.

“**Physiotherapy assistant**” (formerly ‘Heilbademeister/in und Heilmasseur/in’)(EN) is a directly related regulated profession with title “**Medizinischer/r Masseur/in (AT)**” under Directive 2005/36/EC(5), ID 631. General system of recognition- primary application. Qualification level: SEC-Certificate attesting the completion of a secondary course, Art. 11b (7). Useful link: <http://www.bmgf.gv.at/cms/site/inhalte.htm?channel=CH0003&thema=CH0012>

Physiotherapy assistant is a directly related regulated profession with title “**Heilmasseurin/Heilmasseur (AT)**” (formerly Heilbademeister/in und Heilmasseur/in (EN) recognized under Directive 2005/36/EC(5), ID 3795. General system of recognition – primary application. Qualification level: SEC – Certificate attesting the completion of a secondary course Art. 11 b.(7).

Useful link: <http://www.bmgf.gv.at/cms/site/inhalte.htm?channel=CH0003&thema=CH0012>

The commercial masseur (“**gewerblicher Masseur**”) is a regulated trade BGB1. Nr. 194/1994, 1994a (25).

8.2.11 Naprapathy

No specific regulation has been found on naprapathy.

8.2.12 Naturopathy

No specific regulation has been found on naturopathy.

8.2.13 Neural therapy

Diplomas awarded by the Austrian Medical Board specialise physicians in neural therapy.

8.2.14 Osteopathy

Austria has no legal regulation of osteopathy (25) “Osteopathy is neither recognized nor prohibited and can be practised by different people with different professional qualifications, with or without medical background and training” (25). “It is legally unclear if osteopathy represents a ‘specialisation’ of medical-scientific professions (e.g. doctor, physiotherapist) or if it is an ‘independent’ treatment method”. According to the current legal status, the practise of osteopathy (as mechano therapeutic measure of patient treatment) by doctors and physiotherapists is possible” (25).

8.2.15 Traditional Chinese Medicine (TCM)

Practise of TCM is only allowed for medical doctors. Diplomas awarded by the Austrian Medical Board specialise physicians in traditional Chinese medicine.

8.2.16 Other treatments (mentioned if found in legislation)

In Austria **physiotherapy** is regulated by “Bundesgesetz über die Regelung der gehobenen medizinisch-technischen Dienste (MTD-Gesetz)“ BGB1. Nr. 460/1992(3).

The title “**Physiotherapeutin**”, “**Physiotherapeut**”(EN) and the professional activity is protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must obtain a licence to practise. Austria has a code of ethics for physiotherapists. The national authority responsible for legislation concerning the physiotherapy profession in Austria is the "Bundesministerium für Gesundheit" (35).

Physiotherapist is a directly related regulated profession with title “**Physiotherapeutin/ Physiotherapeut(AT)**” recognized under Directive 2005/36/EC(5), ID 617. General system of recognition – primary application. Qualification level: PS3 – Diploma of post-secondary level (3-4 years), Art.11 d(7).

Useful link: <http://www.bmgf.gv.at/cms/site/inhalte.htm?channel=CH0003&thema=CH0012>

8.3 Belgium

Belgium was a founding member of the European Union in 1952 (11) and a founding member of the Council of Europe since 5 May 1949 (12).

8.3.1 The legal and regulatory status of CAM and CAM practices

The practice of health care professionals in Belgium is regulated by the practice of health care professions act, the Royal Decree No. 78 of 10 November 1967 (36). The act includes **physicians, dentists, physiotherapists, pharmacists, nurses, midwives and paramedical practitioners** (37). According to Article 2 of this act, making a diagnosis and establishing the treatment of a physical or mental disorder are reserved for the holders of a medical diploma approved by the competent medical commission (38). Consequently only physicians, dentists or midwives are entitled to make a diagnosis and to prescribe treatment, and only these professions may practise CAM treatments (37). The rights and duties of physicians and patients are regulated in the law on the rights of patients of 22 August 2002 (39, 40).

Doctors can recommend CAM to their patients (or practise CAM themselves), and a number of CAM treatments may be dispensed legally by **physiotherapists** on medical prescription (41).

Professional exercise of a non-conventional practice by a non-doctor is a punishable offence. In real life, however, many non-doctors practise one or another non-conventional treatment.

In order to regulate the practice of non-conventional systems, and give the population a freedom of choice concerning therapeutic treatments, the act on non-conventional practices (the "Law of minister Colla") was adopted by the Belgian Parliament in 1999 (42, 43). Four chambers were to be installed, for **acupuncture, chiropractic, homeopathy and osteopathy**, and the number of non-conventional practices could be extended by the government (37). Practitioners of non-conventional medicine, as defined in the Act of 29 April 1999, are also **health professionals** (39). The law should take effect after a series of implementing orders had been engaged (43).

The Colla act 1999, article 3, established that a joint commission should advise the government on the practice of CAM, particularly registration of practitioners, membership in recognized professional organizations and restrictions on medical acts (44). This should be ensured mainly by a dual registration system for both non-conventional practices and registers for individual practitioners (for which both should satisfy certain conditions)(38).

However, since this joint commission has still not been established (January 2011), it cannot play its key role and consequently the law cannot be fully executed (38). The Colla Act was published in the Belgisch Staatsblad/Moniteur Belge (Official Journal) on 1999-06-24 (45).

In Article 9 of the Colla act of 1999, CAM practitioners who are not also conventional physicians must obtain a recent physician's diagnosis from their patient prior to commencing treatment (44). If patients choose not to consult a physician before seeing CAM, they must put their wishes in writing. Registered CAM practitioners must take precautions to ensure that patients are not deprived of conventional treatment. As a result, CAM practitioners who are not also physicians must keep physicians informed of the health of their patients. With a patient consent, CAM practitioners are permitted to seek the advice of other CAM practitioners who are not conventional physicians (44).

“At the request of two associations representing osteopaths, the Brussels court of first instance ordered the Belgian state on 22 January 2010 to set up the joint commission. The government appealed but the judgement was for immediate execution”(38). The practitioner members of the joint commission must be appointed by the chambers, which must be established, with one chamber per non-conventional medicine referred to in the Colla law”(38).

The Belgian Parliament approved by a Royal Decree of 6 April 2010 the recognition of 13 professional organizations of medical and non-medical practitioners of non-conventional medicine (28, 38, 46). The 13 associations are within the field of the 4 “recognized” CAM treatments, some are only representing physicians, some only non-physicians and some are mixed (45). These organizations nominate members of the Chambers”(28). The act says that every royal decree on the recognition of the professionals’ organizations or their members must be agreed by the parliament. The decree was not approved by the Parliament within sixth months after its publication in the Belgian Official Journal. “The members of the professional association that will be recognized in the future therefore have no legal guarantee as to the delays in which their ‘Royal Decree of recognition’ would be confirmed by law” (38).

Since the Colla law is not fully in effect, the practice of a CAM by a non-doctor is still illegal. Several non-medical practitioners of CAM have been sentenced for this offence (38). In the autumn of 2010 a trial against a physiotherapist practising acupuncture was won by the prosecuted physiotherapist. An appeal in 2010 confirmed the acquittal because the physiotherapist complied with the prerequisite of medical prescription. The judge reserved the diagnosis for the prescribing doctor (47).

In conclusion, when the Colla law is fully executed, Belgium will still restrict the practice of medicine to doctors, with the exception of certain treatments such as those provided by the four mentioned non-conventional medicines (38).

8.3.2 The governmental supervision of CAM Practices

The conduct of medical doctors in Belgium is supervised by the Order of Physicians (47) in application of existing laws. The Order is not legislative nor a governmental institution. It serves as an exclusive tribunal for the conduct of doctors only, directly if (even anonymous) complaint against one doctor is received by the Order, or indirectly, but systematically, after a civil- or criminal court already has convicted a doctor (so a doctor is always convicted twice, once by the regular court and after that by the Order of Physicians (47)). The code of professional ethics contains the rules concerning continuity of care, medical secrecy, handing over of medical data to colleagues and the individual relations between a physician and patients, colleagues, dentists, pharmacists and allied health professionals (48).

A doctor risks a fine (under Article 11) or suspension or withdrawal of his/her licence to practise (under Article 8) if the law is trespassed. The Order of Physicians does not preside over paramedical professions. The Order discourages the practice of any alternative medicine (irrespective of whether the therapist is a doctor or not), as long as the proof of working mechanisms or clinical evidence remain insufficient (47).

According to the code, physicians are expected to practise medicine according to the current knowledge of scientific medicine. On the other hand, physicians have a freedom of therapy, so they can freely practise CAM if they bring no harm to their patients (45).

8.3.3 The reimbursement status of CAM practices and medicinal products

CAM is not reimbursed by compulsory health insurance, organized by the National Institute for Health and Disability Insurance (RIZIV-INAMI), but several health insurance funds incorporate CAM partially in their voluntary health insurance (37).

8.3.4 Acupuncture

The Chamber of Acupuncture was proposed based on the Colla law in 1999. Member nominations have been made according to the Royal Decree in the Belgian Parliament in 2010 (28). The Belgium Association of Medical Doctors Acupuncturists (B.A.M.D.A.) was founded in 1973 (47).

There are two Academies of medicine in Belgium, one in each linguistic region of the country. Both Academies have issued, although separately, concordant advice of reserving the practice of acupuncture exclusively to doctors, but at the same time they discourage this practice altogether. The future of acupuncture will be decided by political feasibility (47).

At the end of 2011 the Chamber of Acupuncture, which serves as an advisory body to the Minister of Health and Social Security was constituted with representatives of the universities, the professional unions of doctor-acupuncturists and non-doctor acupuncturists (47).

8.3.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.3.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.3.7 Chiropractic

The Chamber of Chiropractic was established based on the Colla law in 1999. Member nominations have been made according to a Royal Decree in the Belgian Parliament in 2010 (28).

8.3.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.3.9 Homeopathy

The Chamber of Homeopathy was established based on the Colla law in 1999. Member nominations have been made according to the Royal Decree in the Belgian Parliament in 2010 (28). Homeopaths must be registered with a professional association accepted by the government (49, 50).

8.3.10 Massage

Masseur is regulated according to national regulation “Royal decree of the 21st December 2006 about the professional competence for the independent practice of bodily care, of the optician, the dental technician and the undertaker”(47).

Massage is registered in the EU regulated professions database as follows:

Massage, reconditioning and regeneration services (EN) is a directly related regulated profession with title “Masseur-Masseus” recognized under Directive 2005/36/EC (5), ID 7773. General system of recognition: recognition of professional experience “Crafts”.ex-Directive 1999/42. National legislation: ‘Arrêté royal du 21 décembre 2006 relatif à la compétence professionnelle pour l'exercice des activités indépendantes relatives aux soins corporels, d'opticien, de technicien dentaire et d'entrepreneur de pompes funèbres’. 21 DECEMBER 2006. - Koninklijk besluit betreffende de beroepsbekwaamheid voor de uitoefening van zelfstandige activiteiten op het gebied van lichaamsverzorging, van opticien, dentaaltechnicus en begrafenisondernemer (7). Useful webpage: http://mineco.fgov.be/ministry/formalities/detail_formalities_fr.asp?idformalite=153.

8.3.11 Naprapathy

No specific regulation has been found on naprapathy.

8.3.12 Naturopathy

No specific regulation has been found on naturopathy.

8.3.13 Neural therapy

No specific regulation has been found on neural therapy.

8.3.14 Osteopathy

The Chamber of Osteopathy was established based on the Colla law in 1999. Member nominations have been made according to Royal Decree in the Belgian Parliament in 2010 (28).

8.3.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on traditional Chinese medicine (TCM).

8.3.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Belgium with the professional title “**Kinesitherapeut(e)**”. The title and the professional activity are protected by the law. National legislation is found in “Article 21 bis of the Royal Decree number 78 about the professional practice of health care” (47). Physiotherapists are regulated therapists working on prescription of a physician. In Belgium many **physiotherapists practise osteopathy or chiropractic**, but also other “**non-recognized**” **CAM therapies** (45). The rules of professional conduct (code of ethics) are determined directly by the Ministry of Public Health through national legislation. Belgium requires a registration to practise by the Ministry of Public Health, which is the national authority responsible for the physiotherapy profession in Belgium (51).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**kinésithérapeute/ kinesitherapeut**” recognized under Directive 2005/36/EC (5), ID 160. General system of recognition: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d. National legislation: Article 21bis del’arrêté royal n° 78 relatif à l’exercice des professions des soins de santé / Artikel 21bis van het koninklijk besluit nr. 78 betreffende de uitoefening van de gezondheidsberoepen (7).

Useful webpage: http://www.juridat.be/cgi_loi/loi_F.pl?cn=1967111008.

8.4 Bosnia and Herzegovina

Bosnia and Herzegovina is listed as a potential candidate for European Union membership (52) and has been a member of the Council of Europe since 2002 (12).

Following the dissolution of former Yugoslavia the Dayton Peace Agreement (DPA) ended a 1992-1995 war, and established Bosnia and Herzegovina (BiH) as a state consisting of two entities: Federation of Bosnia and Herzegovina (FBiH) and Republika Srpska (RS), and later the Brcko District (BD). The Federation of BiH consists of ten Cantons, each of them with its own administration.

Under the DPA constitutional construction BiH is a sovereign state with a decentralized political and administrative structure, where the responsibility for social policy, health and education is allocated to the level of entities and BD. In practice, the social sector is organized in three (3) distinct systems with ten subsystems in FBiH. Since 2003, there has been a loose coordination mechanism, among others in the areas of health, social policy and education, established at the state level within the Ministry of Civil Affairs.

8.4.1 The legal and regulatory status of CAM and CAM practices

There is no general CAM law neither at the state level of Bosnia and Herzegovina or the levels of Federation BiH, Republika Srpska or Brcko district. However, recent laws on health care both in Federation BiH and Republika Srpska, have introduced CAM for the first time.

In BiH, graduate and postgraduate education of doctors, dentists and pharmacists is organized by the relevant ministries for education, and held at five faculties of medicine (Universities of Sarajevo, Tuzla, Mostar, Banja Luka, Istočno Sarajevo), three faculties of dentistry (Sarajevo, Banja Luka and Istočno Sarajevo), and three faculties of pharmacy (Sarajevo, Banja Luka and Tuzla). The curricula and syllabi for medicine and dentistry are designed to cover 6 years of study, including both theoretical and practical courses. The faculty of pharmacy provides a 5-year education for undergraduates. Upon completion of the full training course, there is a mandatory 1-year residency (registration course) for newly graduated general practitioners (GPs) and dentists, mostly at the primary health care level. Such “residents” are expected to take the professional state examination, whereby they are then authorized to perform medical duties independently as licensed GPs, or to continue with a specialization training program in a particular field of medicine/dentistry/pharmacy. Specialized training programs take 3–5 years, depending on the professional branch (53).

8.4.2 Republika Srpska

Law on Health Care (Official Gazette of the RS, No 106/2009 (54), Article 121):

(1) Alternative Medicine, in terms of this Act, includes traditional and alternative methods and procedures for diagnosis, treatment and rehabilitation (hereinafter referred to as alternative medicine), which beneficially affect or might have a beneficial impact on human health or the health condition and that in accordance with a valid medical doctrine are not covered by health services.

(2) The minister shall prescribe the methods, procedures, and approval for the performance of alternative medicine in paragraph 1 of this article in the medical institutions.

Additionally, a draft of a bylaw currently under preparation, envisages that only health professionals with a university degree education and with licence issued by responsible chambers will be allowed to practise CAM in the RS. Health professionals with so-called secondary degree education (nurses, physiotherapists and midwives) will be allowed to practise CAM if they possess a valid diploma as well as a licence issued by a responsible chamber (5). The following CAM methods will be covered in this bylaw: **ayurveda, acupuncture, traditional Chinese medicine, homeopathy, phytotherapy, quantum medicine, chiropractic, macrobiotics, traditional domestic medicine, apitherapy, aromatherapy, qigong, reiki, yoga and t'ai chi ch'uan.**

8.4.3 Federation of Bosnia and Herzegovina (BiH)

Law on Health Care of Federation BiH (Official Gazette of FBiH. No. 46/10) (55), Article 46:

“Alternative medicine, in terms of this Act, include those proven and by experts not forbidden complementary and alternative methods and procedures for diagnosis, treatment and rehabilitation (hereinafter referred to as alternative medicine), which has a beneficial impact or which could have a beneficial impact on human health or the health status and which, in accordance with a valid medical doctrine are not covered by health services.

Methods and procedures of alternative medicine in paragraph 1 of this article, can only be introduced in a medical institution or private practice with the consent of the competent Cantonal Ministries of health (hereinafter: Cantonal Ministry) and the relevant chamber.

Methods and procedures of alternative medicine cannot be implemented at the expense of the compulsory health insurance” (53).

Law on Health Care of Federation BiH (Official Gazette of FBiH. No. 46/10) (3), Article 47:

“Allowed are only those methods and procedures of alternative medicine that:

- 1) Have no adverse health effects.
- 2) The user - the patient does not distract from the use of valuable health care services.

- 3) Are performed in accordance with recognized standards of alternative medicine.

Methods and procedures of alternative medicine can be performed only by health workers who have permission to perform the methods and procedures of alternative medicine issued by the Cantonal Ministry. Further conditions, manner and procedure of the methods and procedures of alternative medicine in a medical institution, or private practice will be regulated in bylaws introduced by Federal Minister. Cantonal Ministry supervises the performance of the methods and practices of alternative medicine in institutions or private practice, in accordance with the law. Provisions of this legislation apply to health care workers who perform the procedures and methods of alternative medicine, on the issue, renewal and revocation of licences for independent work (hereinafter licence)"(53).

Law on Health Care of Federation BiH (Official Gazette of FBiH. No. 46/10) (3), Article 48:

"For his work, health care workers who perform the methods and practices of alternative medicine bear experts, ethical, criminal and material responsibility.

According to this law, relevant bylaws envisaged in the Art 47 will be adopted within 18 months of the law enforcement date (August 2011)"(53).

8.4.4 Brcko district of BiH

Law on Health Protection of Brcko District BiH (Official Gazette BD 2/01)(56).

-no provisions on CAM (53).

8.4.5 The governmental supervision of CAM Practices

In **Federation BiH**, supervision of the professional work of medical institutions, health workers, and private health workers is carried out by competent authorities for inspection: the Federal and Cantonal Health Inspectors. Federal health inspectors perform health inspections in health care institutions founded or co-founded by the Federation, and cantonal health inspectors do the same in the health care institutions founded by the canton or the natural (human being) or legal person, as well as private practice.

In cantons which have not established cantonal health inspection, health and work inspection may be performed by federal health inspectors in accordance with the special Law on inspections of the FBiH.

In case of technical failure made by health workers, or violations of the ethics and medical deontology, the competent health inspector will defer the subject to the action of the local Chamber (53).

In **Republika Srpska** supervision is regulated through Law on General Inspectorate and its regular day-to-day implementation. The General Inspectorate deals with any kind of inspectorate job in the RS including the health sector. In practice, health professionals who practise CAM are supposed to carry out their patient treatment in accordance with requirements of the above-mentioned bylaw (bylaw about space, equipment and personnel)(57).

8.4.6 The reimbursement status of CAM practices and medicinal products

In **Republika Srpska**, reimbursement of CAM practices is not regulated by law, and hence not covered by the obligatory health insurance scheme (57).

In **Federation BiH**, CAM reimbursement is regulated; the Law on Health Protection, art 46, para 3: "Methods and procedures of alternative medicine cannot be implemented at the expense of the compulsory health insurance" (53).

8.4.7 Acupuncture

Currently, there are no specific regulations for acupuncture.

8.4.8 Anthroposophic medicine

Currently, there are no specific provisions for anthroposophic medicine.

8.4.9 Ayurveda

Currently, there are no specific regulations for ayurvedic medicine.

8.4.10 Chiropractic

Currently, there are no specific regulations for chiropractic.

8.4.11 Herbal medicine/Phytotherapy

Currently, there are no specific regulations for herbal medicine/phytotherapy.

8.4.12 Homeopathy

Currently, there are no specific regulations for homeopathy.

8.4.13 Massage

Currently, there are no specific regulations for massage.

8.4.14 Naprapathy

Currently, there are no specific regulations for naprapathy.

8.4.15 Naturopathy

Currently, there are no specific regulations for naturopathy.

8.4.16 Neural therapy

Currently, there are no specific regulations for neural therapy.

8.4.17 Osteopathy

Currently, there are no specific regulations for osteopathy.

8.4.18 Traditional Chinese Medicine (TCM)

Currently, there are no specific regulations for traditional Chinese medicine (TCM).

8.4.19 Other treatments (mentioned if found in legislation)

In Republika Srbska (RS) **quantum medicine, macrobiotics, traditional domestic medicine, apitherapy, aromatherapy, qigong, reiki, yoga and t'ai chi ch'uan** will be covered by the above mentioned bylaw (57).

Physiotherapy is a regulated profession in Bosnia and Herzegovina, regulated by law and by-laws (57).

8.5 Bulgaria

Bulgaria became a member of the European union in 2007(11) and has been a member of the Council of Europe since 1992 (12).

8.5.1 The legal and regulatory status of CAM and CAM practices

The Health Law, effective from 1 January 2005, includes regulation of Complementary and Alternative Medicine in Chapter Six, Articles 166-173(58). Article 166 quotes:

“(1) The Minister of Health shall control the application of non-conventional methods for favorable impact on individual health, including:

1. The use of non-pharmaceutical products of organic origin;
2. The use of non-pharmaceutical products of mineral origin;
3. The use of non-conventional physical methods;
4. Homeopathy;
5. Acupuncture and acupressure;
6. Iris, pulse and auricular methods of testing;
7. Dietetics and curative hunger.

(2) The use of non-conventional method for favorable impact on individual health other than those under Paragraph 1 shall be prohibited” (58).

Except for homeopathy, eligible to practise under art.166.1 are holders of

- A master’s degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist’s or bachelor’s degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.

Eligible to practise homeopathy are holders of a master’s degree in the professional areas of medicine or dental medicine (58). We interpret the educational level “Master’s degree in medicine” to be equivalent with “medical doctor”.

According to the health law article 170, practitioners shall register at the regional healthcare center (RHC) in the region where they operate (58). The regional healthcare centers manage a public register for non-conventional providers (58). In the health law article 173 patients of alternative medical practitioners have to be registered in the “visitor’s journal”. The visitor’s journal is managed by the regional healthcare center (RHC). Advertising for alternative treatment methods shall be prohibited according to article 169 (58).

The national office was established in 1988 and is organized as a department of Traditional medicine within the Ministry of Health (59).

Authorization, registration and supervision is delegated to the medical associations (60).

8.5.2 The governmental supervision of CAM Practices

Registered non-conventional practitioners are subject to supervision according to the health law 2005, Chapter six, articles 168-173 (58).

8.5.3 The reimbursement status of CAM practices and medicinal products

Alternative treatment is paid out-of-pocket by the patients themselves (61). The health insurance act, article 45 describes the treatments and medical care which are covered. Article 51 says that no other health service than those mentioned in art. 45 are covered. It is unclear if alternative treatment is covered according to those articles (62).

8.5.4 Acupuncture

Acupuncture and acupressure are regulated under the health law article 166.1.5. and article 167 (58). Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.

8.5.5 Anthroposophic medicine

Anthroposophic medicine is statutory registered as an additional qualification for medical doctors (60).

8.5.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.5.7 Chiropractic

The use of non-conventional physical methods is regulated under the health law article 166.1.3. and article 167 (58). We understand that chiropractic may be covered by this regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.

8.5.8 Herbal medicine/Phytotherapy

The use of non-pharmaceutical products of organic and mineral origin is regulated under the health law article 166.1.1 and 2. and art 167 (58). We understand that herbal medicine may be covered by this regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.

8.5.9 Homeopathy

The Health Law from 1 January 2005 includes homeopathy in chapter six, articles 166-173 (28). Eligible to practise homeopathy are holders of a master's degree in the professional areas of medicine or dental medicine (58). ECH and ECCH interpret this as "only medical doctors and dentists are allowed to practise homeopathy" (28, 50). Until 1989 homeopathy was strictly prohibited (60).

8.5.10 Massage

Massage is a regulated profession in Bulgaria. The use of non-conventional physical methods is regulated under the health law article 166.1.3. and art 167 (58). As the European register for regulated professions refer to the health law we assume that **massage** is covered by the above regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science (58).

Massage is registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title "Масажист " (Qualified masseur/masseuse (EN)) recognized under Directive 2005/36/EC (5), ID 7563. General system of recognition- primary application.

National legislation: Law on Health. Qualification level: PS3 - Diploma of post-secondary level (3-4 years) , Art. 11 d (7). Useful link: nihil.

8.5.11 Naprapathy

No specific regulation has been found on naprapathy.

8.5.12 Naturopathy

No specific regulation has been found on naturopathy.

8.5.13 Neural therapy

No specific regulation has been found on neural therapy.

8.5.14 Osteopathy

The use of non-conventional physical methods is regulated under the health law article 166.1.3. and art 167 (58). We understand that **osteopathy** may be covered by this regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science (58).

8.5.15 Traditional Chinese Medicine (TCM)

The use of non-pharmaceutical products of organic or mineral origin is regulated under the health law article 166.1.1 and 2. and art 167 (58). We understand that TCM may be covered by this regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science (58).

Acupuncture and acupressure are regulated under art. 166.1.5.

8.5.16 Other treatments (mentioned if found in legislation)

Physiotherapy is regulated in Bulgaria. The title "**Kinesitherapist**" (for university graduates) "**Rehabilitator**" (for college graduates) is not protected by the Bulgarian state, nor is the professional activity. There are no official rules of professional conduct or other state legislations. Bulgaria does not require a registration or licence to practise. However, the Bulgarian physiotherapy association has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Bulgaria is the Ministry of Health (63).

The use of non-conventional physical methods is regulated under the health law article 166.1.3. and art 167 (58). We understand that **physiotherapy** may be covered by this regulation. Providers can practise if they are holders of:

- A master's degree in the professional area of medicine, dental medicine or pharmacology.
- A specialist's or bachelor's degree in the professional area of health care.
- A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapist is a directly related regulated profession with title "**Рехабилитатор**" (Rehabilitation specialist (EN)) recognized under Directive 2005/36/EC(5), ID 11965. General system of recognition- primary application. National legislation: Law on Health. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d(7). Useful link: nihil.

8.6 Croatia

Croatia became an independent state in 1991 following the dissolution of the former Yugoslavia, has been listed as a candidate country for EU membership since June 2004, and the country will become the 28th EU member country on 1 July 2013 (52). Croatia has been a member of the Council of Europe since 1996 (12).

8.6.1 The legal and regulatory status of CAM and CAM practices

According to CRONES (Croatian federation for natural energy and spiritual medicine) there is no legal regulation of unconventional medicine in Croatia (64). From 2004 until today there have been different unsuccessful attempts at making legal regulation of CAM in Croatia (64). However, there seems to be consensus on having a separate legislation for CAM separate from the Law on Health Care (64).

The Criminal Law, article 244, mentions “quackery”:

(1) Whoever, lacking prescribed, professional qualifications, medically treats another or renders medical aid to such a person shall be punished by a fine of up to one hundred and fifty daily incomes or by imprisonment not exceeding six months.

(2) Whoever commits the criminal offence referred to in paragraph 1 of this Article for remuneration or pecuniary gain shall be punished by a fine or by imprisonment not exceeding one year (65).

Consequently CRONES claims that no one without medical qualifications may treat people (64). Further CRONES claims that CAM practitioners may only contribute to life quality improvement and they may advise the clients to do a medical check-up.

The practice of CAM can, however, be seen as regulated under Croatian government law from 31 May 2007, “the Law of national classification of services” (66, 67). Healthcare practitioners not statutorily regulated are registered under a separate code nr 2007/ 86.9 “Other services for health protection” (in 2002 code 85.14 “Other services for human medicine”). Practitioners may provide more than one healthcare service, but must list one therapy as their main service (67).

The European Central Council of Homeopaths (ECCH) has forwarded clarifying information on the interpretations of the Criminal Law, Quackery paragraph in September 2011. They write that Article 244 cover regulations for persons with NO education or diplomas but who claim to be conventional healthcare practitioners. ECCH writes that there is no law

restricting the practice of CAM therapies in Croatia and CAM practitioners practise under “law of national classification of services”.

8.6.2 The governmental supervision of CAM Practices

There is no supervision of CAM practitioners (according to CRONES)(64).

8.6.3 The reimbursement status of CAM practices and medicinal products

No CAM treatments or CAM medicinal products are reimbursed in Croatia (64).

8.6.4 Acupuncture

No specific regulation has been found on acupuncture.

8.6.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.6.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.6.7 Chiropractic

No specific regulation has been found on chiropractic.

8.6.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.6.9 Homeopathy

Croatia has no specific restrictions for homeopathy practices (50). Both medical doctors and non-medically qualified practitioners are allowed to practise homeopathy, and there is no statutory regulation of homeopathy in place (28, 60).

Homeopathy practitioners, who are not statutorily regulated healthcare personnel, are from 2007 practising under the “Law of national classification of services” (66, 67). A separate code for homeopathy practitioners are registered under Code 86.9 “Other services for health protection”(68).

8.6.10 Massage

No specific regulation has been found on massage.

8.6.11 Naprapathy

No specific regulation has been found on naprapathy.

8.6.12 Naturopathy

No specific regulation has been found on naturopathy.

8.6.13 Neural therapy

No specific regulation has been found on neural therapy.

8.6.14 Osteopathy

No specific regulation has been found on osteopathy.

8.6.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.6.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Croatia with the title **Bachelor Physiotherapists (Baccalureus Fizioterapeut)**. The Parliament of the Republic of Croatia on 3 October 2008 passed an act on physiotherapy services and initiated the establishment of the Croatian Association of Physiotherapists. The rules of professional conduct (code of ethics) are determined directly by Croatian Council for Physiotherapists. Croatia requires a registration to practise by the Croatian Council for Physiotherapists. The physiotherapist must be registered with the Croatian Council of Physiotherapists and obtain a licence to practise. The national authority responsible for the physiotherapy profession in Croatia is the Croatian Council for Physiotherapists (69).

8.7 Cyprus

The Republic of Cyprus (hereinafter Cyprus) has been a member of the European Union (EU) since 2004 (11) and became a member of the Council of Europe in 1961 (12).

8.7.1 The legal and regulatory status of CAM and CAM practices

Only medical doctors can provide medical treatment in Cyprus (44). “It is a criminal offence for others to practise medicine or give medications”. CAM is not integrated with medicine and only **chiropractic** treatment is recognized and regulated (44). Treatment is **restricted to legally regulated personnel**, however a practitioner approved to practise under United Kingdom regulations, is also approved to practise in Cyprus (43, 70).

The Cyprus Alternative Therapeutics is registered by the Cyprus Government in accordance with the Societies and Institutions Law No-57 of 1972, 1973. In 2004 all alternative Medicine Associations have come under one umbrella body thus forming the Cyprus General Council of Alternative and Complementary Medicine. The council has taken major steps towards self-regulation within the profession (71).

The Alternative Medicine Practitioners are not protected by law like the Medical Association’s members. Only the practice of modern, orthodox medicine by professionals is recognized, however various forms of complementary and alternative medicine practices are tolerated (71).

Alternative practitioners may register in “the Cyprus general council & register of alternative therapists”. Associations included are: Cyprus Alternative Therapies Association (Reg. No.1457), Cyprus Naturopathic Association (Reg.No. 1549), Cyprus Traditional Acupuncture Association (Reg.No. 2120)(71).

8.7.2 The governmental supervision of CAM Practices

No specific regulation has been found on supervision of CAM practices in Cyprus.

8.7.3 The reimbursement status of CAM practices and medicinal products

Information from 2001 states that there is no reimbursement of CAM treatments in Cyprus, and CAM is not included in the National Health Insurance Scheme (44).

8.7.4 Acupuncture

A new medical registration law on acupuncture was in preparation in 2004 (43). In Cyprus alternative practitioners may register in the “Cyprus general council & register of alternative therapists” where the “Cyprus Traditional Acupuncture Association” is included.

8.7.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.7.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.7.7 Chiropractic

In 1991 Cyprus introduced registration for chiropractors by approving the Chiropractors’ Registration Law (72). To practise chiropractic the practitioner must hold a recognized degree, diploma, or certificate. It is a criminal offence to practise chiropractic without being registered (44).

Chiropractic is registered in the EU regulated professions database as follows:

Chiropractic is a directly related regulated profession with title “Chiropractor(EN)” recognized under Directive 2005/26/EC (5), ID 5339. General system of recognition – primary application. Qualification level: DSE-diploma (post-secondary education) including Annex II (ex 92/51, Annex C, D), Art. 11 c (7).

8.7.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.7.9 Homeopathy

No specific regulation or recognition has been found on homeopathy in Cyprus. Medical doctors can provide homeopathy within their medical practise. Non-medically qualified practitioners are practising homeopathy, even if it is a criminal offence for others than medical doctors to practise medicine or give medications (28, 41).

8.7.10 Massage

No specific regulation has been found on massage.

8.7.11 Naprapathy

No specific regulation has been found on naprapathy.

8.7.12 Naturopathy

In Cyprus alternative practitioners may register in the “Cyprus general council & register of alternative therapists” where the “Cyprus Naturopathic Association” is included.

8.7.13 Neural therapy

No specific regulation has been found on neural therapy.

8.7.14 Osteopathy

No specific regulation has been found on osteopathy.

8.7.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.7.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Cyprus. The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise. Cyprus has a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Cyprus is the Ministry of Health (73).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapist is a directly related regulated profession with title “**Φυσιοθεραπευτής**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC (5), ID 1250. General system of recognition – primary application. Qualification level – PS3 –Diploma of post-secondary level (3-4 years), Art. 11 d. (7).

8.8 The Czech Republic

The Czech Republic became an independent state in January 1993 and a member of the EU in 2004 (74). The Czech Republic became a member of the Council of Europe in 1993 (12).

8.8.1 The general legal and regulatory status of CAM and CAM practices

There is no general CAM legislation in the Czech Republic, but regulation of **acupuncture, homeopathy, massage, chiropractic and physiotherapy** has been established. Information given by the Ministry of Health in the Czech Republic (75) in September 2011 confirms that **acupuncture and homeopathy** can only be provided by **physicians**, and **massage, chiropractic and physiotherapy** can only be provided by **health professionals** according to specific regulation (see below).

The Czech Republic has from 2004 harmonized its health legislation to the EU Directive 2005/36/EC (5,76). In 2004 two laws were enacted to establish new requirements for obtaining medical degrees and postgraduate specialized training for physicians and non-physician health professionals. From 2009 legislation for about 40 postgraduate medical specialties was prepared (76). The Ministry of Health in the Czech Republic offers a standardized state licensing exam for health professionals like physicians, dentists, nurses, pharmacists and paramedical personnel. Private health care providers must have a state licence and be registered by the regional health authorities to open a private health practice (76).

A NAFKAM representative visited the Czech Republic in October 2010 and was informed about national discussions in progress of developing CAM legislation in the country. **Acupuncture and homeopathy** treatment provided by physicians is regulated through The Trade Licensing Act (Zivnostenský zákon 455/1991 Sb). A national act about recognition of qualification of EU citizens (Zákon c. 18/2004 Sb)(77) is probably linked to the Directive 2005/36/EC (5). Our informants think that a legal regime can be facilitated by voluntary self-regulation together with creating new “professions” on the list in the Trade Licencing Act (77).

There is no professorial chair for CAM in the Czech Republic (78).

8.8.2 The governmental supervision of CAM Practices

No regulations regarding supervision of CAM practitioners has been found.

8.8.3 The reimbursement status of CAM practices and medicinal products

The Ministry of Health in the Czech Republic confirms in 2011 that acupuncture and homeopathy are listed in the Act on Public Health Insurance (48/1997) as methods of public health care not covered by insurance (75). We found no reimbursement regulations or insurance coverages for CAM therapies (77).

The reimbursement legislation seems unchanged from 2004. The Ministry of Health in the Czech Republic confirmed in 2004 that according to Act NO. 48/1997 Coll on Public Health Insurance there was no reimbursement of acupuncture and homeopathic remedies (79). Consequently changes in health regulation from 2004 to 2011 have not influenced the CAM reimbursement coverage.

8.8.4 Acupuncture

The Ministry of Health in the Czech Republic confirms that only physicians with specialization may practise acupuncture (75, 76).

A training course is jointly sponsored by the Institute for Further Education of Physicians and the Czech acupuncture chamber of the Czech Medical Society (JEPurkyně - in 2004: the Institute of Post-graduate Education in Healthcare (IPVZ))(75, 76).

Acupuncture is listed in the Act on Public Health Insurance (48/1997) as a method of public health care not covered by insurance. Education of physicians is conducted in accordance with the educational law č.95/2004 Coll (75).

Acupuncture is an additional qualification for medical doctors and veterinary surgeons and diplomas are issued by a national doctors' association of acupuncture. Postgraduate training for doctors is also offered at private teaching centres and acupuncture training is offered as optional for medical students. The official document "Vestník Ministerstva zdravotnictví České republiky 1981, částka 1, bod 2" describes how acupuncture can be applied and used (77).

8.8.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.8.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.8.7 Chiropractic

Chiropractic is considered to be a part of regular public health care and as such may only be performed as a part of treatment in health facilities by health care professionals like **doctors or physiotherapists** (75).

8.8.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy treatment.

8.8.9 Homeopathy

Homeopathy may only be provided **by physicians** after completion of courses organized by various homeopathic societies (75).

The Ministry of Health in the Czech Republic offers no homeopathy courses. Homeopathy is listed in the Act on Public Health Insurance (48/1997) as a method of public health not covered by insurance. Education of physicians is conducted in accordance with the educational law č.95/2004 Coll (75).

We have found few changes, rather clarifications, in regulation of homeopathy in the Czech Republic in the last decade. The Ministry of Health in the Czech Republic informed in 2004 that the Ministry “do not prohibit any physician with attestation to provide treatment involving homeopathy” (76).

In 2010 CAM practitioners in the Czech Republic responded in a CAMbrella questionnaire that homeopathy in the Czech Republic is recognized as an additional qualification for medical doctors and veterinary surgeons (77).

8.8.10 Massage

Massage is regulated in the Czech Republic. According to the Ministry of Health, massage performed to treat health problems associated with various **diseases** is regulated for **physiotherapists and medical staff appropriately trained in accordance with the Education Act** No.96/2004 Coll.. Massage **given to healthy people** by masseurs is regulated in **the Trade Licensing Act** (374/2004 Coll. Use of medical devices is only allowed for health professionals) (75).

A massage therapist has to document 150 hours of studies with some specification for theory and practice (or diploma from university- (medical doctor or physiotherapist))(77). See also “other treatments”.

No insurance is needed for massage therapists who are “consulting and advising”(77).

Massage is registered in the EU regulated health professions database as follows:

Masseur is a regulated profession with two national titles: the common EU ID no. 1260 includes two different titles:

Masseur/Blind and Asthenopic Masseur (EN) is a directly related regulated profession with title “Masér/nevidomý a slabozraký maser” recognized under Directive 2005/36/EC (5) , ID 7114. General system of recognition – primary application. National legislation: Act 96/2004 Coll., Art.37. Qualification level: ATT – Attestation competence, Art. 11a. (7). Useful webpage: <http://www.mzcr.cz>.

Massage, reconditioning and regeneration services (EN) is a directly related regulated profession with title “Masérské, rekondiční a regenerační služby” recognized under Directive 2005/36/EC (5), ID 14595. General system of recognition – primary application. National legislation: Sections 6, 7, 8, 24 of Act No 455/1991 Coll., the Trade Licensing Act, as amended. Qualification level: SEC – Certificate attesting the completion of a secondary course, Act 11 b (7). Useful webpage: <http://www.mzcr.cz>.

8.8.11 Naprapathy

No specific regulation has been found on naprapathy.

8.8.12 Naturopathy

No specific regulation has been found on naturopathy.

8.8.13 Neural therapy

No specific regulation has been found on neural therapy.

8.8.14 Osteopathy

No specific regulation has been found on osteopathy.

8.8.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.8.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in the Czech Republic with the professional title “Fyzioterapeut”. The title is not protected, and the professional activity is regulated by law. The Czech Republic has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in the Czech Republic is the Ministry of Health (80).

Physiotherapist is a directly related regulated profession with title “Fyzioterapeut” (Physiotherapist (EN)) recognized under Directive 2005/36/EC (5), ID 7111. General system of recognition - primary application. National legislation: Act No. 96/2004 Coll., Art.25. Qualification level: SEC-Certificate attesting the completion of secondary course, Art.11 b (7) Useful webpage: <http://www.mzcr.cz>.

8.9 Denmark

Denmark has been a member of the European Union since 1973 (11) and a founding member of the Council of Europe since 1949 (12).

8.9.1 The legal and regulatory status of CAM and CAM practices

Sundhedsloven(81) and “Lov om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed”(82, 83) regulate health professionals’ practice in Denmark. Medical doctors are allowed to use the treatment options they find useful. Non-medically qualified practitioners are allowed to provide care with certain restrictions. Treating infectious diseases is considered as a medical act, and except for special regulations for acupuncturists only doctors may give injections (28, 82).

Health professions in Denmark are authorized according to Act no. 877 of 4 August 2011 on Authorization of Health Care Professionals and on Professional Health Care Practice section 12(82). Authorization is given only based on education and practice as described in this regulation. CAM practitioners are not authorized except for chiropractors and physiotherapists who are regulated health personnel and not regarded as CAM professionals (84). In Denmark authorization or not is mainly what separates health professionals from CAM professionals (83).

Denmark has adjusted to professionals’ regulation in (EU) European Union (5) with two main acts:

1. Assessment of Foreign Qualifications etc., 2007 (85).
2. Act on the Right to Exercise Certain Professions in Denmark, 2010 (86).

The law on a self-regulatory registration system for alternative practitioners from 2004 established a voluntary register for non-medically qualified CAM practitioners (87). The register includes practitioners who “fulfill well-defined criteria for education and are members of an organization for practitioners that take on the necessary tasks for registration and maintaining the register”(28).

In Denmark a CAM practitioner with a membership in one of the officially recognized CAM organizations may voluntarily register in the register for CAM professionals and add “Registered Alternative Practitioner” (RAB) to his/her CAM title (50). “Sundhedstyrelsen” gives branch associations for CAM practitioners the right to issue RAB certificates to their members if the branch and the members fulfill certain requirements of education and court of appeal (83).

8.9.2 The governmental supervision of CAM Practices

Supervision of health professionals in Denmark is included in law on authorization of health personnel, Chapter 7, § 26 (82). Authorized health personnel are supervised after § 215 in Sundhedsloven (81). Chiropractors and physiotherapists are regulated health personnel in Denmark and as such included in the supervision regulative system of health professionals. There is no government supervision on non-medically trained CAM practitioners.

8.9.3 The reimbursement status of CAM practices and medicinal products

CAM practitioners are entitled to a lower VAT rate if they have specific training and the treatment follows certain characteristics (84, 88).

There is no reimbursement for CAM treatment or CAM medicinal products except for services given by medically qualified practitioners. Acupuncture is partially reimbursed (60, 88).

Chiropractic consultations are partially reimbursed according to Sundhedsloven chapter 4.2.5. Chiropractors. "The public health care scheme partly pays for treatment provided by chiropractors. It is not necessary to be referred by a general practitioner in order to receive a subsidy. There are approx. 300 chiropractors who have an agreement with the public health care scheme"(81, 88).

8.9.4 Acupuncture

Both medical and non-medical professionals may treat acupuncture in Denmark. There is no accredited training for acupuncture (89).

Needle acupuncture for patient treatment is allowed for persons with or without authorization. Conditions are that the practitioner must not put the patient at risk. Injections with medicinal products are only allowed for doctors and health personnel.

8.9.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.9.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.9.7 Chiropractic

Kiropraktor (Chiropractor) is a regulated health profession in Denmark and authorization is given according to Act no. 877 of 4 August 2011 on Authorization of Health Care Professionals and on Professional Health Care Practice, section 12 (82). Authorization is given only based on education and practice as described in this regulation. Permission to

practise independently as chiropractor is given in “Executive Order no. 650 of 26 June 2009 on permission to practise independently as chiropractor”(90).

Doctors and physiotherapists are allowed to practise chiropractic in Denmark.

According to Sundhedsloven (The Danish Health Act) 4.2.5 Chiropractors, “the public health care scheme” partly pays for treatment by chiropractors. It is not necessary to be referred by a general practitioner in order to receive a subsidy. There are approx. 300 chiropractors who have an agreement with the public health care scheme”(81, 88).

Chiropractic is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with the title “**Kiropraktor**” recognized under Directive 2005/36/EC, ID 386. General system of recognition – primary application. National legislation ACT NO.415 of 6 June 1991 concerning chiropractors. Qualification level: PS3 – Diploma of post-secondary level (3-4 years), Art. 11 d. (7). Useful webpage; <http://le.iu.dk/DetailEN.aspx?aldErhverv=30>

8.9.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.9.9 Homeopathy

The law on a self-regulatory registration system for alternative practitioners from 2004 established a voluntary register for non-medically qualified CAM practitioners including homeopaths (28, 87).

Medical doctors and health professionals may practise homeopathy within the frames of Sundhedsloven (81) and Authorization of Health Care Professionals and on Professional Health Care Practice section 12 (82). For use of homeopathic medicinal products the law “Bekendtgørelse om homøopatiske lægemidler m.v.” gives the regulations (91).

ECCH has detailed information on the terms for being accepted onto the “Registry on Alternative Practitioners” in their report “The legal situation for the Practice of Homeopathy in Europe” from 2010 (50).

8.9.10 Massage

No specific regulation has been found on massage.

8.9.11 Naprapathy

No specific regulation has been found on naprapathy.

8.9.12 Naturopathy

No specific regulation has been found on naturopathy.

8.9.13 Neural therapy

No specific regulation has been found on neural therapy.

8.9.14 Osteopathy

No specific regulation has been found on osteopathy.

8.9.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.9.16 Other treatments (mentioned if found in legislation)

Physiotherapist are regulated as health personnel and not regarded as a CAM profession in Denmark (86). The professional title “**Fysioterapeut**” is protected, but the professional activity is not protected. A physiotherapist must have an authorization to practise and agreements with the social security authorities to obtain reimbursement for the patients. Rules of professional conduct are established by the association “Danske Fysioterapeuter” who apply jurisdiction. The association has developed a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Denmark is the Ministry of Health (92).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapist is a directly related regulated profession with title “**Fysioterapeut**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC (5), ID 380. General system of recognition – primary application. National legislation: Order NO 631 of 30 August 1991 concerning the Therapy Assistent’s’ Act. Qualification level – PS3 –Diploma of post-secondary level (3-4 years), Art. 11 d. (7, 86).

Useful webpage: <http://le.iu.dk/DetailEN.aspx?aldErhverv=21>

The public health care scheme partly pays for treatment by physiotherapists, but persons who have serious physical disabilities due to illness may receive physiotherapy free of charge. The treatment is only subsidized if it has been prescribed by a general practitioner (81).

8.10 Estonia

Estonia regained its independence from the Soviet Union in 1991, and became a member of the European Union in 2004 (11). Estonia became a member of the Council of Europe in 1993 (12).

8.10.1 The legal and regulatory status of CAM and CAM practices

There is no specific CAM legislation in Estonia (41, 43). However, health professionals may provide CAM treatments and consequently CAM is regulated within legislation for health care providers (see chiropractic, massage, osteopathy).

Estonian health care regulation has been rapidly changed firstly after independence from the Soviet Union in 1991 and later after joining the European Union in 2002. The system is changing towards more decentralized primary health care and towards more evidence-based medicine. Estonia has a long tradition of use of herbal products, and healthcare based on traditions and practice experience is accepted and developed in the transition of the Estonian society (93).

The Health Services Organisation Act regulates health care service and health personnel (94). § 2. The act defines health services as: “(1) the activities of health care professionals for the prevention, diagnosis or treatment of diseases, injuries or intoxication in order to reduce the malaise of persons, prevent the deterioration of their state of health or development of the diseases, and restore their health. The Minister of Social Affairs shall establish the list of health services” (94).

No CAM health services were found in Estonian health regulations (94). There are no restrictions of CAM treatment provided by listed health personnel as long as the treatment is according to The Health Services Organisation Act (94).

Health care professionals are **doctors, dentists, nurses and midwives** if they are registered with the Health Board (§3, the health services organisation act) (94). A health care professional may provide health services within the acquired specialty with regard to which the Health Board has issued a certificate of registration of the person as a health care professional. **Health care providers** are health care professionals or legal persons providing health services, §4 (94). The Health Board maintains the registers of health care professionals and activity licences §57 (94).

Regulated professions are regulated according to the Professions act 2008 (95).

§14 states; “The register of professions is a state database used to collect, preserve and systemize information on professional councils, professions, professional standards, awarders of profession and valid professional certificates”(95). According to the Professions

act registered professions follow the criteria set in the EU regulated professions database or the national professions database (95). We could not find any CAM professions from Estonia in the EU regulated professions database (7). In the Estonian professions database there are several CAM-related professional standards and certificated professionals (96). Main professions are **aroma-therapist, homeopath, reflexologist, physiotherapist, masseur and Chinese natural therapist** (95).

The Estonian Manual Medicine & Chiropractic Association (EMMCA) is a professional association and governing body representing and regulating Estonian health care professionals in the fields of manual and natural medicine (97). EMMCA represents the **chiropractic, osteopathic and massage therapy professions** (97). The EMMCA intends to create the Manual Medicine Doctor "M.M.D." to be recognized and regulated. "All M.M.D.'s in Estonia will have subspecialties in their respective areas of expertise such as **Chiropractic Medicine, Osteopathic Medicine, Naturopathic Medicine, Traditional Chinese Medicine** etc."(97).

8.10.2 The governmental supervision of CAM Practices

Health care professionals like **doctors, dentists, nurses and midwives** registered with the Health Board, are supervised according to the health services organisation act, §55 (94). The classifications indicated in the health services list, section 1, shall serve as the basis for organisation of financing, quality control, and supervision of national statistical health observations and health-related activities (98). CAM providers are not included in the health supervision regulative system.

8.10.3 The reimbursement status of CAM practices and medicinal products

We did not find any direct regulation of CAM treatments in the health insurance regulations. According to the health insurance act 2002, § 29 and 30, health services are covered if entered in the list of the health insurance fund and the provision thereof is therapeutically justified (99). According to §31 the following criteria shall be taken into account upon entry of a service in the list of health services:

- 1) the proven medical efficacy of the health service;
- 2) the cost-effectiveness of the health service;
- 3) the necessity of the health service in society and the compatibility of the service with national health policy;
- 4) correspondence to the financial resources of health insurance.

Regulation No. 13 of Minister of Social Affairs of 10 January 2002 § 1 regulates the following health services to be included in the health services list:

- 1) Health services associated with diagnosis and treatment of diseases listed in the International Statistical Classification of Diseases and Related Health Problems Tenth Revision (ICD-10).
- 2) Surgical procedures listed in the Classification of Surgical Procedures of the Nordic Medico-Statistical Committee (NOMESCO NCSP)(98).

Since 1997 **acupuncture is excluded from the list** of medical services covered by government medical insurance. Acupuncture is occasionally reimbursed in very small amounts under the title of rehabilitation packages (100).

Homeopathy is not listed as a regulated health service, thus homeopathic treatment is not reimbursed (41).

8.10.4 Acupuncture

No specific regulation was found on acupuncture. Regulated health personnel may provide acupuncture treatment.

In 1993 the Estonian Acupuncture and Traditional Chinese Medicine Association (EATMA) was founded. From 1995 the name changed to The Estonian Acupuncture Association ((EAA - Eesti Akupunktuuri Assotsiatsioon)). EAA is “a voluntary society that unites medical professionals practising Oriental medicine living and/or working in Estonia”. Since 1994 EAA has been a member of ICMART (International Council of Medical Acupuncture and Related Techniques) and is following its principles of scientific and clinical work (100).

The Centre for Reflexotherapy Methods was founded in 1979 by a decree of the Ministry of Health of the then Estonian SSR. Legally the Centre for Reflexotherapy Methods is part of the Tallinn State Hospital. USSR acupuncture was considered a part of neurology and should therefore belong to the corresponding society. The acupuncture specialists formed the Reflexotherapy Section to the Society of Psychiatrists, Neurologists and Neurosurgeons (100).

8.10.5 Anthroposophic medicine

No specific regulations have been found on anthroposophic medicine. Regulated health personnel may provide anthroposophic medicine.

The Estonian anthroposophic association (Eesti Antroposofiiliste Arstide Selts) organizes the anthroposophic doctors (41).

8.10.6 Ayurveda

No specific regulation has been found on ayurvedic medicine. Regulated health personnel may provide ayurvedic medicine.

8.10.7 Chiropractic

The Chiropractic division of EMMCA specifically represents and regulates Estonian Doctors of Chiropractic Medicine (97).

Estonian Chiropractic Physicians have full medical diagnostic skills and are trained to provide physiotherapeutic modalities as well as prescriptive therapeutics and rehabilitative exercises (97).

“Currently, there is a process in Estonia to have the titles "Doctor of Chiropractic Medicine", Doctor of Chiropractic", 'Chiropractor' and "Chiropractic Physician" fully protected by government legislation so that only qualified Chiropractic Doctors who have graduated from accredited institutions of higher learning are legally allowed to use these titles” (97).

8.10.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy. Regulated health personnel may provide herbal medicine and phytotherapy treatment.

8.10.9 Homeopathy

There is no statutory regulation or restricting legislation of homeopathy in Estonia. Both medical health professionals and non-medically qualified practitioners are allowed to practise homeopathy (28, 41, 50). The profession of homeopathy is regulated with special professional standards (96). At present 14 professionals have obtained a certificate as homeopath and 3 of them (1 doctor, 2 nurses) are also registered with the Health Board (101).

The Estonian Homeopathic Association (Eesti Homöopaatia Ühing) is a member of ECH (the European Committee for Homeopathy)(28).

Non-medical homeopaths that have passed the Professional Board exam (the Professional CAM Board is a state-recognized entity) are free to practice (101, 102).

8.10.10 Massage

The Estonian Manual Medicine & Chiropractic Association (EMMCA) represents the massage therapy profession (9). "Massage" as opposed to "massage therapy" is normally practised by non-licensed individuals who are not qualified to provide therapeutic care and who normally practise simple "relaxation" body rub procedures. "Massage therapy is performed in Estonia by professional Massage Therapists who are registered with EMMCA and licensed to practise massage therapy with the designation of Registered Massage Therapist or R.M.T.”(97).

“Various advanced forms of massage therapy and soft tissue techniques may also be used by other Healthcare practitioners such as Chiropractors, Osteopaths and Physical Therapists. Unqualified masseurs without licence have not met the professional educational and ethical standards set by EMMCA and may not be competent in providing therapeutic care or treatment”(97).

Sports masseurs and paramedical masseurs are not regulated professions, but accepted as professions of which education is not acquired according to regulation RT I 2001, 21, 118, § 34. *"5) services not classified elsewhere, except the services of sports masseurs, paramedical masseurs and mountain guides (subclass 859)"*(103).

8.10.11 Naprapathy

No specific regulation has been found on naprapathy. Regulated health personnel may provide naprapathy treatment.

8.10.12 Naturopathy

No specific regulation has been found on naturopathy. Regulated health personnel may provide naturopathy treatment.

8.10.13 Neural therapy

No specific regulation has been found on neural therapy. Regulated health personnel may provide neural therapy.

8.10.14 Osteopathy

The Estonian Manual Medicine & Chiropractic Association EMMCA represents doctors of osteopathic medicine (D.O.s). D.O.s practise osteopathic manual medicine (OMM), sometimes called osteopathic manipulative therapy (OMT)(97).

8.10.15 Traditional Chinese Medicine (TCM)

TCM is regulated as a professional standard according to the Professions Act 2008(95), but is not regulated in the Health Service Organization Act (94).

In 1993 the Estonian Acupuncture and Traditional Chinese Medicine Association (EATMA) was founded. In 1994 EATMA became a member of ICMART (International Council of Medical Acupuncture and Related Techniques). In 1995 EATMA changed its name to EAA (the Estonian Acupuncture Association)(100).

8.10.16 Other treatments (mentioned if found in legislation)

Physiotherapy (Füsioteraapia) with the professional title **"Füsioterapeut"** is **not** a protected title or regulated health profession in Estonia. Physiotherapy is an accepted profession according to the Professions Act (95). There are no rules of professional conduct or regulations on the physiotherapy profession, and no registration or licence to practise is required. However, Estonia has established a code of ethics for physiotherapists (104). The education follows the Bologna 3+2 system (101, 104). The national authority responsible for the physiotherapy profession in Estonia is the Ministry of Social Affairs (104).

8.11 Finland

Finland became a member of the European Union in 1995(11) and accessed the Council of Europe on 5 May 1989 (12).

8.11.1 The legal and regulatory status of CAM and CAM practices

The Health Care Professionals Act (105) regulates health professionals with a protected occupational title. "The profession of professionals with a protected occupational title can also be practised by other persons with adequate training, experience and professional skills and knowledge" (105). Consequently, in Finland anybody (medically and non-medically qualified) may practise CAM (43, 106).

The National Supervisory Authority for Welfare and Health grants the right to practise the profession of reference (105) and coordinates the automatic recognition of EEA professionals accepted by the act on recognition of professional qualifications (193/2007)(105). According to section 24a, a central register of health care professionals is managed by the National Supervisory Authority for Welfare and Health (105). In addition to medical doctors, nurses, midwives and other conventional health professionals, **masseurs and physiotherapists** are directly mentioned in the law (105). Registered professions of interest in the EU professions database are **chiropractors, naprapaths, osteopaths, masseurs and physiotherapists** (7). These professions are allowed to practise medicine, diagnose patients and charge fees (44, 105).

8.11.2 The governmental supervision of CAM Practices

The National Supervisory Authority for Welfare and Health is responsible for the national guidance and supervision of health care professionals, chapter 5, section 24, health care professionals act (105). Only CAM practitioners regulated as health care practitioners will be supervised according to this law. **Medical doctors and registered chiropractors, naprapaths, osteopaths, masseurs and physiotherapists** are supervised by the medical authorities in practising medicine. Other CAM practitioners are not supervised, nor is their licensing regulated (44).

The Finnish Medical Board gives the advice in their "Ethical Guidelines", that "...it is unethical for a doctor to provide treatments that are not 'generally accepted'...". However, as also many conventional treatments are not fulfilling the criteria for Evidence Based Medicine (EBM), nobody is controlling or prosecuting a doctor who provides CAM therapies,

as long as the doctor treats the patient well. Problems could arise if a doctor would advertise to a third party that he or she is practising something else than mainstream medicine (107).

8.11.3 The reimbursement status of CAM practices and medicinal products

CAM treatment is reimbursed if provided by physicians (43). Chiropractic, naprapathy and osteopathy are reimbursed if provided in collaboration with physicians (43). Private insurance companies cover some CAM treatments (43). The national healthcare insurance system covers fees for consultation with an anthroposophic physician (106). The patient receives partial reimbursement of any consultation with a doctor, independently of what sort of treatment the doctor provides, whether this is homeopathy, acupuncture or anthroposophic medicine (107).

8.11.4 Acupuncture

No specific legislation has been found on acupuncture (106).

In Finland some physicians practise acupuncture. There is a doctors' association for doctors practising acupuncture "Suomen Lääkäreiden Akupunktioyhdistys r.y." (107).

The Finnish Acupuncture Association for physiotherapists have a website partly in English <http://www.akupunktuuriyhdistys.net/index.php/etusivu/68> (107).

8.11.5 Anthroposophic medicine

In Finland diplomas in anthroposophic medicine are not recognized, but consultation fees are covered (106). Postgraduate medical training courses are provided at private teaching centres (106).

8.11.6 Ayurveda

No specific legislation has been found on ayurvedic medicine.

8.11.7 Chiropractic

Chiropractic is from 1994 accepted as part of the ordinary health service by governmental statutory regulation, and the title is protected (43, 106).

Chiropractic is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title "**Kiropraktikko / kiropraktor**" recognized under Directive 2005/36/EC(5), ID 743. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.11.8 Herbal medicine/Phytotherapy

No specific legislation has been found on herbal medicine/phytotherapy.

8.11.9 Homeopathy

ECCH (50) categorizes homeopathy in Finland as allowed to practise by anyone since there is no restricting legislation. A few medical doctors practise homeopathy in Finland (107). Homeopathy is mostly practised by non-medically qualified practitioners (28).

8.11.10 Massage

Masseur is a regulated profession by the act on recognition of professional qualifications (193/2007)(105). According to section 24a, a central register of health care professionals is managed by the National Supervisory Authority for Welfare and Health, and **masseur** is directly mentioned in the law (105).

Massage is registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Koulutettu hieroja / utbildad massör**” (Masseur (EN)) recognized under Directive 2005/36/EC(5), ID 742. General system of recognition- primary application. Qualification level: SEC - Certificate attesting the completion of a secondary course , Art. 11 b (7). Useful link: nihil.

8.11.11 Naprapathy

Naprapathy is from 1994 accepted as part of the ordinary health care system and the title is protected (43). **Naprapath** is a regulated profession by the act on recognition of professional qualifications (193/2007)(105). According to section 24a, a central register of health care professionals is managed by the National Supervisory Authority for Welfare and Health, and **naprapath** is a registered profession (105).

Naprapath is registered in the EU regulated professions database as follows:

Physical therapist is a directly related regulated profession with title “**Naprapaatti / naprapat**” (Naprapath (EN)) recognized under Directive 2005/36/EC(5), ID 744. General system of recognition- primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D) , Art. 11c(7). Useful link: nihil.

8.11.12 Naturopathy

No specific legislation has been found on naturopathy.

8.11.13 Neural therapy

No specific legislation has been found on neural therapy.

8.11.14 Osteopathy

Osteopathy is from 1993 accepted as part of the ordinary health service by governmental statutory regulation, and the title is protected (43, 106). **Osteopath** is a regulated profession by the act on recognition of professional qualifications (193/2007)(105). According to section 24a, a central register of health care professionals is managed by the National Supervisory Authority for Welfare and Health, and osteopath is a registered profession (105).

Osteopath is registered in the EU regulated professions database as follows:

Osteopath is a directly related regulated profession with title “**Koulutettu osteopaatti / utbildad osteopat**” recognized under Directive 2005/36/EC(5), ID 745. General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.11.15 Traditional Chinese Medicine (TCM)

No specific legislation has been found on TCM.

8.11.16 Other treatments (mentioned if found in legislation)

Physiotherapist is a regulated and protected title in Finland (105). The professional title is “Fysioterapeutti”. Legal protection of the title and activity of physiotherapists has been established and they have founded rules of professional conduct for physiotherapists. All physiotherapist members must be registered and obtain a licence to practise physiotherapy. Finland has established a code of ethics for physiotherapists. The "National Authority for Medicolegal Affairs" is responsible for the physiotherapy profession in Finland (108).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**Fysioterapeutti/ fysioterapeut**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC(109) , ID 729. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.12 France

France was a founding member of the European Union (EU) in 1952 (11), and a founding member of the Council of Europe on 5 May 1949 (12).

8.12.1 The legal and regulatory status of CAM and CAM practices

There is no CAM law in France (43, 106). Only legally regulated personnel may treat patients, and by that only medically qualified professionals are allowed to practise CAM (43, 106). Acupuncture, anthroposophic medicine and homeopathy are regulated by the medical association and osteopathy is statutory regulated by the government (106, 110). In the later years the practice of chiropractic, osteopathy and acupuncture are by the medical orders considered as “responsible professional conduct”(43).

Other health professionals provide treatment according to regulations provided by the State Council decree issued after consultation with the National Academy of Medicine (111).

Teaching complementary/alternative medicine to physicians is permitted. Private schools, however, may not issue diplomas to their graduates. According to Article 4 of the Act of 18 March 1880, only the State has this power (44).

The University of Bobigny established the Department of Natural Medicines in 1982. Since then, diplomas have been awarded in acupuncture, homeopathy, phytotherapy, osteopathy, auriculotherapy, naturopathy, oligotherapy, and mesotherapy and from 1990, the University Diploma in Natural Medicines (44).

In addition to the medical acts usually reserved for physicians, the following is strictly restricted to physicians:

- All manipulations of joints, enclosing slipped disc, **osteopathy**, vertebral therapy and **chiropractics**; and
- **Specific physiotherapeutic acts** (112).

8.12.2 The governmental supervision of CAM Practices

The Ministry of Health includes a directorate of social security who is supervising social security organizations including the health insurance funds and schemes (112).

According to “Le code de santé publique” (The Code of Public Health), article L4161-1, “persons other than licensed physicians who habitually or continuously diagnose or treat

illnesses, real or supposed, or who perform activities constituting medical procedures are illegally practising medicine” (28, 111).

Supervision is managed by two types of professional organizations:

- Professional associations for doctors, pharmacists, dentists and midwives who are concerned with medical ethics and the supervision of professional practice.
- Trade unions looking after the interests of different professional groups (112).

Doctors, dental surgeons and pharmacists are self-regulated through their professional organizations at national and department level, in terms of professional ethics and the right to practice (112). The National Agency for Accreditation and Health Care Evaluation (ANAES) is responsible for issuing and disseminating recommendations and practice guidelines and for assisting doctors in evaluating their practices (112).

8.12.3 The reimbursement status of CAM practices and medicinal products

The health insurance schemes are under the supervision of the Social Security Directorate of the Ministry of Social Security. Every year the parliament passes an Act on Social Security (112). The 2001 Act improved the benefits provided by the health insurance scheme for self-employed people, aligning them with those provided by the health insurance scheme for salaried workers. The 2002 Act has renewed an agreement between the health insurance funds and health care professionals’ organizations.

Consultation with a statutorily recognized healthcare practitioner is free of charge (70). Acupuncture, homeopathy and massage is reimbursed by the national insurance system (acupuncture treatment by national and private insurance, consultation with an anthroposophic physician is partially covered by national and private insurance companies)(106, 110). Homeopathic remedies are partly reimbursed (35%) by the basic national insurance system.

Specific medical activities and products are covered, including chiropractic, medical phytotherapy consultations, and complementary/alternative technical sessions with an approved kinesiotherapist (44).

8.12.4 Acupuncture

Acupuncture is regulated by law in France, is offered in hospitals and provided by doctors, midwives and veterinarians (113). Since 1950 the medical association has recognized acupuncture as an additional medical qualification which can be legally practised by medical doctors (106, 110).

The national Capacity Diploma for Acupuncture is implemented by the decree of 26 April 2007 (Official Gazette No.126 of June 2, 2007, page 9993).

In a decision dated February 9, 2010, the Supreme Court affirmed that the practice of acupuncture is reserved only for medical doctors, midwives and veterinarians because it is a medical procedure whose practice is limited to medical doctors (Court of Cassation, Criminal Division, February 9, 2010, appeal No.: 09-80681).

Familiarization courses in acupuncture are offered as separate subjects in the undergraduate curriculum and postgraduate training courses at the universities (106). The medical association issues the National Capacity Diploma for Acupuncture (Diplôme de Capacité en Acupuncture)(106).

A non-physician acupuncturist, whose status is not regulated by the Code of Public Health, commits the offense of illegal practise of medicine as defined in Article L.4161-1 of the Code Law No. 2001-504 of 12 June 2001. The penalty of this offense has been strengthened.

Acupuncture training for doctors with a national diploma has been provided since 2007 (113).

8.12.5 Anthroposophic medicine

Anthroposophic medicine is offered by MDs or regulated health personnel (113). There is no national regulation of anthroposophic medicine in France. Diplomas in anthroposophic medicine are not recognized by the national association for medical doctors. Postgraduate medical training courses in anthroposophic medicine are offered at private teaching centres (106).

8.12.6 Ayurveda

No specific regulation has been found on ayurvedic medicine in France (113).

8.12.7 Chiropractic

Chiropractic is regulated in France. Ministerial Decree No. 2011-32 of 7 January 2011 allows medical doctors, midwives, physiotherapists, nurse practitioners and other practitioners to practise chiropractic. Practitioners not being medical doctors themselves are only allowed to treat patients after a diagnosis is made by a medical doctor (114).

In September 2011 a new bill on chiropractic and osteopathy was proposed with the purpose of establishing a High Council of chiropractic and osteopathy. Additional medical qualifications in osteopathy and chiropractic as well as Master's degrees in osteopathy and chiropractic could give individuals the right to practise these therapies as distinct disciplines in themselves (115). The bill is not yet passed.

8.12.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.12.9 Homeopathy

Homeopathy is officially recognized as a therapy since 1965 when it was incorporated in the French Pharmacopoeia. Only medical doctors, dentists, midwives and veterinarians are allowed to practise homeopathy in France (28). Non-medically qualified practitioners are not

authorized to prescribe and may even be prosecuted for “illegal practise for medicine“. The Ordre National des Médecins (National Medical Council) in their report of 27 February 1997 (Labatard-Sartre report) recognized homeopathy as a medical therapeutic method and recommended the creation of a Diplôme Inter-Universitaire (DIU) of homeopathy”(28).

The Ordre National des Médecins allows General Practitioners (GPs) who have taken additional training in homeopathy to use the qualification “orientation homéopathie”, but without submission of diplomas (28). Both undergraduate and postgraduate courses in homeopathy are offered at the universities. Some hospitals offer homeopathic treatment (106).

8.12.10 Massage

Massage therapy is not regulated, but offered in hospitals and provided only by other medical practitioners (113).

8.12.11 Naprapathy

No specific regulation has been found on naprapathy.

8.12.12 Naturopathy

The profession of naturopathy belongs to the category "Self-employed". To register as a naturopath a code NAF (Nomenclature of French Activities) assigned to the profession is NAF 8690 F "human health activities not elsewhere classified".

There are two categories of professionals:

- One category is protected by registration with a professional order requiring a state diploma or equivalent French licence validated for the exercise of the national territory.
- The other is a set of activities that do not, to date, guarantee a degree of training of professional activity in question. The consultancy work or that of "health practitioner", unacknowledged by the French state, falls into the latter category. This professional activity can be exercised in different structures, either personally, or in partnership” (<http://www.omnes.fr/sinstaller/profession-liberale>).

Naturopathy is not statutory legally regulated or offered in hospitals in France (113) (www.omnes.fr/).

8.12.13 Neural therapy

No specific regulation has been found on neural therapy.

8.12.14 Osteopathy

The legislation provides that it is necessary to have a medical qualification to practise osteopathy in France (116, 117). The Ordre National des Médecins (National Medical Council) has recognized the validity of a University Diploma (DIU) of Manual Medicine (Osteopathy)(118).

In September 2011 a new bill on chiropractic and osteopathy was proposed with the purpose of establishing a High Council of chiropractic and osteopathy. Additional medical qualifications in osteopathy and chiropractic as well as Master's degrees in osteopathy and chiropractic could give individuals the right to practise these therapies as distinct disciplines in themselves (115). The bill is not yet passed.

The Union of Medical Osteopaths of France, the only organization representing medical doctors of practising osteopathy, are opposing the bill (118).

8.12.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.12.16 Other treatments (mentioned if found in legislation)

Balneotherapy (bath, spa) is considered as a part of conventional treatment and offered in hospitals (113).

Physiotherapy is coordinated by the “**Fédération Française des Masseurs Kinésithérapeutes Rééducateurs (F.F.M.K.R.)**” There is a State Diploma course of 3 years for physiotherapy studies, but this is currently outside the academic structure, with access to postgraduate education at universities. There are developments to extend physiotherapy education to 4 years with the first year shared with medical students (119). The professional title is **Diplome d'Etat de Masseur Kinesitherapeute** (119). There is a medical code of ethics and professional secrecy is determined by law. The activity of the physiotherapist is also defined by law. The Ministry of Health is the national authority responsible for the physiotherapy profession in France (119).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**Masseur-kinésithérapeute**” recognized under Directive 2005/36/EC (5), ID 238. General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7). Useful link: nihil.

8.13 Germany

Germany was a founding member of the European Union (EU) in 1952 (11) and became a member of The Council of Europe on 13 July 1950 (12).

8.13.1 The legal and regulatory status of CAM and CAM practices

CAM given by non-physicians has been legally regulated in Germany since 1939 by the passing of the “Heilpraktikergesetz” (HeilprG), which also established the protected title “Heilpraktiker” (120, 121). According to the Heilpraktiker act practitioners of homeopathy must be registered after passing an exam administered by local healthcare authorities in order to prove that they possess sufficient knowledge in medicine and healthcare legislation (50, 121).

The HeilprG states among others that:

- § (1) Whoever wants to practise medical treatments without being accredited as a medical doctor needs a special permission.
- §2 Medical science/treatment in the meaning of the law is every kind of activity, which is practised as a profession, directed at diagnosing, treating or relieving illnesses, sicknesses, or disabilities in humans, also if they are practised in the service of others.
- §3 A person who has practised medical science/treatment at a professional level up to date and plans to continue to do so, will receive permission in accordance to the rules of the implementing regulations (121).

In order to practise medicine or carry out specialty training in Germany, all physicians must be in possession of a valid full or temporary licence to practise (122). The “Bundesärztekammer” offers additional certificates in some CAM treatments, so called “Zusatzbezeichnungen”, treatments are naturopathy, acupuncture, homeopathy, manual medicine, physiotherapy.

Only **medical doctors and Heilpraktikers** (non-medically qualified practitioners) are allowed to provide CAM treatments, but there are restrictions on the performance of particular medical acts (28, 41). Only medical doctors are allowed to treat sexually-transmitted, communicable and epidemic diseases, deliver specific medications, give or provide anaesthetics and narcotics, practise obstetrics and gynecology, take X-rays, perform autopsies and issue death certificates (28, 123).

A Heilpraktiker(non-conventional health practitioner) must meet certain criteria, pass a public exam and register in order to get the licence to practice (41). According to the HeilprG, implementing provisions §2 (120), permission is not granted:

- If the applicant has not yet reached the age of 26 (a).
- If he/she does not have German citizenship (b).
- If he/she cannot prove at least completion of primary education (d).
- If it appears that he/she lacks moral reliability, especially heavy criminal or ethical misconduct(f).
- If, in terms of health he/she is unfit to practise (g).
- If it can be assumed with certainty that he/she is practising medicine in addition to any other profession (h).
- If a review of the knowledge and skills of the applicant by the Health Department indicates that the practice of medicine by the person would mean a danger to the Public Health (i).

Acupuncture, anthroposophic medicine, homeopathy and naturopathy are legally regulated as therapeutic systems (28). The Medicines Act have accredited treatment forms in homeopathy, anthroposophy, and phytotherapy in a special law called “Besondere Therapierichtungen“, "Special treatment directions" (124).

8.13.2 The governmental supervision of CAM Practices

The medical associations focus on regulation of the professional practice and specify requirements for CME training, the professional code of conduct and routines for accusations of medical malpractice (125). Breach of regulations for treating patients may result in penalties (28). The health insurance companies are supervised by the state (125).

8.13.3 The reimbursement status of CAM practices and medicinal products

The statutory health insurance system (SHI) (since 2009 funded by the “Gesundheitsfonds”) manages the covering of health care services in Germany. Physicians must be approved and registered as “SHI physicians” to bill the statutory health insurance companies for treatment of patients (125).

The state insurance companies reimburse partly acupuncture (only for chronic knee pain due to osteoarthritis and for chronic low back pain), homeopathic and anthroposophic treatment performed by contracted (SHI) qualified medical doctors, but patients must pay for medicines (41, 106, 125). Anthroposophic medicine is also reimbursed by private insurance companies (106). Some private insurance companies cover homeopathic remedies and acupuncture (106).

The health insurance will pay the costs for normal physiotherapy sessions, but most likely the patient will co-pay for the osteopathy part of it.

From 2012 a new law (GKV-Versorgungsstrukturgesetz)(126) came into effect. The law allows the statutory health insurances to offer additional benefits to its customers. E.g. the Technical Krankenkasse (TK) decided to take over costs of up to 100€ per year and per insured person for homeopathic, phytotherapeutical and anthroposophic medicinal products which are obtainable only in pharmacies, but without a prescription.

8.13.4 Acupuncture

Acupuncture is regulated by law as a distinct therapeutic system (Besondere Therapierichtung) in the Code of Social Law (Sozialgesetzbuch V), and additional medical qualification and diplomas as medical acupuncturist are recognized and issued by the German medical association. Acupuncture training is provided within the CAM courses as a part of the medical undergraduate curriculum. Acupuncture training is an official part of the Continuous medical educational programme (CME) for doctors, and CME is mandatory for doctors included in the national insurance system(SHI)(106,122).

8.13.5 Anthroposophic medicine

Anthroposophic medicine is regulated by law as a specific therapeutic system (Besondere Therapierichtung) by the Medicines Act- Arzneimittelgesetz (AMG) and by the Code of Social Law (Sozialgesetzbuch V)(106,124,127). The statutory regulation of anthroposophic medicine is delegated to the German medical association, and recognized as an additional qualification for medical doctors. The medical association of anthroposophic doctors issues and recognizes diplomas and regulates the statutory, mandatory Continuous Medical Educational programme (CME) for anthroposophic doctors (106, 122).

Optional introductory courses in anthroposophic medicine are provided as part of the medical undergraduate curriculum at some universities (106). Postgraduate training is offered at private teaching centres (106). Anthroposophic medicine is offered at some hospitals in Germany (106).

In Germany there is a small group of anthroposophic Heilpraktikers with their own professional body (106).

8.13.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.13.7 Chiropractic

Chiropractic is regulated by law within the medical association (106, 128). The German Medical Assembly (German Ärztetag) in 2003, introduced the additional term "Chiropractic" for "Manual medicine" and a training programme "(Muster-) Kursbuch – manuelle medizin/chirotherapie" for doctors. The term manual medicine or chiropractic therapy may both be used (128).

8.13.8 Herbal medicine/Phytotherapy

The treatment is common among German doctors and Heilpraktikers. Phytotherapy in Germany is regulated by the Medicines Act 'Arzneimittelgesetz (AMG)' as a distinct therapeutic system (Besondere Therapierichtung)(124, 127).

8.13.9 Homeopathy

Both doctors and Heilpraktikers are allowed to practise homeopathy (28).

Homeopathy in Germany is regulated by law as a distinct therapeutic system (Besondere Therapierichtung) by the Medicines Act- Arzneimittelgesetz (AMG) and by the Code of Social Law (Sozialgesetzbuch V) since 1998 (106, 124, 127). The German Medical Association (The "Bundesärztekammer") acknowledges homeopathy as an official additional qualification "homeopathic doctor", for medical doctors who have passed an examination in homeopathy (28). The national medical association issues diplomas. Optional courses in CAM/homeopathy in the medical undergraduate curriculum are offered at one university and postgraduate homeopathy courses are offered at some universities in Germany (28, 106).

Homeopathy is provided by physicians at some hospitals in Germany (106). Homeopathy was in 1978 recognized as a particular therapeutic approach "Besondere Therapierichtung" in the Medical Products Act – "Arzneimittelgesetz" – section 25, sub (2)2 and section 105, sub 4f (28).

8.13.10 Massage

"Masseur – nicht-medizinischer Bademeister/in" is a regulated health profession in Germany and is registered in the European regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title "Masseur – nicht- medizinischer Bademeister/in" recognized under Directive 2005/36/EC (5), ID 2770. General system of recognition - primary application. Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b (7). Useful link: nihil.

8.13.11 Naprapathy

No specific regulation has been found on naprapathy.

8.13.12 Naturopathy

The Code of Social Law (1998) recognizes naturopathic medicine as a distinct therapeutic system (106). The Medical Chamber has recognized a specific naturopathic curriculum leading to an official additional qualification for medical doctors (106).

Various medical associations provide postgraduate training courses in naturopathic medicine, issue diplomas, and have developed quality standards (106).

Naturopathic medicine is commonly offered by trained doctors in many rehabilitation clinics, acute care hospitals within "naturopathy departments" and also in regular hospitals (106).

8.13.13 Neural therapy

No specific regulation has been found on neural therapy, but some aspects of neural therapy such as injection treatment are provided in Germany on a regular basis.

8.13.14 Osteopathy

There are presently no statutes or regulations defining the scope of practise of osteopathy. Osteopathy has recently been recognized by the national Ministry of Health (129). "The regulation of the profession is presently adequate through the existing medical societies for physicians and the Heilpraktiker organizations"(129).

"There is a difference in the osteopathic education between non-physician osteopaths, physiotherapists, and medical physicians. Physiotherapists are a recognized health profession, but they have to meet a lower educational standard and can achieve a degree of "Diploma in Osteopathic Therapy (D.O.T.)", whereas physicians achieve a degree of "D.O.-DAAO" or "D.O.M.", from the DAAO and DGOM respectively. Osteopathic physicians in Germany are fully licensed with at least 6,500 hours in 6-years medical school, at least 7,000 hours in specialty training, which is 3 to 6 years, plus at least 680 hours of training in manual medicine and osteopathy before attaining their degree"(129).

"Non-physician osteopaths are not medically licensed. They have an average total of 1200 hours of training, roughly half being in manual therapy and osteopathy, with no medical specialization before they attain their degree. Non-physician osteopaths in Germany officially work under the "Heilpraktiker" law" (129).

There are many schools of osteopathy in Germany. There is presently no official national recognition.

8.13.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM except acupuncture.

8.13.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a 3 year education in Germany (including 1/3 of practical work at hospitals/private practices), at private or state schools. After graduating, you are "staatlich anerkannter Physiotherapeut" (129-131).

Physiotherapy is registered in the European regulated profession database as follows:

Physiotherapy is a directly related regulated profession with title "**Physiotherapeut/in Krankengymnast/in** under Directive 2005/36/EC (5), ID 954. General system of recognition-primary application. Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b (7). Useful link: nihil.

Physiotherapists from EU-and EEA-countries are governed by the EU Directive 2005/36/EC. For physiotherapists from a non-EU country a corresponding law has been adopted by the Federal Government to improve the assessment and recognition of foreign professional qualifications approved by the Bundesrat (4 November, 2011)(130).

8.14 Greece

Greece became a member of the European Union (EU) in 1981 (11) and a member of the Council of Europe on August 9, 1949 (12).

8.14.1 The legal and regulatory status of CAM and CAM practices

There is no law governing the practice of CAM in Greece. Regulation of CAM practices is a difficult combination of self-regulation combined with statutory regulation. CAM is recognized as an additional qualification for medical doctors (132). Only medical doctors are authorized to practise acupuncture, and diplomas are issued by a national doctors' association (132). Postgraduate training is provided by private teaching centers (132). Other CAM treatments are practised by both doctors and non-doctors, and there are no official qualification requirements for such treatment (132). The Ministry of Trade is responsible for CAM (homeopathy)(41, 132).

The Ministry of Health and social solidarity in Greece has in a report dated 27.8.2010 (133) evaluated how the EU Directive 2005/36/EC(5) about recognition of professional qualifications has been followed up from 2005 to 2008. Doctors, nurses, general practitioners, dentists and orthodontists have used the automatic recognition system without any problems. Physiotherapists are included in the evaluation (17.9.2010/ref No. 115870/IA). The Health Directorate of the Prefectural Authority is responsible for granting an authorization to practise a profession. From 2011 this is delegated to the competent regional authorities. We have not found any description of CAM professionals in this evaluation (133).

8.14.2 The governmental supervision of CAM Practices

Authorization, diplomas and CME training are delegated to and controlled by the medical associations (132). No law requires any formal qualifications for practising CAM, on the other hand practitioners have complete responsibility for their practice (132).

8.14.3 The reimbursement status of CAM practices and medicinal products

The tax offices have certain codes for reflexology, aromatherapy, homeopathy and acupuncture for tax purposes. Some private insurance companies cover CAM treatments

(like acupuncture and homeopathy) provided by doctors, but CAM medicines are not reimbursed (41, 132). CAM provided by non-medical practitioners is not reimbursed (41).

8.14.4 Acupuncture

Acupuncture is regulated by law as a distinct therapeutic system in Greece (106). According to the decree 574/A4/1191/21-2-1980 of the Greek Ministry of Health, "Acupuncture can be applied only by physicians, dentists and veterinarians with adequate experience and proper training in acupuncture"(134-136). Doctors practising acupuncture must be a member of the medical association (136). The Ministry of Health (MOH) has given instructions for practising acupuncture (132). The medical association has recognized acupuncture as an additional medical qualification, and as an official part of the Continuous Education Programme (CME) for doctors (106).

Even if only medical doctors are authorized to practise acupuncture, other CAM therapists provide the treatment (135). Acupuncture clinics are established in some university faculties of medicine and hospitals of education and research (132).

The "Hellenic Medical Society of Acupuncture" was founded in 1992 and is a member of the "International Council of Medical Acupuncture and Related Techniques" (I.C.M.A.R.T). There are various acupuncture associations in Greece. In 2010 the "Scientific Association of Medical Acupuncture Greece" was founded (134).

8.14.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.14.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.14.7 Chiropractic

No specific regulation has been found on chiropractic medicine.

8.14.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.14.9 Homeopathy

There is no specific regulation on homeopathy within health care in Greece (28, 41). Medical doctors are allowed to practise homeopathy as a part of their medical profession (28). The profession of homeopathy is mentioned in legislation for labour and employment under the Ministry of Trade/Economics (41). Non-medical practitioners of homeopathy may practise under legislation of labour registered within the Ministry of Economics (50).

Postgraduate training in homeopathy for doctors is provided at universities in Greece (106).

The Hellenic Homeopathic Medical Society (H.H.M.S.) supports homeopathy in Greece. The association is a member of the European Committee for Homeopathy (ECH)(28). Various homeopathic associations support homeopathic practitioners in Greece.

8.14.10 Massage

No specific regulation has been found on massage.

8.14.11 Naprapathy

No specific regulation has been found on naprapathy.

8.14.12 Naturopathy

No specific regulation has been found on naturopathy.

8.14.13 Neural therapy

No specific regulation has been found on neural therapy.

8.14.14 Osteopathy

No specific regulation has been found on osteopathy.

The Greek Osteopathic Association is a member of the European Federation of Osteopaths (137).

8.14.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.14.16 Other treatments (mentioned if found in legislation)

Physiotherapists in Greece may practise CAM (like shiatsu, reflexology and/or aromatherapy) (132). Physiotherapist is a regulated health profession. “The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise. Greece has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Greece is the Ministry of Health”(138).

Physiotherapy in Greece is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**Physiotherapeftís**” (**TEI**) recognized under Directive 2005/36/EC (109) ID 421. General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.15 Hungary

Hungary declared itself an independent republic on October 23, 1989 (139). Hungary became a member of the European Union in 2004 (11) and of the Council of Europe on November 6, 1990 (12).

8.15.1 The legal and regulatory status of CAM and CAM practices

Comprehensive changes in the national and regional health legislation has been introduced in Hungary over the last decade (140). In Hungary CAM legislation is integrated in the public health system and all CAM providers must be a part of the official health system (140). All CAM practitioners must have a licence to practise; for MD-s a university exam, and for no-MD-s an education in health care and a licence to practise from the Hungarian Further Education institute for nurses and other health providers (140). **Medical acupuncture, traditional Chinese medicine, neural therapy, antroposophic medicine, ayurvedic medicine and manual medicine** have been accepted as post graduate courses (2 year study period) since 1997. A final exam performed at medical universities is accepted as a licence for specialist practise in those medical fields (141).

The comprehensive CAM legislation came into force on 1 July, 1997(139, 142-144). The Act CLIV of 1997 on Health institutionalized the “National health promotion programme” with the principles “health for all” and “equal access to health services”(139, 144). The Act on Health (144), the Governmental Decree on CAM (143) and the Decree of the Ministry of Social Welfare on the practice of CAM (142) confirm a definition of CAM treatment, regulate the scope of CAM treatments, and state that “non-conventional procedures that substitute conventional therapy shall only be applied under the supervision of a physician”(28, 140, 144).

The CAM legislation from 1997 (142) regulates the following CAM treatments; **acupuncture, chiropractic, homeopathy, naprapathy, naturopathy, osteopathy, and phytotherapy**. CAM physicians and practitioners must have a licence to practise according to regulations. The non-medical practitioners have to be official registered members of the public health system. The CAM law is under reconstruction by the Ministry of Health and the revised version is expected to be passed in 2012.

Hungary follows the tradition of detailed regulation of practitioners and treatments; consequently each CAM treatment has been included in the public health system and legislation with regulation of education, licences, authorization etc. (140). Act XXVIII of 1994 made membership of the Hungarian Medical Chamber compulsory for practising physicians and dentists. The Chamber of Non-medical Health Professionals (2003/13) was established

to extend professional self-regulation to other qualified health care workers (139). The Chambers are responsible for the follow-up of CAM regulations (139).

There are three categories of authorized medical practitioners in Hungary; **physicians, practitioners** with a non-academic higher health qualification and **other practitioners** (43). In 2011 a wide range of CAM treatments were regulated in detail and most medical universities and schools offer training courses. **Only physicians** are allowed to practise acupuncture, anthroposophic medicine, ayurvedic medicine, chiropractic, homeopathy, manual medicine, traditional Chinese medicine (TCM), traditional Tibetan medicine and Kneipp practices (28, 50). Acupressure, kinesiology, shiatsu (in complementary moving and massage therapies), phytotherapy and reflexology may be **provided by practitioners** (non-medical doctors)(50).

The University of Pécs is the unique CAM educational institution for medical doctors in Hungary (141). All providers of CAM in Hungary must take a 2 year education in CAM and pass a licence exam. Medical doctors are offered continuing medical education (CME) mostly at universities; non-MD practitioners take courses mostly at the Institute of Continuing Education for health workers in registered evaluated courses. The CAM Department of the University of Pécs provides education, controls and exams. Studies are offered for MDs only, and the following treatments are examples of courses provided: acupuncture, TCM, manual medicine (chiropractic, osteopathy), neuraltherapy, anthroposophic medicine, life-style adviser (140).

Courses at other educational institutions offer studies for **non-medical providers** (= natural healers, additionally part of the health system) for courses like acupressure, reflexology, NADA (detoxification), eye training, herbal medicine, kinesiology, complementary moving and massage therapies, complementary physiotherapies (Kneipp courses, electro, magneto, UV e.t. practice)(140).

Health practitioners (non-medical educated practitioners) may offer CAM treatments like; acupressure, reflexology, NADA (detoxification), eye training, herbal medicine, kinesiology, complementary moving and massage therapies, complementary physiotherapies (Kneipp courses, electro, magneto, UV e.t.) practice (4).

National CAM legislation regulates health products and the use, practice and education of CAM. However, CAM non-medical practitioners (herbalist, many non-MDs, and acupressure therapist and others) are not regulated by the state. The Provincial and Territorial Government Agency regulates and controls regional health care practitioners. This public health system constitutes a heterogeneous regulation system in Hungary and challenges the CAM legislation (141). Legislative review and re-organization in several provinces have resulted in the establishment of permanent mechanisms for regulation of CAM practitioners including possible statutory self-regulation as health care practitioners in the future (141).

8.15.2 The governmental supervision of CAM Practices

The national government of Hungary exercise statutory supervision of health services, including the Health Insurance Fund (HIF)(144). The National CAM Supervisor Committee has the right to control and punish. Regulated CAM providers are included in the governmental supervisor Head Physician-system (141).

8.15.3 The reimbursement status of CAM practices and medicinal products

The Health Insurance Fund (HIF) and the National Health Insurance Fund Administration (NHIFA) contract with health care providers and reimburse them according to various payment methods (139). Act XCVI of 1993 on Voluntary Mutual Insurance Funds is the legal platform for private non-profit health insurance (139). Act LXXXIII of 1997 define treatments excluded from reimbursement by the national health insurance fund. Among others are treatments not proved effective in improving health (1997/8), and recreational purposes massage (1997/11)(139). CAM is partially covered; massage, acupuncture, manual medicine, neuraltherapy in state hospitals or state outpatients surgeries have an agreement with NHIFA. Insurance is, however, mostly covered by additional private insurance companies (140).

8.15.4 Acupuncture

Acupuncture is a part of TCM treatment and is provided only by medical doctors in Hungary. The University of PECS offers educational acupuncture courses only for MDs (141). The Hungarian Medical Acupuncture Association was founded in 1987 (www.maot.hu). Since then the acupuncture education is official in Hungary.

8.15.5 Anthroposophic medicine

Anthroposophic medicine may be provided only by medical doctors in Hungary. Educational courses are offered only for MDs at the University of Pécs (141).

8.15.6 Ayurveda

Ayurvedic Medicine is recognized as an individual complex medical system (diagnostic and treatment) provided only by medical doctors in Hungary (141).

8.15.7 Chiropractic

Chiropractic (as not separated from manual medicine) is a registered treatment and profession only for MDs with an exam from a medical university (141).

8.15.8 Herbal medicine/Phytotherapy

The CAM legislation from 1997 (142) regulates Phytotherapy. Physicians and practitioners must have a licence to practise according to regulations. The non-medical practitioners have to be official registered members of the public health system.

8.15.9 Homeopathy

Only medical doctors may practise homeopathy in Hungary (142, 143). The Magyar Homeopata Orvosi Egyesület (Hungarian Homeopathic Medical Association) was founded in 1991 (www.homeopata.hu). The University of Pécs offers a 3-year educational programme for homeopathy only for medical doctors (60). Homeopaths are registered in a statutory register.

8.15.10 Massage

In 2011 massage was regulated in detail and training courses are offered by most medical universities and schools. Massage therapies may be provided by practitioners (non-medical doctors)(50).

Massage is a registered profession in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**gyógymasszőr**” (**Massage therapist** (EN)) recognized under Directive 2005/36/EC (5), ID 16907. General system of recognition - primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D), Art. 11 c (7). Useful link: <http://www.professionalrecognition.gov.hu>.

8.15.11 Naprapathy

This terminology is not used in Hungary.

8.15.12 Naturopathy

This terminology is not used in Hungary.

8.15.13 Neural therapy

Neural therapy has been regulated by the CAM laws since 1997 (142-144). The University of Pécs (PTE) provides a 2- years course in neural therapy for medical doctors (141).

8.15.14 Osteopathy

The CAM legislation from 1997 (142) regulates osteopathy as manual medicine. **Only physicians** are allowed to practise **manual medicine**. CAM physicians must have a licence to practise according to regulations.

8.15.15 Traditional Chinese Medicine (TCM)

TCM is regulated as acupuncture.

8.15.16 Other treatments (mentioned if found in legislation)

The “Natural health practitioner” is a regulated health profession in Hungary since 1997 (142) and is registered in the EU regulated professions database as:

The “**Natural health practitioner**” is a directly related regulated profession with the title “**természetgyógyászati/nemkonvencionális tevékenység**” recognized under Directive 2005/36/EC (5), ID 14428. General system of recognition - primary application. National Legislation: 11/1997. (V.28.) NM rendelet). Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b. All regions included. Qualification obtained in

Germany from 2009 with a Positive Automatic General System (no compensation measures imposed (7)). Useful link: <http://www.professionalrecognition.hu>.

Physiotherapy is a regulated health profession in Hungary with the title “Fizioterápia”. The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise. Hungary has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Hungary is the Educational Ministry (145).

8.16 Iceland

Iceland is an EFTA and European Economic Area (EEA) member. Iceland is listed as a European Union candidate country and submitted its application for EU membership to the European Council in July 2009 (11). Iceland became a member of the Council of Europe on 7th March 1950 (12).

8.16.1 The legal and regulatory status of CAM and CAM practices

Lög um græðara (Healers Act) No. 34/2005, as amended by Act No. 88/2008 (Law on criminal procedure) regulates CAM in Iceland (146). Græðari (healer) in the law refers to those who provide health-related services outside the general health system. Services included in the law are, among others, treatments with the aim of improving health, relieving pain, reducing discomfort and promoting healing (§2)(146). Both medically and non-medically qualified professionals are allowed to practise CAM (106).

A voluntary registration system for healers is established. The healer will be registered as a member of a professional association if the practitioner fulfills the qualifications and standards acquired by the association in question (146). Regulation No. 877/2006 specifies the criteria a professional association and its members must fulfill to be accepted to the registration system, and to be allowed to use the title “registered” in connection with the CAM profession (146, 147).

Restrictions on healers health-related services is dealt with in article 7 in the healers act (146). “Treatment for serious diseases shall be provided only by licensed health workers, or by a healer after consultation with a physician” (146). Healers must not provide treatment which “entail grave risk to the patient’s health”. “The same applies to treatment of diseases which are subject to the provisions of the Communicable Diseases Act and entail a risk to the public” (146).

Althingi (The Icelandic Parliament) has passed different acts to incorporate and harmonize The Professionals Directive 2005/36/(5) and EEA agreements into national legislation. Recognition of health professionals’ qualifications and titles have been harmonized with the EU regulated professionals database and national legislation (148). In the report to the European Commission of the changes in national legislation a list of new health laws is attached in chapter 3 (148). The following health professions are registered in the EU professionals database: **Chiropractor** (Hnykkir)(149), **Masseur** (Sjúkranuddari)(150), **Osteopath** (Osteópati)(151), **Natural health practitioner** (Náttúrufræðingur í heilbrigðisþjónustu) - EU translation “**Biologist in a specialized health institution (EN)**”, **Physiotherapist** (Sjúkraþjálfari), **Doctor of medicine with a specialist medical training** (Orku- og endurhæfingarlækningar, Physiotherapy (EN)).

8.16.2 The governmental supervision of CAM Practices

The Federation of Icelandic Healers supervises the voluntary register for healers (§3)(146). Regulation No 876/2006 regulates the minimum insurance coverage required for a healer practitioner (146). The Directorate of Health is responsible for issuing licences to health personnel. The General Criminal Code Act NO.88/2008 (152) regulates the penalties for violating the healers act (146).

8.16.3 The reimbursement status of CAM practices and medicinal products

Patients are insured by the Act on health Insurance NO 112/2008, and reimbursement for treatment is covered according to the law (153). Physiotherapy treatment is reimbursed according to article 21 (153). Other specialized health services will be covered (a co-payment may be charged) if provided by contract professionals according to article 22 (Reg. 1215/2008) and chapter IV (153). No specific reimbursement regulations have been found on CAM treatments. If regulated practitioners like chiropractors, osteopaths, natural health practitioners and masseurs are contracted, consultation fees will be reimbursed (153).

8.16.4 Acupuncture

No specific regulation has been found on acupuncture.

8.16.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.16.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.16.7 Chiropractic

Chiropractor is a regulated health profession in Iceland since 1990 (7, 106).

Chiropractor is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title “**Hnykkir**” recognized under Directive 2005/36/EC(5), ID 568. General system of recognition- primary application. National legislation: Act no. 24/1985 on the professional titles and professional rights of health professions and regulation 60/1990 on the education, rights and duties of chiropractors(149). Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.16.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.16.9 Homeopathy

No specific regulation has been found on homeopathy.

8.16.10 Massage

Masseur is a regulated health profession in Iceland since 1987.

Masseur is registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Sjúkranuddari**” (Massage therapist (EN)) recognized under Directive 2005/36/EC (5), ID 3624. General system of recognition- primary application. National legislation: Act no. 24/1985 on the professional titles and professional rights of health professions and regulation no. 204/1987 on the education, rights and duties of massage therapists. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D), Art. 11 c (7).

8.16.11 Naprapathy

No specific regulation has been found on naprapathy.

8.16.12 Naturopathy

No specific regulation has been found on naturopathy.

8.16.13 Neural therapy

No specific regulation has been found on neural therapy.

8.16.14 Osteopathy

Osteopathy is a regulated health profession in Iceland since 2005 (106). The Icelandic Osteopathic Association (Osteópatafélag Íslands) was founded in 2002 (154). No one can work or call themselves osteopaths in Iceland unless they are registered as such with the Ministry of Health which seeks an opinion from the Icelandic Osteopathic Association before granting a registration (154). The Icelandic osteopathic profession is a registered health profession according to regulation 229/2005 (151, 154).

Osteopathy is registered in the EU regulated professions database as follows:

Osteopathy is a directly related regulated profession with title “**Osteópati**” recognized under Directive 2005/36/EC(5), ID 14467 General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.(7).

8.16.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM:

8.16.16 Other treatments (mentioned if found in legislation)

Natural health practitioner is a regulated profession in Iceland.

The profession is registered in the EU regulated professions database as follows:

Natural health practitioner is a directly related regulated profession with title “**Náttúrufræðingur í heilbrigðisþjónustu**” recognized under Directive 2005/36/EC(5), ID 576. EU translation “**Biologist in a specialized health institution (EN)**”. General system of recognition - primary application. National Legislation: **Act no. 24/1985** on the professional titles and professional rights of health professions and **regulation no. 272/1991** on the education, rights and duties of natural scientists in the health service. Incorporated EEA **Decision No 142/2007 in 2009** (155). Qualification level PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7) All regions included.

Useful link: <http://www.llv.li/amtstellen/llv-agd-home.htm>

Physiotherapist is a regulated profession in Iceland. Legal protection of the title of physiotherapists has been established, but not for the professional activity. All physiotherapist members must be registered and obtain a licence to practise physiotherapy. Iceland has established a code of ethics for physiotherapists. The "Ministry of Health" is responsible for the physiotherapy profession in Iceland (156).

Physiotherapy is registered in the EU regulated professions database with two titles:

Physiotherapy is a directly related regulated profession with title “**Sjúkraþjálfari**” recognized under Directive 2005/36/EC (5), ID 583. General system of recognition- primary application. National legislation: **Act no. 58/1976 on physiotherapy**. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

Doctor of medicine with a specialist medical training (Article 25 of Directive 2005/36/EC) is a directly related regulated profession with title “**Orku- og endurhæfingarlækningar**” (**Physiotherapy (EN)**). Recognition under Directive 2005/36/EC(5), ID 11689. Qualification level undefined. Doctor in basic and specialized medicine both listed in Annex V (7).

8.17 Ireland

Ireland became a member of the European Union (EU) in 1973 (11). Ireland was a founding member of the Council of Europe on 5 May 1949 (12).

8.17.1 The legal and regulatory status of CAM and CAM practices

None of the CAM treatments are regulated or restricted in Ireland (41) Consequently, both medically and non-medically qualified professionals are allowed to practise CAM (106). Medically qualified practitioners with a university degree in medicine (MD, nurse, midwife) and physiotherapists are recognized as regulated health professionals (7, 157). The Medical Practitioners Act 25/2007 establishes that medical personnel must be registered in the General Register of Medical Practitioners, and article 47 links this act to the EU Directive 2005/36/EC (5, 157). Different sources from 2002 – 2010 categorize Ireland as a country with “CAM legislation in preparation”(28, 43, 106). Only medical doctors are permitted to “treat venereal diseases, practise obstetrics, certify death, issue medical certificates for official purposes, prescribe a wide range of controlled drugs, give advice in court on specific issues, supply services to police for alcohol-linked traffic offences and administer anaesthetics” (28).

Two Ministry of Health reports consider establishment of a register for CAM practitioners:

1. Report on the regulation of practitioners of complementary and alternative medicine in Ireland (2002)(158).
2. Report of the National Working Group on the regulation of Complementary Therapists to the Minister for Health and Children, December 2005 (159).

The 2005 (159) report made 7 recommendations which were accepted by the Minister of Health:

1. Statutory regulation for herbalists/acupuncturists/Traditional Chinese Medicine Practitioners.
(Meetings held, but no proposals for regulation produced so far(160)).
2. A robust system of “voluntary self-regulation” (VSR) for all others.
(FICTA, the national umbrella body for CAM professional associations, has implemented a VSR framework for its members and has sent it to the Department of Health. The response received stated that the priority of the DoHC is to progress statutory regulation for the concerned therapies and that they support greater voluntary self-regulation for all other therapies(160)).
3. Arrange workshop to encourage federation into one representative organization for those therapies where there was more than one.
(A few have been held(160)).

4. A report on the state of the sector following the workshops.
(Has not been produced (160)).
5. Publication of an information booklet with a client/therapist charter for the public.
(A general leaflet (not a booklet) was published that advised people to check that therapists were qualified and members of a professional association (160)).
6. Establishment of a forum for dialogue between the complementary and conventional medical sectors.
(Has not happened)(160).
7. Establishment of a National Annual Forum for the sector.
(Has not happened (160)).
8. Establishment of a working group to establish a Complementary Therapies Council to oversee issues in the complementary therapies area.
(Has not happened)(160)).

8.17.2 The governmental supervision of CAM Practices

No specific CAM regulations found on supervision of health practices in Ireland.

8.17.3 The reimbursement status of CAM practices and medicinal products

No CAM treatment is reimbursed in Ireland (41). Private insurance may partially cover some treatments (41).

8.17.4 Acupuncture

No specific legislation has been found on acupuncture.

8.17.5 Anthroposophic medicine

No specific legislation has been found on anthroposophic medicine.

8.17.6 Ayurveda

No specific legislation has been found on ayurvedic medicine.

8.17.7 Chiropractic

No specific legislation has been found on chiropractic.

8.17.8 Herbal medicine/Phytotherapy

No specific legislation has been found on herbal medicine/phytotherapy.

8.17.9 Homeopathy

“Absence of legislation which specifically restricts the practice of homeopathy to any particular type of practitioner means that anyone may practise”(50).

Homeopathy is mainly practised by non-medically qualified practitioners in Ireland. However, also medical doctors provide homeopathic treatment in their practices (28).

8.17.10 Massage

No specific legislation has been found on massage.

8.17.11 Naprapathy

No specific legislation has been found on naprapathy.

8.17.12 Naturopathy

No specific legislation has been found on naturopathy.

8.17.13 Neural therapy

No specific legislation has been found on neural therapy.

8.17.14 Osteopathy

No specific legislation has been found on osteopathy.

8.17.15 Traditional Chinese Medicine (TCM)

No specific legislation found on traditional Chinese medicine.

8.17.16 Other treatments (mentioned if found in legislation)

Physiotherapy is regulated in Irish legislation S.I No 135 of 1996, Regulation 19, part 1, professions and professional activities regulated by law. There is no legal protection of the title of physiotherapist; membership of the Irish Society confers the right to use the term Chartered Physiotherapist (161). There is no legal protection of activity of physiotherapists but nor is there any legal limitation of activity (161). The Irish Society of Chartered Physiotherapists is acting with the approval of the Minister for Health. Professions and professional activities are regulated by professional bodies which are recognized in a special form by the State. Physiotherapist is organized in MISCP (The Irish Society of Chartered Physiotherapists)(162). Ireland has a code of ethics for physiotherapists and The Irish Society has adopted the European Core Standards of Physiotherapy Practice (161).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**chartered physiotherapist**” recognized under Directive 2005/36/EC (5), ID 100. General system of recognition- primary application. National legislation: S.I. Number 135 of 1996. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.18 Israel

Israel is connected to the European Commission Seventh Framework Programme (FP7) Third Country Agreement: Israel (EC) – the Science and Technology Agreement 2007, and as such included in the CAMbrella survey of CAM legislation in Europe. Israel is neither a member of the Council of Europe nor listed as a candidate or potential candidate country to the European Union (11).

8.18.1 The legal and regulatory status of CAM and CAM practices

There is no regulation of CAM in Israel at the moment (2010)(163). The Israeli parliament “Knesset” in February 2010 ordered a paper (document only in Hebrew) on future discussion of the subject of CAM regulation (164). In 1988 a committee appointed by the Minister of Health examined the subject of natural medicine. “The committee recommended that only those therapies proven to be efficient by scientific standards should be authorized (Eilon Committee, 1988)”. In the year 2002 no legislation had yet been passed (165).

According to WHO Israel was in 2005 in the process of developing a national policy, laws and regulations, a national programme and a national office for TM/CAM (28).

On 30 July, 2008, the Israeli Parliament “Knesset” passed the law regulating the practice of medical professions (166). The Ministry of Health licenses professionals working in the legally recognized medical professions. The professionals are legally required to obtain a license to practise or obtain a status recognition from the Ministry of Health. For most professions, the applicants are required to pass government licensing examinations (167). Listed regulated professions of interest are chiropractic and physiotherapy.

CAM is offered in most of the “Not-for-profit public health maintenance organizations” (HMOs) clinics. Practitioners are mostly physicians, apart from those providing reflexology and shiatsu treatment (165).

Among other educational institutions, The Medicine College and the Complementary Medicine College had already in 2002 introduced CAM studies (165).

8.18.2 The governmental supervision of CAM Practices

There is no regulation of CAM supervision in Israel. Several governmental committees have been working on a framework, but none have been approved (163).

8.18.3 The reimbursement status of CAM practices and medicinal products

The Compulsory Health Insurance Law was passed in 1995, with discussions on how to include CAM treatments in the insurance scheme (165). In 2002 the law only referred to acupuncture. The Health Insurance Law, clause 8 recognized the use of acupuncture in pain relief clinics for treatments of patients with tumors (165).

“Not-for-profit public health maintenance organizations” (HMOs) are clinics funded by the Israeli health funds (165). If CAM/acupuncture treatment is provided in a public HMO or hospital clinic the patient pays a low co-payment as a member of that HMO. If the treatment is provided by a private practitioner reimbursement may be covered if the patient has a private health insurance (163).

8.18.4 Acupuncture

The practice of acupuncture is not regulated in Israel. Medical doctors are practicing acupuncture without the need for a special licence. The non-medical practitioners of acupuncture usually graduate from a 4-year programme at a CAM college (163).

There have been several government-assigned committees suggesting a framework for the definition of the CAM practice, with a special emphasis on acupuncture. This framework has not yet been approved by all the relevant parties (163).

Reimbursement of Acupuncture is regulated in the Health Insurance Law from 1995 (165).

8.18.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.18.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.18.7 Chiropractic

Chiropractor is from 2010 a regulated health profession in Israel.

“On March 24, 2010, an amendment to the law regulating the practice of medical professions, 2008 (the “Health Professions” law, hereinafter), was published. As a part of this, the practice of chiropractic was regulated. Those who meet the legal requirements, will be eligible for a chiropractic certificate from the Ministry of Health”(167).

“The Ministry of Health is currently preparing for the implementation of the law. At present, only those who had a Chiropractic Status Recognition Certificate from the Ministry of Health, either permanent or temporary, which was valid on July 22, 2005, are permitted to submit an application for a chiropractic certificate, provided that the application is submitted before March 24, 2012”(167).

“The Medical Professions Licensing Department will later on publish the procedures for applying for a certificate for those who do not have a Status Recognition Certificate (permanent or temporary)”(167).

8.18.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.18.9 Homeopathy

“The absence of legislation which specifically restricts the practice of homeopathy to any particular type of practitioner means that anyone may practise”(50). Homeopathy is offered within the setting of the national health care system, but it is no reimbursed (70).

8.18.10 Massage

No specific regulation has been found on massage.

8.18.11 Naprapathy

No specific regulation has been found on naprapathy.

8.18.12 Naturopathy

No specific regulation has been found on naturopathy.

8.18.13 Neural therapy

No specific regulation has been found on neural therapy.

8.18.14 Osteopathy

No specific regulation has been found on osteopathy.

8.18.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.18.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a recognized health profession in Israel (166). According to the law, the Ministry of Health issues a certificate of practice for the physiotherapy profession. By law, applicants for the certificate are required to be holders of a Bachelor’s degree as a minimum and they must pass a government examination in this profession (166).

“Whoever began their studies in a non-academic course (which was recognized by The Medical Professions Licensing Department for the purpose of a Status Recognition Certificate) until January 30, 2009, and who will be completing their studies no later than July 30, 2012, and who has completed practical training in the course of the studies and has successfully passed a special examination, is eligible to submit to a request for a certificate of practice for physiotherapy, provided that the request is forwarded no more than one year after completion of the studies (meaning no later than July 30, 2013)” (166).

8.19 Italy

Italy was a founding member of the European Union in 1957 (11) and a founding member of the Council of Europe on 5 May 1949 (12).

8.19.1 The legal and regulatory status of CAM and CAM practices

Italy has no general CAM legislation. The Italian Parliament and government have several times been requested to pass CAM legislation (28, 168). The Supreme Court of Justice (Suprema Corte di Cassazione (1982, 1999, 2003, 2005, 2007) has ruled that Non-Conventional Medicines may be practised only by medical doctors. The Supreme court stated that acupuncture is a medical act, homeopathic remedies must be prescribed only by medical doctors and it is an infringement of medical powers for anyone without a degree in medicine to practise Traditional and Non-Conventional Medicines (169-172).

The Italian “National Federation of the Orders of Doctors and Dentists” (Federazione Nazionale Ordini dei Medici Chirurghi e Odontoiatri) (**FNOMCeO**) has by statement of 18 May 2002 urged the Italian Parliament to approve legislation of practice as a responsibility of a medical doctor, a dentist or regulated health professionals for the following treatments: Acupuncture, Traditional Chinese medicine, ayurvedic medicine, homeopathic medicine, anthroposophic medicine, homotoxicology, phytotherapy, chiropractic and osteopathy (28, 168).

The professional ethical code for medical doctors and dentists, approved 16 December 2006, article 15, confirms the following statement adopted in 2002: “physicians must not collaborate in any way with, or promote the activities of any person who is not a physician in the professional practice on Non-Conventional Medicines (in Italy)”(173).

The Permanent Conference of the Deans and Presidents of the Italian Schools of Medicine issued on July 2011 its position paper saying that the acquisition of skills related to CAM is not an educational goal of the Degree in Medicine at the Italian Schools of Medicine, quoting the Italian text is "L'acquisizione di competenze relative alle CAM non rappresenta un obiettivo didattico del Corso di Laurea in Medicina."

“Non-medically qualified practitioners can be prosecuted under Article 348 of the Italian Penal Code, although this rarely occurs”(28).

8.19.2 The governmental supervision of CAM Practices

We have found no specific governmental supervision regulations of CAM practice in Italy.

8.19.3 The reimbursement status of CAM practices and medicinal products

CAM in general is not included in the national health insurance service (60). If decided by the regional health authorities, CAM treatments provided by medical doctors may be reimbursed by both public and private insurance companies. Chiropractic may be reimbursed (43). Each Italian region has its own reimbursement regulation on medical acts (21). In some Italian regions acupuncture treatment is covered by the national health insurance system (106). Anthroposophic treatment is partially covered only by private insurance (106). Homeopathy treatment is covered by private insurance (106).

8.19.4 Acupuncture

Acupuncture in Italy must be provided only by medical doctors. The Supreme Court of Justice (Suprema Corte di Cassazione(1982, 1999, 2003, 2005, 2007) has ruled that acupuncture is a medical act and it is an infringement of medical powers for anyone without a degree in medicine to practise Traditional and Non-Conventional Medicines (168, 170-172).

The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) has acknowledged acupuncture treatment as a responsibility and an additional medical treatment of a medical doctor or a dentist (106, 168). Diplomas of medical acupuncturists are issued and approved by the national medical council/chamber in Italy (106).

8.19.5 Anthroposophic medicine

The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) has acknowledged anthroposophic treatment as a responsibility of a medical doctor or a dentist (168, 170-172). Anthroposophic medicine is recognized through a statutory regulation by the local medical associations in Bologna, Terni and Palermo (106).

Diplomas are issued by the associations of anthroposophic doctors and recognized by the national medical association. Anthroposophic medicine is provided in some hospitals in Italy (106).

8.19.6 Ayurveda

The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) has acknowledged ayurvedic treatment as a responsibility of a medical doctor or a dentist (168, 170-172).

8.19.7 Chiropractic

Both The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) and different court rulings have acknowledged chiropractic treatment as a responsibility of a medical doctor, a dentist or primary health professionals with internationally approved chiropractic education (170-172, 174, 175).

The Register of Chiropractic doctors is established, but not yet activated, within the Italian Labour, Health and Social Policy Ministry under art 2, comma 355, of Law N° 244/2007 (168, 170-172). “In Italy there are *de facto* local regulations, administrative rules or court-stated guidelines” for regulation of chiropractic treatment (174, 175).

8.19.8 Herbal medicine/Phytotherapy

The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) has acknowledged phytotherapy treatment as a responsibility of a medical doctor or a dentist (168, 170-172).

8.19.9 Homeopathy

Practise of homeopathy is restricted to medical doctors and veterinarians (60). The Supreme Court of Justice (Suprema Corte di Cassazione(1982, 1999, 2003, 2005, 2007) has ruled that homeopathic products must be prescribed only by medical doctors and that it is an infringement of medical powers for anyone without a degree in medicine to practise Traditional and Non-Conventional Medicines (168, 170-172).

Both The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) and different court rulings have acknowledged homeopathic treatment as an additional medical qualification and a responsibility of a medical doctor or dentist (106, 168). FNOMCeO has called on the government to provide necessary legislation (106).

Public registers for homeopaths is not yet in force. Italian medical practitioners of homeopathy have completed post-graduate training in homeopathy, anthroposophic medicine or homotoxicology (60).

8.19.10 Massage

Massage is a regulated health profession in Italy.

Masseur is registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Massaggiatore e bagnino terapeutico/ balneoterapista/ idroterapista**” recognized under Directive 2005/36/EC(5), ID 3305. General system of recognition- primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C,D) , Art. 11 c(7). Useful link: nihil.

8.19.11 Naprapathy

No specific regulation has been found on naprapathy.

8.19.12 Naturopathy

No specific regulation has been found on naturopathy.

8.19.13 Neural therapy

No specific regulation has been found on neural therapy.

8.19.14 Osteopathy

Both The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) and different court rulings have acknowledged osteopathic treatment as a responsibility of a medical doctor, a dentist or regulated health professionals with internationally approved education in osteopathy (168, 170-172).

8.19.15 Traditional Chinese Medicine (TCM)

The Italian “National Federation of the Orders of Doctors and Dentists” (FNOMCeO) has acknowledged TCM treatment as a responsibility of a medical doctor or a dentist (168, 170-172).

8.19.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a **regulated profession** in Italy with the title “**Fisioterapista**”. Legal protection of the title and the professional activity of the physiotherapist profession have been established. Professional ethics have been established, and disciplinary jurisdiction is established by the State. There is no requirement for the physiotherapist to be registered and/or have a license to practise. The "Ministero della Salute" is responsible for the physiotherapy profession in Italy, and the "Ministero dell'Università" for the education (176).

Physiotherapy is registered in the EU regulated professions database with two professions:

Physiotherapy is a directly related regulated profession with title “**Terapista della riabilitazione**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC(109). General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

Physiotherapy is a directly related regulated profession with title “**Fisioterapista**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC(109). Since 2003 this profession corresponds only to terapista della riabilitazione) (EN)(7).

8.20 Latvia

The Baltic state Latvia regained its independence from the Soviet Union in 1991, and became a member of the European Union in 2004 (11). Latvia became a member state of the Council of Europe on 10 February 1995 (12).

8.20.1 The legal and regulatory status of CAM and CAM practices

Acupuncture, anthroposophic medicine and homeopathy, are regulated in Latvia, and only medically qualified professionals are allowed to practise CAM (50, 106). Acupuncture and homeopathy are considered medical specialties since 1993 (177).

Only qualified Medical Doctors have the legal right to provide CAM diagnostic methods and treatment (178). The regulation of acupuncture, homeopathy and ayurvedic medicine is delegated to the Latvian medical society (Latvijas Ārstu biedrība) (28, 50).

“The Administrative Codex prohibits non-medically qualified practitioners for practising medicine of any kind”(28, 178). The Cabinet Regulation No. 431/1997 gives “Procedures for Certification of Medical Practitioners”(179).

Regulated professions in medicine and pharmacy are described in Chapter III and chapter IX, § 50 in “the Act on regulated professions and recognition of professional qualifications” (180). Doctor, dentist, pharmacist, nurse (medical nurse), assistants of those professions and physiotherapist are professions of interest for CAM (180).

If unified requirements exists for all foreign countries for the above professions, chapter VII, article 34 regulates the special system for recognition of foreign citizens (180). If a person applies for temporary or occasional work in Latvia the professionals act recognizes the persons’ professional qualifications if his profession is regulated in an EU/EFTA country and in Latvia. If the profession is not regulated in the applicant’s state of residence, he may practise if the profession is regulated in Latvia and he fulfills specific practise claims (181).

8.20.2 The governmental supervision of CAM Practices

CAM professionals providing acupuncture, homeopathy and ayurvedic medicine are supervised by a commission of experts representing the Medical Society of the Republic of Latvia and the professional medical associations (28, 50).

8.20.3 The reimbursement status of CAM practices and medicinal products

CAM, in particular acupuncture and homeopathic treatments, are partially covered by some private insurance companies in Latvia (41, 106, 177).

8.20.4 Acupuncture

Acupuncture is recognized as an “equal-in rights” therapeutic system and a medical specialty for doctors in Latvia (106). The Cabinet Regulation No. 431/1997 Procedures for Certification of Medical Practitioners item 29 (the Register of Medical Specialties and Methods) has authorized the status of additional medical specialty “Acupuncture” (code SS-07). Post-graduate training courses in acupuncture for doctors are provided through the professional medical Association of Medical Society of Latvia at the academic level (106, 178).

The certification authority and control of any professional activities of doctors in the field of acupuncture is delegated to the professional Association of Medical Acupuncture and Related Techniques (founded 30.11.1990)(178).

8.20.5 Anthroposophic medicine

Anthroposophic medicine is statutorily regulated and recognized by the medical association as an additional qualification for doctors in Latvia (41, 106). Diplomas are issued by the national association of anthroposophic doctors and recognized by the national medical association (106).

8.20.6 Ayurveda

Ayurvedic medicine is legally recognized and was recommended as safe with wide applications in the institutions of public health services of Latvia (178).

8.20.7 Chiropractic

No specific regulation has been found on chiropractic.

8.20.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.20.9 Homeopathy

Homeopathy is since 1997 recognized by law as a distinct therapeutic specialty in Latvia, with regulation and supervision delegated to the Latvian Homeopathic Medical Association. Only medical doctors may practise homeopathy, and the medical by-law recognized homeopathy as a medical specialty in 1998 (106, 182). The national homeopathic doctors' association issues diplomas recognized by the national medical council in Latvia. CME (continuous medical education) is obligatory for all homeopathic doctors (106). Since 1988, the Latvian medical association granted medical doctors the right to add the title “homeopath” if they have more than 4 years of practical experience (41).

8.20.10 Massage

No specific regulation has been found on massage.

8.20.11 Naprapathy

No specific regulation has been found on naprapathy.

8.20.12 Naturopathy

No specific regulation has been found on naturopathy.

8.20.13 Neural therapy

No specific regulation has been found on neural therapy.

8.20.14 Osteopathy

On the grounds of the order of the Latvian Ministry of Health from 28 May 2002 osteopathy was declared as a method of treatment and science, as well as specialty (183).

“The Latvian osteopathic centre” was created in 1988, and in 2005, was re-registered as the Baltic Osteopathic Association (183). The association has a licence from the Ministry of Health of Republic of Latvia Nr. 11, supplement 2 from 16.09.2005. BOA is a public professional society, the members have a doctor of osteopathy (D.O.) degree and are practising in this sphere (183). All the doctors who serve patients have a rank of “**Doctor of osteopathy**”, which is confirmed by the diploma in accordance with international standards (183).

There are about 10 osteopaths in Latvia who have the diploma of the Higher School of Osteopathy – a branch of the European osteopathic university in Geneva. They are also members of the Baltic Osteopathic Association (BOA) and are included in the European Register of osteopaths (183).

8.20.15 Traditional Chinese Medicine (TCM)

There is no specific regulation on TCM in Latvia, since the theory of TCM is a basic and inseparable part of the training process of the acupuncture specialty for doctors (177).

8.20.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Latvia, with the professional title **Physiotherapist (Bachelor degree)**. Legal protection of the title and activity of physiotherapists has been established and they have founded rules of professional conduct for physiotherapists. Whether physiotherapist members must be registered and obtain a licence to practise physiotherapy has not been specified by the Latvian association. Latvia has established a code of ethics for physiotherapists. The "Welfare Ministry" is responsible for the physiotherapy profession in Latvia (184).

Physiotherapy in Latvia is registered in the EU regulated professions database as follows:

“**Physiotherapist**” is a directly related regulated profession with title “**Fizioterapeits**” recognized under Directive 2005/36/EC(109), ID 12365. General system of recognition-primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.(7).

8.21 Liechtenstein

Liechtenstein has been a member of The European Free Trade Association (EFTA) since 1960, and became a full participant of The European Economic Area (EEA) from 1 May 1995. Liechtenstein is included in the CAMbrella survey through The European Commission Seventh Framework Programme (FP7) Third Country Agreement: EFTA: (Article 1 of protocol 31 of the EEA agreement amended on 15 June 2007 by a decision of the EEA Joint Committee).

8.21.1 The legal and regulatory status of CAM and CAM practices

The new health care law, “Gesundheitsgesetz” (GesG) of 2007, introduces the new profession and **protected title “Naturheilpraktiker”**(185). Practise of **homeopathy, naturopathy and Traditional Chinese Medicine (TCM)** must be practised by a registered “Naturheilpraktiker” (50, 185). **Chiropractic, medicinal massage and physiotherapy** are regulated professions (185). Details about the regulation of the above professions are found in the Gesundheitsverordnung (GesV) of 2008 (186).

CAM treatment is restricted to legally regulated health personnel (21). To be registered documentation must be provided to prove they have carried out education which enables them to practise the therapy in question. Non-medical providers using complementary medicine are regularly prosecuted, but overall Liechtenstein is practising a tolerant system for providers of “natural medicine” (21, 43).

Liechtenstein follows most of the Swiss regulation of CAM education, approval of training institutions and registration as CAM practitioners (186).

According to the health law of 2007 (185) license to practise homeopathy, TCM or the European traditional naturopathy is provided according to regulations of the newly regulated profession **“Naturheilpraktiker”**. Licence is given by “Amt für Gesundheit” based on authorization from a governmental approved educational institution and a following statutory exam (185). Licence as **Naturheilpraktiker with homeopathy, TCM or naturopathy specialty** is depending on educational regulations and registration in Switzerland and the Swiss exam for each of the treatments (186). Useful webpage: <http://www.llv.li/amtstellen/llv-ag-gesundheitsberufe/llv-ag-gesundheitsberufe-naturheilpraktiker.htm>.

8.21.2 The governmental supervision of CAM Practices

Patient safety is managed by “Amt für Gesundheit” (185).

8.21.3 The reimbursement status of CAM practices and medicinal products

Except for homeopathy, CAM is not covered by the health insurance system. CAM treatment may unofficially be covered if provided by regulated health care personnel. Private insurance may cover some CAM therapies (21, 43).

By November 2011 we could not find that the profession Naturheilpraktiker was included in the reimbursement regulations.

8.21.4 Acupuncture

No specific regulation has been found on acupuncture.

8.21.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.21.6 Ayurveda

No specific regulation has been found on anthroposophic medicine.

8.21.7 Chiropractic

The national regulation of chiropractor follows the health law from 2007 art.6, 1c and E art. 27a, b. (185). According to **“Gesundheitsgesetz Art. 7 ff sowie Gesundheitsverordnung Art. 29 bis 31”**(186) educational demands for chiropractors practising in Liechtenstein are:

- a) a diploma documenting the accomplishment of the chiropractor educational programmes prescribed in Switzerland, or
- b) an external diploma according to the list of approved international educational programmes (according to “Art. 33 des schweizerischen Medizinalberufegesetzes durch Verordnung des Departements des Inneren” (EDI)) and minimum 2 years supervised by a chiropractor.

In regulation for **“Chiropraktoren”**, health law E art. 27 (185) a chiropractor is legally entitled to **submit medical questions** of a patient **to a physiotherapist** if they are not convinced what will be the best treatment (185).

Chiropractor is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title **“Chiropraktiker”** recognized under Directive 2005/36/EC (5), ID 4755. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.

National Legislation: Art. 6 Abs. 1 lit. c Gesundheitsgesetz, LGBl. 2008 Nr. 30 iVm. Art. 29 ff Gesundheitsverordnung, LGBl. 2008 Nr. 39 (7, 185, 186).

8.21.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.21.9 Homeopathy

According to the health law of 2007 (185) licence to practise homeopathy is provided according to regulations of the newly regulated profession “**Naturheilpraktiker**”. Licence is given by “Amt für Gesundheit” based on authorization from a governmental approved educational institution and a following statutory exam (185). Licence as **Naturheilpraktiker with homeopathy specialty** is depending on homeopathic education and registration in Switzerland and the Swiss homeopathic exam (186). See more information under the description of Naturheilpraktiker.

Liechtenstein has a statutory regulation by Act of Parliament of non-conventional homeopaths. Homeopaths must be registered through the Government established system (50).

8.21.10 Massage

„**Medizinischer Masseur**“ is regulated according to the national legislation “Gesundheitsgesetz Art. 7 ff sowie Gesundheitsverordnung Art. 51 bis 53” (185, 186). The work specifications include water-, heat- chill- and electrotherapy as well as manual massage. The educational level is at least two years of training at an approved school of medicinal massage. The law describes in detail post-graduate training and restrictions of treatment like diagnoses and prescriptions.

Massage is registered with two professions in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Medizinischer Masseur**” recognized under Directive 2005/36/EC (5), ID 3304. General system of recognition- primary application. Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b (7). Useful link: <http://www.llv.li/amtsstellen/llv-agd-home.htm>.

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Medizinischer Masseur**” recognized under Directive 2005/36/EC (5), ID 287. General system of recognition- primary application. National legislation: Art. 6 Abs. 1 lit. I Gesundheitsgesetz, LGBl. 2008 Nr. 30 iVm. Art. 51 ff Gesundheitsverordnung, LGBl. 2008 Nr. 39. Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b (7). Useful link: <http://www.ag.llv.li>.

8.21.11 Naprapathy

No regulation has been found on naprapathy.

8.21.12 Naturopathy

According to the health law of 2007 (185) licence to practise naturopathy is provided according to regulations of the newly regulated profession “**Naturheilpraktiker**”. Licence is given by “Amt für Gesundheit” based on authorization from a governmental approved educational institution and a following statutory exam (185). Licence as Naturheilpraktiker

with naturopathy specialty is depending on naturopathic education and registration in Switzerland and the Swiss naturopathic exam (186). See more information under the description of Naturheilpraktiker.

For the European Traditional Naturopathy the approval is given by the “Naturärztevereinigung der Schweiz” (SPAK)(186).

8.21.13 Neural therapy

No specific regulation has been found on neural therapy.

8.21.14 Osteopathy

Osteopathy is regulated by national legislation under the health law art 6 n (185) and regulation of the professions 13 art 57-59 (‘Gesundheitsgesetz Art. 7ff sowie Gesundheitsverordnung Art. 57 bis 59’)(187). Educational requirements are either “interkantonale Prüfung für Osteopathie in der Schweiz mit Erfolg bestanden hat” or another approved bachelor study of Osteopathy (187).

Osteopathy is registered in the EU regulated professions database as follows:

Osteopath is a directly related regulated profession with title “**Osteopath**” recognized under Directive 2005/36/EC (5), ID 14805. General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d. National legislation: Art. 6 Abs. 1 lit. n Gesundheitsgesetz, LGBl. 2008 Nr. 30 iVm Art. 57 ff. Gesundheitsverordnung, 2008 Nr. 39 (7)

Useful link: <http://www.llv.li/amtsstellen/llv-agd-home.htm>

8.21.15 Traditional Chinese Medicine (TCM)

TCM is legally regulated in Liechtenstein as a treatment that may be provided by the “**Naturheilpraktiker**” (185). According to the health law of 2007(185) licence to practise TCM is provided according to regulations of the newly regulated profession the **Natural health practitioner – “Naturheilpraktiker”**. Licence is given by “Amt für Gesundheit” based on authorization from a governmental approved educational institution and a following statutory exam (185). Licence as Naturheilpraktiker with TCM specialty is depending on TCM education and registration in Switzerland and the Swiss TCM exam (186). See more information under the description of Naturheilpraktiker. Practitioners must register. See more details under the description of the Natural health practitioner (Naturheilpraktiker).

8.21.16 Other treatments (mentioned if found in legislation)

In national legislation **Naturheilpraktiker** is regulated by the health law of 2007 Art 6 m and D art 22-24 (185). The working fields are homeopathy, Traditional Chinese Medicine and Traditional European naturopathy treatment. Restrictions of treatment for the Naturheilpraktiker are described in the health law art 24 (185).

Natural health practitioner is registered in the EU regulated professions database as follows:

Natural health practitioner is a directly related regulated profession with title “**Naturheilpraktiker**” recognized under Directive 2005/36/EC (5), ID 14807. General system

of recognition - primary application. Qualification level PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d. All regions included. National legislation: Art. 6 Abs. 1 lit. m Gesundheitsgesetz, LGBl. 2008 Nr. 30 iVm Art. 54 ff. Gesundheitsverordnung, 2008 Nr. 39 (7, 185, 186). Useful link: <http://www.llv.li/amtstellen/llv-agd-home.htm>.

Physiotherapy is a regulated profession with the title **Physiotherapeut** according to national legislation in the health law Art.6 p. and “Gesundheitsgesetz Art. 7ff sowie Gesundheitsverordnung Art. 63 bis 65”(185, 186). The title and the professional activity is protected by the state (188). The physiotherapist must be state registered and obtain a licence to practice (188). In regulation for “Chiropraktoren”, health law E art. 27 (185) chiropractors are legally entitled to submit medical questions of a patient to a physiotherapist if they are not convinced what will be the best treatment (185).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapist is a directly related regulated profession with title “**Physiotherapeut**” (Physiotherapist (EN)) recognized under Directive 2005/36/EC (5), ID 285. General system of recognition – primary application. National legislation: Art. 6 Abs. 1 lit. p Gesundheitsgesetz, LGBl. 2008 Nr. 30 iVm. Art. 63 ff Gesundheitsverordnung, LGBl. 2008 Nr. 39 (185-187). Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11b (7). Useful webpage: <http://www.ag.llv.li>.

8.22 Lithuania

Lithuania regained its sovereignty from the Soviet Union via the declaration of independence on 11 March 1990 (11). Lithuania became a member of the European Union in 2004 (11) and became a member state of the Council of Europe on 14 May 1993 (12).

8.22.1 The legal and regulatory status of CAM and CAM practices

Since independence, medical education has undergone substantial reforms following EU requirements and WHO recommendations (189). Only medically qualified professionals are allowed to practise CAM treatment in Lithuania (106, 190). In Regulation 1999 No. 62, homeopathy, manual therapy and reflexology are listed as medical specialties only to be practised by medical doctors (191).

Only practices offered by licensed medical professionals are regulated by the state. Any other practices (health promotion or similar) are allowed, unless they are dangerous, called “medical” or offered as treatment (190).

The State Accreditation Agency, Ministry of Health (MOH) is responsible for licensing and certification of health care professionals in both the public and private sector. Specialists require a certificate from the Ministry of Health to practice (50, 189). The act of medical practice No 68-2365 on 28 June 2004 states that a physician must have a basic licence for medical practise in some specialty. No CAM specialties are listed in the this law (190, 192). Consequently no CAM therapists are certified by the state (190).

Other specialties called “narrow specialization of medical practice” (No.V-469) are not certified by the State Accreditation Agency. The specialist only needs a certificate for fulfilled introductory course in the specific CAM practice (Order No. V-680)(190).

If the physician wants to practise legally as a CAM therapist (homeopath, manual therapist, reflexotherapist) he has to work in an institution, public or private, which is licensed to offer such therapy. An order of MOH, V-364 of 14 May 2004, lists the out-patient health care services which require a licence given by State service for accreditation in health care. Homeopathy, manual therapy and acupuncture are the only CAM therapies listed as such services. The document was published in the Official Gazette “Valstybės žinios” No 86-3152 on 28 May 2004 (193). Other CAM treatment may be offered as “good practice” within the specialty of the physician, not as a CAM practitioner.

The National Board of Health is responsible for the coordination of health policy in Lithuania. It coordinates and regulates education and training, licensing and certification, and performance standards. The Ministry of Health is responsible for establishing standards in CME (continuing medical education) and partly funding it (189).

The list of professionals is the basis for licensing of health professionals. In the absence of licence, having an expired licence or no issued licence in the specialty, it is illegal to provide medical practice which legally is to be performed by a defined "doctor by professional qualification and the competence of health care", including personal health condition, disease prevention, diagnosis and treatment of patients.

8.22.2 The governmental supervision of CAM Practices

The Medical Audit Inspectorate under the Ministry of Health, established in 1998, is involved in the establishment of medical standards and quality control with respect to health care providers (189). In the period between 1995 and 2001, the Ministry of Health, in conjunction with the Ministry of Education, the universities and the professional organizations, prepared and approved medical standards for different categories of physicians and nurses (189).

8.22.3 The reimbursement status of CAM practices and medicinal products

Health care, provided by public or private health care, are covered from the Compulsory Health Insurance Fund (CHIF). Acupuncture and manual therapy are included in the Health Care approved by the Ministry of Health as paid medical services.

Homeopathic treatment is not reimbursed in Lithuania (41).

8.22.4 Acupuncture

A medical doctor may practise acupuncture as a specialty called "narrow specialization of medical practice" (No.V-469), which are not certified by the State Accreditation Agency. The specialist only needs a certificate for fulfilled introductory course in the specific CAM practice (Order No. V-680)(190).

If the physician wants to practise legally as a CAM therapist (homeopath, manual therapist, reflexotherapist) he has to work in an institution, public or private, which is licensed to offer such therapy. An order of MOH, V-364 of 14 May 2004, lists the out-patient health care services which require a licence given by State service for accreditation in health care. Homeopathy, manual therapy and **acupuncture** are the only CAM therapies listed as such services. The document was published in the Official Gazette "Valstybės žinios" No 86-3152 on 28 May 2004 (193).

No other specific regulation has been found on acupuncture.

8.22.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine. Lithuania has no Anthroposophic Medical Association, but there are a few anthroposophic doctors.

8.22.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.22.7 Chiropractic

No specific regulation has been found on chiropractic.

8.22.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.22.9 Homeopathy

Only physicians may legally practise homeopathy in Lithuania(190). From 1999 (No. 62, 5 February 1999, updated in the order of Health care Minister V-680 of 29th of September 2004) homeopathy is listed as “a narrow specializations of medicine” (190). There is no governmental certification system for those specializations (190). To be allowed to practise a person must have a licence of medical doctor of any specialty and have fulfilled basic training (at the Vilnius University or the Kaunas Medical University), in addition to 80 hours of postgraduate education in this specialty every 5 years (“Valstybės žinios” No 149-5426 of 9 October 2004)(194).

With the order of MOH-V-364/2004 homeopathy is listed as an out-patient health care service which requires a licence given by state service for accreditation in health care (193). The medical association recognizes homeopathy as an additional medical qualification (almost specialty) and issues diplomas as such (106).

An institution can get a licence of homeopathic practice if in addition to other requirements the documents of a person who is allowed to practise homeopathy are provided to the state institution for licensing (193). There is no procedure of personal licensing for homeopathic doctors (190).

The right to practise homeopathy for medical doctors is retained after additional homeopathy training for about five years (50). The title homeopath is in some way protected through governmental regulation (50).

The following diseases may not be treated with homeopathy: cancer, tuberculosis, acute infectious diseases, schizophrenia and affective insanity (41).

8.22.10 Massage

Massage is a regulated professional qualification (listed as manual therapy). As a legally licensed treatment, massage service is health care, and may only be provide by persons who meet the professional masseur qualification and only in institutions with health care licence for this activity.

Massage in Lithuania is registered in the EU regulated professions database as follows:

Masseur/Message therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Masažuotojas**” (Masseur (EN)) recognized under Directive 2005/36/EC (5),ID 4858. General system of recognition- primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D), Art. 11 c (7). Useful link: <http://www.sam.lt>.

8.22.11 Naprapathy

No specific regulation has been found on naprapathy.

8.22.12 Naturopathy

No specific regulation has been found on naturopathy.

8.22.13 Neural therapy

No specific regulation has been found on neural therapy.

8.22.14 Osteopathy

No specific regulation has been found on osteopathy.

8.22.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.22.16 Other treatments (mentioned if found in legislation)

Licensed ambulatory health care services depend on physical therapy and massage. Physical therapy is listed as "next higher" - meaning non-medical educated health care specialties. Physical therapist practice in health care facilities is licensed to provide medical rehabilitation services for children with disabilities in educational institutions, and health and recovery services. The Lithuanian Kinesitherapy Association is a member of The World Confederation of Physio Therapy (195).

Physiotherapy in Lithuania is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**Kineziterapeutas**” (Physiotherapist(EN)) recognized under Directive 2005/36/EC (5),ID 4812. General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7). Useful link: <http://www.sam.lt>.

8.23 Luxembourg

Luxembourg is a founding member of the European Union since 1952 (11), and a founding member of the Council of Europe on 5 May 1949 (12).

8.23.1 The legal and regulatory status of CAM and CAM practices

Treatment is restricted to legally regulated health personnel (both doctors and other regulated health personnel) in Luxembourg (41, 43). CAM in general is not regulated (43).

The act of 29 April 1983 on the professions of doctors, dentists and veterinarians regulates the practice of medicine. Authorization is given by the Minister of Health, issued on the advice of the medical college (196). According to article 7, only doctors may provide treatment, diagnosis and prevention of disease. Persons who practise or participate in the diagnosis or treatment of real or supposed pathological disorders through personal acts, oral or written consultations and without the required qualifications and authorizations can be prosecuted (28, 196). The Act of 14 July 2010 harmonizes the provisions of Directive 2005/36/EC on the recognition of professional qualifications of the professions of doctor, dentist, veterinary surgeon, pharmacist and certain other health professions (197).

The Code of Professional Ethics states that it is unethical for allopathic physicians to recommend, to either their patients or acquaintances, therapies that are based on illusory methods or which are not scientifically proven (44).

The Code de la Santé (The Code of Health) compiles the legislation in the field of Health. It is regularly updated so as to present the state of such act, regulation, order or other normative act on the day of its date of update. The Health Portal (www.sante.lu) also offers a set of laws in the field of Health and Social.

The modified law of 29 April 1983 regulates doctors, dentist and veterinarians (198). The modified law of 26 March 1992 regulates certain regulated health professions like nurse, masseur, midwife and physiotherapist (199). The exercise of these professions requires a licence issued by the Minister of Health under the following conditions: the candidate must hold a diploma in Luxembourg on the relevant profession, or a foreign degree recognized by the Minister of National Education or the Minister of Higher Education (199).

A national of a Member State of the European Community, established in another Member State of the Community, with an European professions subject to an EU directive on mutual recognition of degrees, can practise in Luxembourg in service delivery activities of self-employed without the profession concerned obtaining authorization from the Minister (199).

The person authorized to exercise one of these professions has the professional title corresponding to that profession. The person authorized to exercise one of these professions must be registered by the Department of Health (199).

It is highly possible that the practise of unregulated techniques (see below) implicates actions/manipulations that fall under the sphere of competence of a regulated health profession. Thus the practise of such actions/manipulations can only be carried out by a health professional authorized to practise by the Minister of Health. Persons who don't have an authorization to practise and carry out such actions/manipulations face possible prosecution (200).

8.23.2 The governmental supervision of CAM Practices

The Ministry of Health supervises the application of the provisions of the modified law of 26 March 1992 (199).

A higher council for the health care professions governed by this law supervises the adherence of these professionals to the code of ethics and is the competent authority for disciplinary actions against these professionals (199).

8.23.3 The reimbursement status of CAM practices

Homeopathy is not officially reimbursed, but may be covered if provided by a recognized health personnel (41).

8.23.4 Acupuncture

Only medical doctors may practise acupuncture in Luxembourg (200). Regulations are managed by the Ministry of Health (200).

The Luxemburg Medical Association of Acupuncture (Association Luxembourgeoise des médecins-acupuncteurs) is a professional association within ICMART (International council of medical acupuncture and related techniques).

8.23.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.23.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.23.7 Chiropractic

Chiropractic is not a recognized profession in Luxembourg (200). No specific regulation has been found on chiropractic.

8.23.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.23.9 Homeopathy

Homeopathy is not regulated nor officially recognized by the state, but may be practised by medical doctors, although they are not allowed to advertise their homeopathic practice (28, 41).

8.23.10 Massage

Masseur and **masseur-kinésithérapeute** are recognized as **regulated health personnel** in Luxembourg. The practice of these professions is subject to a prior authorization to practise by the Minister of Health (201). **Masseur-kinésithérapeute** and **masseur** is regulated since 1969 within certain **paramedic** professions (202)(see physiotherapy).

“**Spa-therapists**” or “**Masseur-Aestheticians**” are not regulated health care professions in Luxembourg. However, since every kind of massage falls under the sphere of competence of the masseur or masseur-kinésithérapeute, even spa- or wellness massages can only be carried out by authorized masseurs (200).

Massage is registered in the European regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthician is a directly related regulated profession with title “**Masseur (infirmier)**” recognized under Directive 2005/36/EC, ID 2114. General system of recognition- primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D) , Art. 11 c (7).Useful link: nihil

8.23.11 Naprapathy

No specific regulation has been found on naprapathy.

8.23.12 Naturopathy

No specific regulation has been found on naturopathy.

8.23.13 Neural therapy

No specific regulation has been found on neural therapy.

8.23.14 Osteopathy

No specific regulation found on osteopathy.

8.23.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.23.16 Other treatments (mentioned if found in legislation)

Physiotherapy is regulated as “**Masseur-Kinésithérapeute**”. **Masseur** and **masseur-kinésithérapeute** are recognized as **regulated health personnel** in Luxembourg. The title and the professional activity is protected by the state (203). The practice of these professions is subject to a prior authorization to practise by the Minister of Health (201, 202). The physiotherapist must be state registered (203). **Masseur-kinésithérapeute** and **masseur** is regulated since 1969 within certain **paramedic** professions (202)(see massage). The national authority responsible for the physiotherapy profession in Luxembourg is the "Ministère de L'Éducation Nationale" and the "Ministère de la Santé" (203).

Physiotherapy is registered in the European regulated professions database as follows:

Physiotherapist is a directly related regulated profession with title “**Masseur – kinésithérapeute**” recognized under Directive 2005/36/EC (5), ID 348. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d(7). Useful link: nihil.

8.24 Macedonia (Former Yugoslav Republic of Macedonia)

The Former Yugoslav Republic of Macedonia (hereinafter Macedonia) became independent in 1991 following the break-up of Yugoslavia (11), and was granted candidate country status for European Union (EU) membership in 2005 (11). Macedonia became a member of the Council of Europe on 9 November 1995 (12).

8.24.1 The legal and regulatory status of CAM and CAM practices

The process of reviewing health legislation in Macedonia started in 1991 (204). The Law on Public Health (2010) has included CAM in chapter VI Special provisions: *“Traditional and complementary medicine, tattoo, piercing, permanent makeup, acupuncture and beauty care activities”* (205). *“A legal and natural person (human being) can perform activities related to CAM... only if a permit from the Minister of Health is obtained”*. Permits are issued if criterias regarding the facilities, equipment and skilled staff are fulfilled (205). Further, according to article 35, information of health effects and risk to the client shall be prescribed by the Minister of Health (205). The Law on health care (206) and the Health Insurance Act (207) regulate the health care services (204). According to Kamcev N et al.(2010); *“The terms such as complementary and alternative medicine do not exist in the national law legislation in Macedonia”* (208). However, the use of homeopathic and traditional herbal drugs is accepted, described and regulated as practice in providing health care for the general population. Non-qualified professionals do not have rights to practise CAM”(208). *“The ongoing process on EU accession shall reflect the need to follow EU policy and legislation related to free movement of people, goods and profession regarding implementation of CAM practices in the country”*(208). WHO reports that laws and regulations on TCM/CAM were issued in 1998 (59). CAM medicinal products were included in legislation from 1998 and CAM practices have been introduced in legislation from 2010.

On 19 December 2009 a visa liberalization with EU came into force (11). A web-news report from MOH 7 July 2009 commented that this would contribute to increased mobility for health personnel and medical students and Macedonian diplomas would be acknowledged in the countries in Europe. Since Macedonia is a candidate country we have not found any health professions from Macedonia registered within the EU regulated professions database (7, 133).

8.24.2 The governmental supervision of CAM Practices

According to the Public Health Law, VIII Supervision, article 42 (205) supervision will be carried out by the Ministry of Health and the State Sanitary and Health Inspectorate. Complementary and traditional medicine, with acupuncture treatment specified, is included in the law, and by that included in the supervision regulative system.

8.24.3 The reimbursement status of CAM practices and medicinal products

We have no information of the status of reimbursement of CAM treatment.

8.24.4 Acupuncture

Acupuncture is regulated by the Public Health law, article 33 (205). Acupuncture can be performed by a legal or natural person (human being) if a permit by the Ministry of Health is obtained (205). Criteria regarding the facilities, equipment and skilled staff must be fulfilled as prescribed by the Minister of Health (205). According to the Public Health law, article 35(205), Information about health effects and risk to the clients of the services shall be prescribed by the Minister of Health (205).

8.24.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.24.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.24.7 Chiropractic

No specific regulation has been found on chiropractic.

8.24.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.24.9 Homeopathy

Non-conventional practitioners may practise homeopathy in Macedonia under the absence of specific legislation (50).

8.24.10 Massage

No specific regulation has been found on massage.

8.24.11 Naprapathy

No specific regulation has been found on naprapathy.

8.24.12 Naturopathy

No specific regulation has been found on naturopathy.

8.24.13 Neural therapy

No specific regulation has been found on neural therapy.

8.24.14 Osteopathy

No specific regulation has been found on osteopathy.

8.24.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.24.16 Other treatments (mentioned if found in legislation)

Physiotherapy is not a regulated profession in Macedonia (209).

8.25 Malta

Malta became a member of the European Union in 2004 (11) and a member of the Council of Europe on 29 April 1965 (12).

8.25.1 The legal and regulatory status of CAM and CAM practices

According to the Health Care Profession Act 2003, part V “No person shall practise any of the professions complementary to medicine unless his name is entered in the respective register kept by the Council for Professions Complementary to Medicine, in accordance with the provisions of this act” (210). The health care profession act, third schedule, article 28 lists **acupuncture, chiropractic, osteopathy and physiotherapy** as statutory regulated CAM treatments (210), and the professions are registered in the EU regulated professions database (106). Other CAM providers are not legally regulated in Malta, so anybody may treat if the treatment is not restricted to regulated CAM practitioners (43). Physicians may practise CAM (43).

8.25.2 The governmental supervision of CAM Practices

According to the Health Care professions act, part VII, article 31-41 the relevant Council (Council for each profession) have the power to investigate misconduct or a breach of ethics by registered professionals falling under its supervision (210). There are restrictions on advertising treatments and clinics (43).

8.25.3 The reimbursement status of CAM practices and medicinal products

Some therapies are covered by public insurance in Malta (60).

8.25.4 Acupuncture

Acupuncture is a legally regulated CAM profession regulated by the Health Care Profession Act (210). Licence to practise is granted for persons registered by the Council for Professions Complementary to medicine (210) and who fulfill conditions of qualifications and minimum 2 years of practise (subsidiary legislation 464.16 licence to practise regulations)(211). In 2010, 15 acupuncturists was registered in Malta (212).

Acupuncture is registered in the EU regulated professions database as follows:

Acupuncturist is a directly related regulated profession with title “**acupuncturist**” recognized under Directive 2005/36/EC (5), ID 4748. General system of recognition-primary application. Qualification level: PS3- Diploma of post-secondary level (3-4 years), Art.11 d (7).

Qualifications are obtained in Switzerland from 2007 with “negative Automatic General System and professional experience (‘crafts’)(7).

8.25.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.25.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.25.7 Chiropractic

Chiropractic is a legally regulated CAM profession regulated by the Health Care Profession Act (210). Licence to practise is granted for persons registered by the Council for Professions Complementary to medicine (210) and fulfill conditions of qualifications and minimum 2 years of practise (subsidiary legislation 464.16 licence to practise regulations)(211). In 2010, seven chiropractors were registered in Malta (212).

Chiropractic is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title “**chiropractor**” recognized under Directive 2005/36/EC (5), ID 4755. General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art.11d (7).

8.25.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine or phytotherapy treatment.

8.25.9 Homeopathy

The title “homeopath” is not protected in Malta (60). Absence of statutory regulation of homeopathy and legislation which restricts the practice of homeopathy allow medical and non-medically qualified practitioners to practise homeopathy (28, 50).

8.25.10 Massage

No specific regulation has been found on massage treatment.

8.25.11 Naprapathy

No specific regulation has been found on massage treatment.

8.25.12 Naturopathy

No specific regulation has been found on naturopathy treatment.

8.25.13 Neural therapy

No specific regulation has been found on neural therapy.

8.25.14 Osteopathy

Osteopathy is a legally regulated CAM profession regulated by the Health Care Profession Act(210). Licence to practise is granted for persons registered by the Council for Professions Complementary to medicine (210) and fulfill conditions of qualifications and minimum 2 years of practise (subsidiary legislation 464.16 licence to practise regulations)(211). We found no registered osteopaths (212).

Osteopathy is registered in the EU regulated professions database as follows:

Osteopathy is a directly related regulated profession with title “**osteopath**” recognized under Directive 2005/36/EC (5), ID 4756. General system of recognition - primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art.11d. (7).

8.25.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM treatment.

8.25.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a legally regulated CAM profession regulated by the Health Care Profession Act (210). Licence to practise is granted for persons registered by the Council for Professions Complementary to medicine (210) and fulfill conditions of qualifications and minimum 2 years of practise (subsidiary legislation 464.16 licence to practise regulations)(211). In 2010, 324 physiotherapists were registered in Malta (212).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title “**physiotherapist**” recognized under Directive 2005/36/EC(5), ID 736. General system of recognition - primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art.11d (7).

8.26 Montenegro

Following the dissolution of former Yugoslavia Montenegro became an independent state in 2006, recognized by the EU Member States the same year. Montenegro submitted an application for EU membership on 15 December 2008. From 17 December 2010 the European Union granted Montenegro the official status of candidate country (11).

Montenegro is connected to the FP7 research programme through a memorandum of understanding and as such included in the CAMbrella survey of CAM legislation in Europe. As Serbia and Montenegro was in a union from 2003-2006 some of the documents found in our survey include both countries.

Montenegro became 11 May 2007 a member of the Council of Europe (12).

8.26.1 The legal and regulatory status of CAM and CAM practices

Montenegro currently (April 2012) has no CAM laws or regulations. The Ministry of Health of Montenegro confirmed in a meeting with NAFKAM in October 2011 that establishing a national CAM law and regulations of CAM practices is in progress. The work is attended to by a comprehensive compounded governmental committee. How to regulate conventional health professionals who practise CAM is mostly clarified, the inconclusive part of the work is how to regulate non-medical CAM providers. It seems that the legislation will follow the tradition of “all-regulating”, which means that all types of CAM treatments allowed to practise will be defined in the new law. Montenegro has no formal CAM education at University level. There are CAM training programmes offered in cooperation with CAM associations and MOH.

According to the master plan of healthcare development for 2010-2013 (213) the healthcare regulation is based on Law on Health Care and Law on Health Insurance from 2004. The health policy introduces the principle of integrated and interdisciplinary care and transition from structurally-based to process-based health care. The health care system of Montenegro will be developed with national values and strategies. At the same time health is a priority task in defining and implementing all policies and activities of the EU (213). We found no professions in Montenegro registered in the EU regulated professions database according to DIRECTIVE 2005/36/EC (5).

We were informed that introducing CAM chambers and professional bodies could be a way of undertaking the role of quality and safety. According to the master plan of healthcare “Traditional treatment under surveillance is an additional opportunity for a patient, if so decided”(213).

8.26.2 The governmental supervision of CAM Practices

As CAM practitioners are not regulated professions there is no supervision of CAM practices.

8.26.3 The reimbursement status of CAM practices and medicinal products

As CAM is not regulated there is no reimbursement of CAM treatment in Montenegro.

8.26.4 Acupuncture

Acupuncture is not legally recognized in Montenegro, but will be included in the CAM legislation in progress.

8.26.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.26.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.26.7 Chiropractic

No specific regulation has been found on chiropractic

8.26.8 Herbal medicine/Phytotherapy

No specific regulation found on herbal medicine/phytotherapy except for medicinal products regulated according to EU Directives.

8.26.9 Homeopathy

No specific regulation has been found on homeopathy. Non-conventional practitioners may practise under absence of legislation which restricts the practice of homeopathy (50).

8.26.10 Massage

No specific regulation has been found on massage.

8.26.11 Naprapathy

No specific regulation has been found on naprapathy.

8.26.12 Naturopathy

No specific regulation has been found on naturopathy.

8.26.13 Neural therapy

No specific regulation has been found on neural therapy.

8.26.14 Osteopathy

No specific regulation has been found on osteopathy.

8.26.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.26.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a **regulated profession** in Montenegro. The University of Montenegro, Faculty of Applied Physiotherapy is located in Igalo. From the 2004/2005 school year the degree is called Applied Bachelor's degree in physical therapy (214).

8.27 Norway

Norway has been a member of EFTA (The European Free Trade Association) since 1960 (215) and a founding member of the Council of Europe since 1949 (12).

8.27.1 The legal and regulatory status of CAM and CAM practices

Alternative treatment in Norway is from 1 January 2004 regulated by LOV-2003-06-27-64 Lov om alternativ behandling av sykdom mv.) (English version: Act No.64 of 27 June 2003 relating to the alternative treatment of disease, illness, etc.)(216). The law is based on the governmental policy document OT.prp. nr.27 (2003-2003) Om lov om alternativ behandling av sykdom mv. (About act of alternative disease etc.) (217). The regulation recognizes that alternative treatment can be provided by both medical and non-medical professionals and within or outside of health services. No specific CAM practitioners or treatments are mentioned.

Norway has two national regulations on CAM complementing the act related to alternative treatment of disease, illness etc.

LOV-2003-06-27-64 section 3 says: “**Section 3 Registration scheme.** The Ministry shall issue regulations regarding a voluntary registration scheme for health personnel and others who practise alternative treatment”(216). To fulfil this section the Ministry of Health passed the following national regulation: **FOR-2003-12-11-1500** Forskrift om frivillig registerordning for utøvere av alternativ behandling (Regulation of a voluntary registration system for practitioners of alternative treatment)(218). The Brønnøysund Register Centre (Brønnøysundregistret) is a government body under the Norwegian Ministry of Trade and Industry, and consists of several different national computerised registers, including registers for alternative treatment practitioners.

LOV-2003-06-27-64 (216) **section 8 Protected title and marketing** refers to the **Health Personnel Act Section 48 to 51** (219) which regulate protected titles for health professionals in Norway. “Only persons who have been granted authorisation, a licence or specialist approval pursuant to Section 48 to 51 of the Health Personnel Act may use a title designating the group of health personnel concerned. Only persons who are registered as practitioners of alternative treatment in the register established pursuant to Section 3 of this Act may use the designation ‘**registered**’ along with their professional title of alternative therapist”.

To fulfil the marketing section the Ministry of Health passed the following national regulation: **FOR 2003-12-11 nr 1501:** Forskrift om markedsføring av alternativ behandling av sykdom (220) (Regulation related to marketing of alternative treatment of disease).

LOV-2003-06-27-64 section 5, 6 and 7 restricts treatment with medical intervention, treatment which may entail a serious health hazard for patients and treatment for communicable diseases or other serious diseases and disorders only to be practised by health personnel (216).

To strengthen the development of CAM research the Norwegian Research Council in 2000 established a research group in complementary and alternative medicine at the University of Tromsø which later became the National Research Center in Complementary and Alternative Medicine (NAFKAM). In 2005 the Ministry of Health and the Norwegian Directorate of Health initiated improved CAM-related information to the public by establishing the National Information Center for Complementary and Alternative Medicine (NIFAB). NIFAB is organized as a unit within NAFKAM and launched their first websites in 2007.

The Norwegian Directorate of Health (221) has established positions responsible for CAM-related health questions.

8.27.2 The governmental supervision of CAM Practices

CAM practitioners with a health profession are supervised as health personnel according to the Supervision Act (222). Non-medical CAM practitioners fall within the jurisdiction of the Criminal Act.

8.27.3 The reimbursement status of CAM practices and medicinal products

CAM treatment in hospitals is fully reimbursed in Norway. Norwegian Health Insurance covers treatment, medication or hospital accommodation when you are admitted to hospital and are a member of the National Insurance Scheme. Out-patient CAM treatment at hospitals are partially reimbursed.

If you undergo a health check or receive medical treatment with a GP or as an outpatient at a health institution in Norway you are obliged to pay a 'user fee'. CAM treatment given out of hospitals is mainly not covered, but may be reimbursed if combined with conventional treatment given by health personnel. More information can be found on The Norwegian Health Economics Administration's web site (HELFO)(223).

CAM treatment given by practitioners that are not registered health care professionals is not reimbursed.

8.27.4 Acupuncture

The Norwegian Health College (Norges Helsehøyskole Campus Kristiania (NHCK)) is now the owner of The Acupuncture College (Akupunkturhøyskolen). They issue an accredited Bachelor degree in acupuncture.

In Norway acupuncture is partly integrated in hospital treatments. Some associations who organize acupuncturists are listed at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.27.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.27.7 Chiropractic

Chiropractors are from 1988 approved as regulated health care personnel in Norway and by that regulated under the Health Personnel Act (219). Chiropractic treatment is reimbursed as conventional health treatment.

Chiropractic is registered in the EU regulated professions database as follows:

Chiropractor is a directly regulated profession with title “**Kiropraktor**” recognized under Directive 2005/36/EC(5), ID 593. General system of recognition-primary application. Qualification level: PS3- Diploma of post-secondary level (3-4 years), Art 11d (7).

Useful link: <http://www.safh.no/>

8.27.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy.

8.27.9 Homeopathy

Some homeopathy associations are registered at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.10 Massage

Some massage associations are registered at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.11 Naprapathy

One naprapath association is registered at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.12 Naturopathy

One naturopath association is registered at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.13 Neural therapy

No specific regulation has been found on neural therapy.

8.27.14 Osteopathy

The Norwegian Health College (Norges Helsehøyskole Campus Kristiania (NHCK)) has in 2011 forwarded an application to the national authorities (NOKUT) for accreditation of a Bachelor degree in Osteopathy. One osteopath association is registered at The Brønnøysund Register Centre (Brønnøysundregistret).

8.27.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.27.16 Other treatments (mentioned if found in legislation)

Physiotherapist is a regulated profession in Norway with the title **“Fysioterapeut”**. “The title is protected by the state, but the professional activity is not. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registrated and obtain a licence to practise. Norway has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Norway is “The National Ministry of Health and Care Services” (224).

Physiotherapist is a directly related regulated profession with title **“Fysioterapeut”** recognized under Directive 2005/36/EC (5), ID 2996. General system of recognition - primary application. Qualification level: PS3 – Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.28 Poland

Poland became a member of the European Union (EU) in 2004 (11) and a member of the Council of Europe on 26 November 1991 (12).

8.28.1 The legal and regulatory status of CAM and CAM practices

In Poland only medical doctors and dentists are allowed to treat patients (225). Consequently only medically qualified professionals may provide CAM treatment (106).

Legal regulation of professions describe that all medical professions may be divided into two categories: professions regulated by law and others. The first category includes **physicians, dentists, veterinary surgeons, laboratory technicians, pharmacists, psychologists, nurses and midwives, barber surgeons, and dental technicians.**

To practise the medical profession for doctors and dentists means to provide health services, in particular to: examine patients' health condition, diagnose diseases and prevent them, apply appropriate therapy and rehabilitation, ensure consultations, issue expert opinions and health certificates (226). Only physicians who have completed specialisation in one of the basic disciplines may apply for admission to specialisation courses in any other discipline (226).

According to Law on Nursing and Midwifery Professions, the professions of nurse and midwife are independent professions. They are entitled to provide health and particularly medical services on their own not being entirely dependent on doctors orders (226).

The National Centre for Quality Assessment in Health Care manages the accreditation of health care providers and the training of health care professionals (189).

8.28.2 The governmental supervision of CAM Practices

Health professions are organized by statute into three associations, or chambers, membership of which is mandatory. The chambers cover physicians and dentists, nurses and midwives, and pharmacists. All oversee claims of professional malpractice and can revoke the permission to practise. District chambers represent each profession at regional level and maintain a register of eligible practitioners and private practices. The chambers also issue licences to physicians, nurses and midwives for private practice (189).

8.28.3 The reimbursement status of CAM practices and medicinal products

Homeopathy consultations are free of charge, provided the patient is treated by a homeopathic doctor working within the national healthcare service. Homeopathic treatment may be free of charge if provided by a homeopathic doctor in a hospital (70).

Health care funding in Poland is regulated mainly by the law on health benefits funded from public means (227).

From 2012 the Polish Parliament adopted a new law governing the reimbursement of medicinal products, medical devices and food for special medical purposes (228).

8.28.4 Acupuncture

No specific regulation has been found on acupuncture.

8.28.5 Anthroposophic medicine

The medical association of doctors does not recognize diplomas in anthroposophic medicine (106). The Polish national association of anthroposophic doctors offers postgraduate courses in anthroposophic medicine at private teaching centres (106).

8.28.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.28.7 Chiropractic

No specific regulation has been found on chiropractic.

8.28.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy treatment other than the general EU regulation of medicinal products.

8.28.9 Homeopathy

Homeopathy is not a regulated treatment in Poland. Only medical doctors or dentists are allowed to treat patients, by that doctors can treat homeopathically without any interference (28, 225).

Non-doctor practitioners may practise CAM if they do not claim to treat patients (50). This is legal according to Polish Classification of Goods and Services, according to which a homeopath registers his activity at point 85.14.13-00.30 defined as (55): "Services delivered by paramedical personnel, including homeopathic services and similar, excluding services delivered by medical doctors"(70).

A law published in April 2010 defines "Practitioners of unconventional or complementary methods of therapy" and the title "homeopath" is specifically mentioned (50). Art. 5 of the

Articles of Association “The Company’s scope of business activities” refers to homeopathy treatment in *PKD 86.90.D) Activities of paramedics include homeopathy treatment* (226).

Homeopathy in Poland is not recognized as a medical specialization (41). “On 4 April 2008 Poland’s Supreme Medical Council adopted a resolution disapproving of homeopathy” (41, 225). The resolution seems to be not consistent with the Polish and European Pharmaceutical Law which accepts Pharmacopeia with homeopathic remedies (225).

Polish homeopaths are associated in a few homeopathic associations (225). Basic homeopathic training for medical doctors is organized by Center for Practical Training in Classical Homeopathy (Ośrodek Praktycznego Szkolenia Homeopatii Klasycznej). Seminars in classical homeopathy are held by Polish Homeopathic Association (PTH) and Great Poland Homeopathic Physicians' and Pharmacist' Association (WSHLiF)(225).

8.28.10 Massage

Masseur is a regulated profession in Poland and registered in the European regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Masażysta**” (Massager (EN)) recognized under Directive 2005/36/EC (5), ID 4621 General system of recognition- primary application. Qualification level: DSE - Diploma (post-secondary education), including Annex II (ex 92/51, Annex C, D) , Art. 11 c (7). Useful link: <http://www.mz.gov.pl> .

8.28.11 Naprapathy

No specific regulation has been found on naprapathy.

8.28.12 Naturopathy

No specific regulation has been found on naturopathy.

8.28.13 Neural therapy

No specific regulation has been found on neural therapy.

8.28.14 Osteopathy

No specific regulation has been found on osteopathy.

The Polish Osteopathy Society accepts members with recognized diplomas from osteopathy schools (Polska Szkoła Osteopatii /European School of Osteopathy)(229).

8.28.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.28.16 Other treatments (mentioned if found in legislation)

Physiotherapy is regulated in Poland with the title “**Fizjoterapeuta**”. There is no state protection of the physiotherapy title or the professional activity. The rules of professional conduct are determined directly by the state through national legislation. Registration or

licence to practise is not required but a code of ethics for physiotherapists has been established (230).

Physiotherapist is regulated as two professions in the European regulated professions database as follows:

Directly related regulated profession **“Physiotherapist”** with title **“Fizjoterapeuta (magister)” (Physiotherapist (Master) (EN))** recognized under Directive 2005/36/EC (5), ID 13747. General system of recognition- primary application. All regions. Qualification level: PSM - Diploma from post-secondary level (more than 4 years), Art. 11e (7).

Useful link: <http://www.mz.gov.pl>.

Directly related regulated profession **“Physiotherapist”** with title **“Fizjoterapeuta (technik/licencjat - Aneks A - Kodeks Dobrej Praktyki)** recognized under Directive 2005/36/EC (5), ID 6989 General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7). Useful link: <http://www.acss.min-saude.pt>

8.29 Portugal

Portugal became a member of the European Union in 1986 (11) and a member of the Council of Europe in 1976 (12).

8.29.1 The legal and regulatory status of CAM and CAM practices

Since 2003 six CAM therapies have been recognized by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies. The regulated CAM therapies are **acupuncture, homeopathy, osteopathy, chiropractic, naturopathy and phytotherapy** (231). CAM terminology adopted by governmental policy in Portugal is “non-conventional therapeutics” (232, 233). The word “medicine” was banned from the term and the new bill legitimises and defines “non-conventional therapeutics” (233).

Since 2002 the Medical Council has included acupuncture as a “medical competency” (233, 234).

The recognition of non-conventional therapeutics as different from conventional medicine and the use of distinct processes of diagnosis and their own therapeutics is expressed in the law (231, 232). Further the law recognized technical and ideological autonomy in the professional activity of the practice of non-conventional therapeutics (231, 232). Article 13 on the Law No. 45/2003 states that “the citizens have right to choose freely the therapeutic that they prefer”(231).

The law No 45/2003 did not define criteria for practise and curriculum for CAM professionals (233). The statutory regulation for non-conventional practitioners states that in order for someone to practise a regulated therapy they have to be registered through the Government established system (Article 10)(50, 231). An official Portuguese Government/ State Inter-Ministerial Commission to Study and Propose the Regulation of “Non-Conventional Therapeutics” was to be established to draft detailed law regulations of CAM professionals (235). Rules relating to qualifications and professional status, including procedure for accreditation, training and certification of non-conventional therapy professionals were to be implemented before the end of 2005. Up to date that has not happened.

On 21 October 2011 in the National Assembly (RA), there was a unanimous vote of approval to the draft resolution No 146/2011, with publication in the Official Gazette No 215, Series I, 09/11/2011. The Government recommends that the regulations on Law no 45/2003 of 22 August, based on the framework of the therapeutic/non-conventional medicine are approved (<http://dre.pt/redirect.html>).

No protected titles were found for the regulated CAM therapies. The regulated professions physiotherapist and masseur are registered in the EU regulated professions database.

8.29.2 The governmental supervision of CAM Practices

The practice of non-conventional therapeutics is to be accredited and supervised by the Ministry of Health (CAM law 2003, article 6 “Supervision and Professional Accreditation”)(231).

8.29.3 The reimbursement status of CAM practices and medicinal products

Reimbursement is covered if the treatment is given by medical doctors (234).

8.29.4 Acupuncture

From 2002 the Medical Council included acupuncture as a medical competency (233).

Since 2003 Acupuncture treatment has been regulated by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies (231).

8.29.5 Anthroposophic medicine

No specific regulation has been found on anthroposophic medicine.

8.29.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.29.7 Chiropractic

Since 2003 chiropractic treatment has been regulated by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies (231).

8.29.8 Herbal medicine/Phytotherapy

Since 2003 Phytotherapy treatment has been regulated by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies (231).

8.29.9 Homeopathy

Since 2003 Homeopathy treatment has been regulated by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies (231). It is legal to practise homeopathy in Portugal both for health professionals and for non-medical professionals according to the legislation passed in 2003 (50).

Homeopath is not a protected title in Portugal (50). Homeopathy is neither reimbursed by social security nor covered by private insurance (60).

The statutory regulation for non-conventional practitioners states that in order for someone to practise homeopathy they have to be registered through the Government established system (50, 231). Homeopathy is registered as no. 2230.2 in the Portuguese Classification of Occupations 2010 (<http://aphomeopatia.weebly.com>).

The Portuguese Medical Association does not recognise homeopathy. However doctors are allowed to prescribe as they deem right for their patients (Freedom of Therapy)(60).

8.29.10 Massage

Masseur is a regulated profession in Portugal and registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “Massagista de Estética” (Masseur-aesthetician (EN) recognized under Directive 2005/26/EC (5), ID 4621. General system of recognition – primary application. National legislation : Portaria n° 799/90 de 6 Setembro; regulamento n° 22/70 de 30 Novembro. Qualification level : SEC – Certificate attesting the completion of a secondary course. Art. 11b (7). Useful link: <http://www.iefp.pt> .

8.29.11 Naprapathy

No specific regulation has been found on naprapathy.

8.29.12 Naturopathy

From 2003 Naturopathy treatment was regulated by Portuguese Law No 45/2003 of 22 august 2003 on the provision of non-conventional therapies (231).

8.29.13 Neural therapy

No specific regulation has been found on neural therapy.

8.29.14 Osteopathy

Since 2003 Osteopathy treatment has been regulated by the Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies (231).

Detailed regulation of Osteopathy was approved by Resolution No 64/2003 (235). Osteopathy regulation is included in the tasks for the Official Portuguese Government / State Inter-Ministerial Commission to Study and Propose the Regulation of Osteopathy (Law 45 / 2003 - Conjunct Dispatch n° 261 / 2005; - Resolution of the Portuguese Parliament for Osteopathy n° 64 / 2003) (235).

8.29.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.29.16 Other treatments (mentioned if found in legislation)

Physiotherapist is a regulated profession in Portugal with the title “Fisioterapeuta”. The title is protected by state legislation but not the professional activity. The rules of professional conduct are determined directly by the state through national legislation. Registration or licence to practise is not required but a code of ethics for physiotherapists has been

established. The national authority responsible for the physiotherapy profession in Portugal is the "Ministry of Health" (236).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapist is a directly regulated profession with title "**Fisioterapeuta**" recognized under Directive 2005/36/EC (5), ID 1493. General system of recognition – primary application. Qualification level: PS3 – Diploma of post- secondary level (3-4 years), Art 11 d (7). Useful link: <http://www.acss.min-saude.pt> .

8.30 Romania

Romania has been a member of the European Union since 1 January 2007 (11). Romania became a member of the Council of Europe in 1993 (12).

8.30.1 The legal and regulatory status of CAM and CAM practices

In 2005 and 2007 national CAM legislation was introduced and from 2007 adjusted to EU Directives and Regulations. The new classification of occupation issued by order of the government 1832/2011 includes for the first time the denomination “non-MD associate practitioners of CAM”(237).

From 2007 citizens' rights and access to CAM therapies are regulated by “Law on Complementary and Alternative Medicine **nr. 118/2007**” (238). The law regulates the activities and practices of Complementary and Alternative Medicine for the prevention of illnesses and the promotion of health, healing of diseases and optimization of the human health from the biopsychosocial and spiritual points of view (28, 238).

According to chapter III, Art.16 in the Law on CAM nr. 118/2007 (238) all persons have free access to the treatments and practices of complementary and alternative medicine, regulated according to the law. Law nr. 118/2007 states that patients receiving CAM treatment must receive information, preferably written, accessible and easy to understand of the benefits and risks of CAM treatment (237). CAM therapies legally practised in Romania are grouped in pharmacologic and biological therapies, herbal practice, diet-nutrition and lifestyle, alternative therapies, manual therapies, energetic and bio-electromagnetic applications. The therapy group “**alternative therapies**” includes among others **acupuncture, homeopathy, naturopathy, ayurveda and Chinese medicine** (237). Among others the group “**manual therapies**” includes **chiropractic, osteopathy and massage**.

In 2005 the Ordin nr. 418/2005 National Catalogue of Programmes for CAM studies was established. The studies were organized, according to Art I, in order to certify the competence of medical doctors, dentists and pharmacists and the methodological standards for its organisation and progress (28, 239). CAM studies included were among others acupuncture, homeopathy phytotherapy and apitherapy.

According to the Ordin nr. 418/2005 “Certification of graduation in the programme of complementary studies implied obtaining a competence issued exclusively by the Ministry of Health through the National Center of Continuous Education Bucharest only for medical doctors, dentists and pharmacists” (239).

Only medical doctors (MDs), dentists and pharmacists are allowed to practise **acupuncture, homeopathy, apitherapy, phytotherapy, chiropractic, osteopathy and TCM**. CAM practices

are regulated by the Ministry of Health (29) and the CAM professions are recognized as an additional qualification for medical doctors (240). “In order to become a practitioner of complementary/alternative medicine, the persons (medical doctors, dentists, pharmacists, psychologists) are obliged to add the specific competence obtained (acupuncture, phytotherapy, homeopathy..), with the approval of the National Center of Continuous Education for Medical Doctors, Dentists and Pharmacists Bucharest (238) on the authorization of free practise provided, according to the law, by the Ministry of Public Health”. CME is not obligatory for approved CAM therapy doctors (240).

According to the CAM Medical Practitioners Order specialized committees for certain areas of practice (e.g. **acupuncture, herbal therapy, homeopathy, apitherapy**) will regulate professionals (239).

“In medical schools or faculties of pharmacy, students can take optional courses in **homeopathy, phytotherapy or acupuncture**, but none of the CAM modalities are taught in the core curriculum. Attempts are being made to arrange postgraduate courses in integrative medicine, accredited by the Romanian College of Physicians and addressed mainly to general practitioners”(29).

Romanian national CAM law on patients’ rights complement the formulations given in the 2011/24/EU Directive on the application of patients' rights in cross-border healthcare (6, 29).

“Practitioners without a diploma of MD, dentist or pharmacist are authorized to practise CAM therapies (except those allowed only to MDs) after a short special training accredited by the Ministry of Health” (29).

We found no CAM professions registered for Romania in the EU regulated professions database (Directive 2005/36/EC) (7).

8.30.2 The governmental supervision of CAM Practices

Supervision and practice control activities of CAM in Romania is regulated by the law on professional organizations of medical practitioners of CAM (237).

- With the Medical Practitioners Order, CAM specialized committees for each area of practise of CAM, are bound to regulate professional practitioners in the specific area.
- The Order of Practitioners of CAM is required to develop code of ethics, supported by specialist committees. Code of ethics includes the rights to practise, disciplinary sanctions for professional incompetence, practise restrictions in case of incompatibility or damage to patient health.
- A register of practitioners of CAM is held at the headquarters of the Order of Practitioners of CAM, communicating with the National Centre for Training in Healthcare.

- The Ministry of Public Health, College of Physicians in Romania, Dental College and College of Pharmacists in Romania shall, in consultation with the Order of Practitioners of CAM, approve study curricula for institutions that prepare practitioners of CAM to ensure level qualification.
- The Ministry of Public Health and the National Training Center in Healthcare, Department of CAM directs and controls activities in the field, including professional training for practitioners of CAM. Department of CAM supplies and accredits training programs for practitioners of CAM (237).

8.30.3 The reimbursement status of CAM practices and medicinal products

CAM treatment and medicinal costs are partially covered for acupuncture, homeopathy, phytotherapy and psychotherapy (House of National Insurance of Health)(106, 240). Since 2010 manual therapies are not covered anymore due to the economic crisis in Romania (237).

8.30.4 Acupuncture

Acupuncture is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007 (238).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise acupuncture in Romania (239). A specialized committee for acupuncture regulates the profession (NATL)(239).

In medical schools or faculties of pharmacy students can take optional courses in acupuncture (29).

There is a professional society of acupuncture that has annual national congresses. There is a National Institute of research in CAM in Bucharest; its present director is also the president of the Romanian association of Acupuncturists (237).

There is no professorial chair for CAM therapy in Romania, but there are clinics of acupuncture in some faculties of medicine and hospitals of education and research (240).

8.30.5 Anthroposophic medicine

In Romania diplomas for anthroposophic doctors are not recognized. Postgraduate training courses in anthroposophic medicine are provided at private teaching centers (106). “The national associations of anthroposophic doctors require their members to complete significant numbers of hours of CME in anthroposophic medicine”(106).

8.30.6 Ayurveda

Ayurveda is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007 (238).

There is a course that provides accredited qualifications in Ayurveda organized by the NATL Center for Training in Health care. Only MD’s, dentists, nutritionists can participate (237).

8.30.7 Chiropractic

Chiropractic is legally recognized as a CAM therapy in the group “manual therapies” in the law on CAM 118/2007 (238).

Only medical doctors, dentists and pharmacists with approved additional qualifications are allowed to practise chiropractic in Romania (239). The therapists allowed to practise specialized kinetic therapies are called kinetherapists in Romania (see other treatments)(237).

8.30.8 Herbal medicine/Phytotherapy

Herbal therapy is legally recognized as a CAM therapy in the group “herbal practice” in the law on CAM 118/2007 (238).

Only medical doctors, dentists and pharmacists with approved additional qualification, minimum a one year course with a diploma of competences, are allowed to practise phytotherapy in Romania (239). A specialized committee for herbal therapy regulates the profession (239) and there is an association of MD phytotherapists. ANATECOR (national association for CAM therapies) organizes courses of herbal therapies for practitioners, and the courses are approved by the Ministry of Labour (237).

In medical schools or faculties of pharmacy students can take optional courses in phytotherapy (29).

8.30.9 Homeopathy

Homeopathy is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007 (238).

Homeopathy has historically from 1981 and 1995 been recognized by law as a distinct therapeutic system in Romania. Practise has been limited to medical doctors with specific homeopathic training (106).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise homeopathy in Romania (239). A specialized committee for homeopathy regulates the profession (239) and, both by law and by the medical association, homeopathy is recognized as a medical specialty (106, 239). Diplomas of homeopathic doctors are approved by the government according to law and regulations (106, 239).

In medical schools or faculties of pharmacy students can take optional courses in homeopathy (29). Postgraduate training courses in homeopathy for doctors are provided at

universities and homeopathy is an official part of the Continuous Education Programme for doctors (106, 239). Homeopathic doctors' associations require a number of obligatory CME for their members (106).

8.30.10 Massage

Massage is legally recognized as a CAM therapy in the group "manual therapies" in the law on CAM 118/2007 (238).

Massage courses are offered by training providers authorised by CNFPA – Consiliul National de Formare Profesionala a Adultilor. Participants to the courses are awarded with a Certificate, recognized by the Ministry of Labour, Family and Social Protection and Ministry of Education, Youth and Sports. The Certificate will be accompanied by a transcript explaining the professional competencies acquired (237).

Certificates awarded for the courses enjoy professional recognition, according to law (OUG 129/2000 republished) and can be registered in the Employment Record for the relevant professional occupation, based on the Classification of Occupations in Romania (COR)(241).

Further qualifications can be obtained, as detailed on the website of the Association of Professional Masseurs, www.maseuri.ro/useful/certified.php (237).

8.30.11 Naprapathy

We have not found legislation on naprapathy in Romania.

8.30.12 Naturopathy

Naturopathy is legally recognized as a CAM therapy in the group "alternative therapies" in the law on CAM 118/2007 (238).

8.30.13 Neural therapy

We have not found legislation on neural therapy in Romania.

8.30.14 Osteopathy

Osteopathy is legally recognized as a CAM therapy in the group "manual therapies" in the law on CAM 118/2007 (238).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise osteopathy in Romania (239).

8.30.15 Traditional Chinese Medicine (TCM)

Chinese medicine is legally recognized as a CAM therapy in the group "alternative therapies" in the law on CAM 118/2007 (238).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise TCM in Romania (239).

8.30.16 Other treatments (mentioned if found in legislation)

Physiotherapy/Kinetotherapy (physiotherapy/chiropractic) is a regulated profession in Romania with the title “**Kinetoteraput**”. The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practice (242). Kinetotherapists have a higher education, usually 3 or 4 years. The law regulating kinetotherapy was issued in December 2009. The profession is regulated by the National Order of Kinetotherapists. <http://kinetoprofesional.blogspot.com/2009/03/proiect-lege-al-ordinului.html> (237). Romania has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Romania is the Romanian Federation for Physical Therapy (FRAK)(242).

8.31 Serbia

The Republic of Serbia (hereinafter Serbia) applied for European Union (EU) membership 22 December 2009 and is listed as a potential candidate country to EU (11). Serbia is connected to the FP7 research programme through a memorandum of understanding and as such included in the CAMbrella survey of CAM legislation in Europe. Serbia became a member state of the Council of Europe on 3 April 2003 (12).

8.31.1 The legal and regulatory status of CAM and CAM practices

The health legislation in Serbia is in transition towards mainstream European healthcare regulation and European standards (243). Different health strategy documents are issued for the period from 2002-2015. The perception of health and illness has moved towards lifestyle and health risk factors and consequently national health problems are addressed with preventive healthcare programs (243).

Complementary and alternative medicine in Serbia has been legally regulated since 2005. The new Law on Civil Health Protection (Healthcare Law) includes three articles dealing with alternative medicine (244). A CAM bylaw to the Healthcare law was approved by the Minister of Health in December 2007. ("Pravilnik o blizim uslovima, nacinu I postupku obavljanja metoda I postupaka tradicionalne medicine")(245).

The bylaw lists the following CAM methods as suitable for practise in Serbia:

- A. **Methods of treatment:** Ayurveda, Chinese traditional medicine, Homeopathy, Phytotherapy, Bioresonance therapy, Chiropractic, Macrobiotics, Traditional local medicine.
- B. **Methods of health promotion:** Apitherapy, Aromatherapy, Chi Gong, Spiritual medicine, Energy medicine, Yoga, Tai chi chuan, others.

According to the bylaw, CAM may be **practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and medical technicians (like physiotherapists)**(246). CAM is recognized by the national medical association as an additional qualification for medical doctors (247). Postgraduate training courses in CAM therapies are offered at private teaching centers (247).

For all health workers and all CAM treatments the regulation is the same. Officially **all health workers are allowed to practise CAM after relevant education**. There are variations regarding education in various methods, and efforts are introduced to stimulate and support the improvement of the education (246).

The Commission for Traditional medicine within the Ministry of health is dealing with various matters covered by the bylaw. The main task of the commission so far has been to refer to

the Minister of health which institutions and which practitioners that are eligible for obtaining work permits. The Minister of Health issues permits (246).

Diplomas are issued by both relevant “sections” of the Serbian medical association (there are e.g. section of acupuncture and section of homeopathy) and by associations organized by (mostly) health workers interested in a relevant CAM method. The local medical association is not involved in recognition of diplomas (246).

8.31.2 The governmental supervision of CAM Practices

CAM practice is supervised by the Traditional Medicine Committee of the Serbian Ministry of Health (34).

The Minister shall issue “Regulation on detailed conditions for issuing, renewal and revocation of licences of health professionals” to Members of Commerce. The "Official Gazette of the Republic of Serbia (RS)", no. 119/2007 on the basis of Article 190 Paragraph 8. Law on Health Care ("Official Gazette of RS", No. 107/05), (16) gives details.

8.31.3 The reimbursement status of CAM practices and medicinal products

CAM is not a part of the existing health insurance scheme. It is practised by private practitioners and in some health care institutions but patients have to pay for the treatment (246, 248).

The regulation of CAM products is a difficult issue which still has to be resolved (246). Medicinal products are recognized through the Medicines and Medical Devices Agency of Serbia (34).

8.31.4 Acupuncture

The CAM bylaw lists acupuncture as a method of treatment suitable for practise in Serbia (245). According to the bylaw, acupuncture can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists (246). All regulated practitioners are allowed to practise after relevant CAM education. Today only medical doctors are practising acupuncture (246).

The Section of acupuncture of Serbian Physicians’ Association organizes acupuncture education for medical doctors (246).

8.31.5 Anthroposophic medicine

No specific regulation found on anthroposophic medicine. Regulated health workers are allowed to practise CAM after relevant education.

8.31.6 Ayurveda

The CAM bylaw lists Ayurvedic medicine as a method of treatment suitable for practise in Serbia (245). According to the bylaw, Ayurveda may be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists. All regulated practitioners are allowed to practise after relevant CAM education (246).

8.31.7 Chiropractic

The CAM bylaw lists chiropractic as a method of treatment suitable for practise in Serbia (245). According to the bylaw, chiropractic can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists. All regulated practitioners are allowed to practise after relevant CAM education (246).

8.31.8 Herbal medicine/Phytotherapy

The CAM bylaw lists phytotherapy as a method of treatment suitable for practise in Serbia (245). According to the bylaw, phytotherapy can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists. All regulated practitioners are allowed to practise after relevant CAM education (246).

8.31.9 Homeopathy

The CAM bylaw lists homeopathy as a method of treatment suitable for practise in Serbia (245). According to the bylaw, homeopathy can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists (246).

All regulated practitioners are allowed to practise after relevant CAM education. The Section of homeopathy of the Serbian physicians' association provides homeopathy education for medical doctors. The Association of Classical Homeopathy provides homeopathy education for regulated health workers and others (246).

8.31.10 Massage

No specific regulation has been found on massage.

8.31.11 Naprapathy

No specific regulation has been found on naprapathy.

8.31.12 Naturopathy

No specific regulation has been found on naturopathy.

8.31.13 Neural therapy

No specific regulation has been found on neural therapy.

8.31.14 Osteopathy

No specific regulation has been found on osteopathy.

8.31.15 Traditional Chinese Medicine (TCM)

The CAM bylaw lists Traditional Chinese Medicine (TCM) as a method of treatment suitable for practise in Serbia (245). According to the bylaw, TCM can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists. All regulated practitioners are allowed to practise after relevant CAM education (246).

8.31.16 Other treatments (mentioned if found in legislation)

The CAM bylaw lists Bioresonance therapy, Macrobiotics and Traditional local medicine as methods of treatment suitable for practise in Serbia (245). The bylaw lists the following methods of health promotion suitable for practise in Serbia: Apitherapy, Aromatherapy, Chi Gong, Spiritual medicine, Energy medicine, Yoga, Tai chi chuan, Others (245). According to the bylaw, CAM can be practised only by health workers, i.e. physicians, stomatologists, pharmacists, nurses and health/medical technicians like physiotherapists (246).

Physiotherapy is a **regulated profession** called physiotherapist (физиотерапевт). It is managed by the legal department of the Chamber of medical nurses and medical technicians of Serbia; however, a medical technician is a broader term including also other orientations. Educationally it is more than required for a nursing degree (two years of education more) but less than the university degree. It is mostly practised under the guidance and supervision of physicians (specialists of physiatry)(246). The Serbian Society of Physiotherapists was established in 2001, and they founded the Society of Occupational Therapists of Serbia.

8.32 Slovakia

The Slovak Republic became an independent state in January 1993 after Czechoslovakia split into its two constituent parts. Slovakia joined the European Union in 2004 (11). Slovakia became a member of the Council of Europe on 30 June 1993 (12).

8.32.1 The legal and regulatory status of CAM and CAM practices

The term Complementary and Alternative medicine (CAM) or similar terminology is not found in health legislation in Slovakia. A few regulations concern or influence CAM treatments and CAM practitioners.

Two main acts regulate health care and health care providers; **Act No. 576/2004 Coll.** on healthcare, health care-related services and on the amendment and supplementing of certain acts (249), and **Act No. 578/2004 Coll.** on health care providers, health workers and professional organizations in the health service, and amending and supplementing certain acts, as amended by later regulations (250). The regulated health professions (medical workers) of interest are **doctors, nurses, midwives, physiotherapists, public health workers, medical assistants and masseurs** (250).

According to **Act 576/2004 Coll §2** (249) **“healthcare** is a set of professional activities **performed by medical workers**, *“including provision of medicaments, medical aids and dietetic foodstuffs in order to prolong life of a natural person (hereinafter “person”), improve the quality of his/her life and ensure the healthy development of future generations; healthcare includes prevention, dispensation, diagnostics, treatment, bio-medical research, nursing care and midwifery”*. This act **does not express that healthcare should be provided exclusively by medical workers**. Act 576/2004 §50 article III(249) **regulates and recognizes natural springs and natural healing springs including declarations of spa towns and natural treatment spas**.

The Ethical code- attachment No 4 of the Act No.578/2004 Coll. regulates that “the health worker must not support the activities of non-health workers pursuing an activity which can be performed only by medical staff”(251).

It is unclear how legislation on healthcare and health providers influence CAM treatment practised by non-medical workers. Since practising CAM treatments is not forbidden by law it may be practised by anybody according to the Slovak Constitution. On the other hand, if you do so and harm the individual you can be punished according to the Penal Code- Act No.300/2005 Coll, §162 *“Damage to health”*(251). Act No 348/2008 Coll. Trades Licensing Act may effect professional (for profit) CAM practice (251).

According to **the Act No. 578/2004**, and recognized by The Ministry of Education of the Slovak Republic, **the medical chambers** (associations) manage qualified health personnel, **licences and registration** (252). Of relevance are **the Slovak Chamber of Nurses and Midwives** (Slovenská komora sestier a pôrodných asistentiek) and **the Slovak Medical Chamber** for physicians (Slovenská lekárska komora). According to **Article 50 of Act No. 578/2004** membership of the Slovak Medical Chamber is voluntary (250).

Slovakia has harmonized national legislation to the European Union Directives and Regulations since they became an EU member state in 2004. Examples of acts are (252):

- Gov.regulation 212/2004 Coll of 24 March 2004 Coll on the competence of health professionals.
- Gov.regulation 213/2004 Coll of 24 March 2004 Coll on continuing education of health professionals.
- Ordinance of Ministry of Health 366/2005 of 24 June 2005 Coll on the criteria and the evaluation of continuing education of health professionals.
- Act No. 576/2004 Coll of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain acts.
- Act No 577/2004 Coll of 21 October 2004 on the scope of healthcare covered by public health insurance and on the reimbursement of healthcare-related services, as amended by later regulations.
- Act No 578/2004 Coll. of 21 October 2004 on healthcare providers, health workers and professional organizations in the health service, and amending and supplementing certain laws, as amended by later regulations.

A list of changes in national acts is given in the declaration by the Slovak Republic pursuant to Article 5 of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (253).

8.32.2 The governmental supervision of CAM Practices

Since 1 November, 2004, the provision of health care and public health care insurance is supervised by the Health Care Surveillance Authority (Úrad pre dohľad nad zdravotnou starostlivosťou)(254). Their work is based on Act. No 581/2004 Coll. on health insurance companies and healthcare supervision, and amending and supplementing certain acts as amended (255). The authority applies only to regulated health care personnel, consequently only CAM treatment provided by regulated health care personnel will be subject to supervision.

8.32.3 The reimbursement status of CAM practices and medicinal products

Since 1 January, 1993, the Health Insurance Fund (part of the National Insurance Agency) has ensured compulsory health insurance. Since 1 January, 1995 health insurance companies have executed the collection of health insurance contributions and reimbursement of health care expenditures. CAM is not directly reimbursed.

Act No.577/2004 Coll. on the scope of healthcare covered by public health insurance and on the reimbursement of healthcare-related services, as amended by later regulations, states what treatment is covered by the national health insurance (252, 253, 256).

Acupuncture is excluded from public health insurance system by legislation. Government regulation No 777/2004 Coll. attachment No.2, part I, establishes a list of diseases for which medical services are partially reimbursed or not reimbursed by public health insurance.

On 13 September 2011, the members of the National Council of the Slovak Republic adopted the bill on the scope and conditions of reimbursement of drugs, medical devices and dietary foods covered by public health insurance and on the changes and amendments to certain laws, replacing the existing law on reimbursement of drugs, medical devices and dietary foods – Act No. 577/2004 Coll. At the same time they approved the new act on drugs and medical devices, replacing the Act No.140/1998 Coll.

The above Insurance laws include direct provision for medical treatment in hospitals, special health institutions, specialized facilities for children and **spa treatment** (ústavná starostlivosť v nemocniciach, odborných liečebných ústavoch a kúpeľná starostivosť). Public (state or regional), non-profit and private health care institutions are contracted by the health insurance agencies (information: Eurostat section S1111211 NMT)(257).

8.32.4 Acupuncture

Acupuncture in Slovakia is influenced by and included in the following regulations (251):

- The Government regulation 513/2011 Coll. on the use of professional titles and corresponding abbreviations are bound to the competence to perform medical profession.
- The Government regulation 296/2010 Coll. on the competence to perform a medical profession, on methods of training of health workers, on the system of training courses, and on the system of certified work activities.
- The Government regulation 743/2004 Coll. on further education of health professionals, on the system specialized training courses, and on the system of certified work activities.

8.32.5 Anthroposophic medicine

No specific legislation has been found on anthroposophic medicine.

8.32.6 Ayurveda

No specific legislation has been found on ayurvedic medicine.

8.32.7 Chiropractic

Chiropractic in Slovakia is legal pursuant to general law. Among others are Act. No. 477/2003 Coll, on recognition of professional qualifications (classification “any other medical worker”), and supplementing Act of the National Council of the Slovak Republic. 145/1995 Z.z. on Administrative Fees as amended.

8.32.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy except for medicinal products.

8.32.9 Homeopathy

There is no statutory regulation of homeopathy in Slovakia (28, 106). Obligatory Continuing Medical Education (CME) is required for the members of the national homeopathic doctors' association (106).

Practising homeopathy is not forbidden by law and therefore according to the Slovak Constitution it can be practised by anybody. On the other hand, when you do so and harm an individual you can be punished according to the Penal Code - Act No. 300/2005 Coll., §162 Damage to health.

8.32.10 Massage

Masseur is a regulated health profession in Slovakia (250).

Massage is registered in the EU regulated professions database with two professions:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Masér (kondičné, rekondične, regeneračné a športové masáže)**” (**Self-employed masseur (reconditioning and regenerating and sport massages) (EN)**) recognized under Directive 2005/36/EC (5), ID 5972. General system of recognition- Level to be checked. Qualification level: undefined (7).

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title “**Masér - zdravotnícky pracovník v kategórii asistent**” (**Masseur - medical worker in the category assistant (EN)**) recognized under Directive 2005/36/EC (5), ID 5901. General system of recognition- Level to be checked. Qualification level: undefined (7).

8.32.11 Naprapathy

No specific regulation has been found on naprapathy.

8.32.12 Naturopathy

No specific regulation has been found on naturopathy.

8.32.13 Neural therapy

No specific regulation has been found on neural therapy.

8.32.14 Osteopathy

No specific regulation has been found on osteopathy.

8.32.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on naprapathy.

8.32.16 Other treatments (mentioned if found in legislation)

Physiotherapist is a regulated profession in Slovakia (258).

Physiotherapy is registered in the EU regulated professions database with 2 professions:

Physiotherapy is a directly related regulated profession with title “**Diplomovaný fyzioterapeut - zdravotnícky pracovník v kategórii asistent**” (**Certified physiotherapist - medical worker in the category assistant (EN)**) recognized under Directive 2005/36/EC (5), ID 5899. System of recognition and application to be checked. All regions. Qualification level: Undefined (7).

Physiotherapy is a directly related regulated profession with title “**Fyzioterapia - zdravotnícky pracovník v kategórii asistent (Physiotherapy - medical worker in the category assistant (EN))**” recognized under Directive 2005/36/EC (5), ID 5624. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.33 Slovenia

Slovenia became an independent state in 1991 following the dissolution of the Republic of Yugoslavia (11) and became a member state of the European Union in 2004 (11). Slovenia acceded the Council of Europe on May 14, 1993 (12).

8.33.1 The legal and regulatory status of CAM and CAM practices

Slovenia passed the Complementary and Alternative Medicine Act (**Official Gazette of the Republic of Slovenia, No. 94/2007; Act Zakon o zdravilstvu (ZZdrav)**) in October 2007 (259). CAM treatments included (§4) are **Traditional Chinese medicine (TCM), Ayurveda (traditional Indian medicine), homeopathy and other CAM systems like “methods of interaction between mind and body”, “biological methods”, “manipulative and body-based methods”, “energy methods”** (259). The Chamber of CAM should be a legal body with the aim to manage CAM interests, registers and in addition control CAM systems, CAM methods and practitioners (§5, §23, §24)(259). The CAM Chamber was not properly established, and is now closed down (260). The CAM act enables practitioners of CAM to be registered if they have at least a secondary education in the domain of healthcare or secondary education and a knowledge test in healthcare, plus a valid licence (details in §39). Article 35 and 36 give the criteria for CAM practitioner licences (259).

However, **homeopathy, chiropractic and osteopathy** can only be legally practised by those who have a **diploma from a medical faculty**, knowledge of homeopathy, chiropractic or osteopathy and a valid licence. Those **MDs** who apply for such a licence are also obliged not to ‘discourage anyone from the use of biomedicine’ (Uradni list, paragraph 15, line 2, p. p. 12646 / No. 94 / 16. 10. 2007)(259, 260).

According to §9 the CAM chamber sets criteria for CAM practices, CAM companies, technical and sanitary requirements of the treatment premises and professional titles (259).

The CAM act includes regulations for practitioners insurance, advertisement of services and patient information(259). In accordance with the Act provisions, the Chamber of CAM has the authority of licensing professionals for a period of seven years (28).

The consequences of closing down the CAM chamber is that the CAM act is not yet fully implemented (28, 260).

In June 2008 the Medical Chamber of Slovenia introduced an article in the Medical Doctors Service Act (Official Gazette of the Republic of Slovenia, No. 58/2008) to strictly prohibit medical doctors from practising **homeopathy** (28). As we understand it is the intention of the Slovene Medical Chamber to take licence to practise away from those who practise homeopathy (260, 261).

8.33.2 The governmental supervision of CAM Practices

According to the CAM act (259) the CAM chamber shall pass a code of ethics for the CAM profession, perform monitoring and evaluations of CAM practices , including checking CAM practitioners' conduct by carrying out professional supervision, as well as take measures in connection with code violations. Article 42 of the CAM act gives specifications for technical supervision over CAM practitioners' remedies and equipment (259).

Legal entities and individuals already practising CAM shall bring their operations into compliance with article 9 of the CAM act within 2 years of the establishment of the chamber (259).

8.33.3 The reimbursement status of CAM practices and medicinal products

No CAM treatments are reimbursed in Slovenia (260).

8.33.4 Acupuncture

Acupuncture is included in the Traditional Chinese Medicine (TCM) CAM treatment system (§4) in the CAM act (259). **Medical doctors** with a licence can practise acupuncture (28).

8.33.5 Anthroposophic medicine

We found no direct regulation of anthroposophic medicine. Probably this treatment may fit into some of the "other CAM systems" mentioned in the CAM act (259).

8.33.6 Ayurveda

Ayurveda is listed in the CAM act §4 as a CAM system that may be used when carrying out CAM practices (259). The CAM act enables practitioners of Ayurvedic medicine to be registered if they have at least a secondary education in the domain of healthcare or secondary education and a knowledge test in healthcare, plus a valid licence (details in §36 and §39)(259).

8.33.7 Chiropractic

Chiropractic is listed within "other CAM systems", a method defined within "manipulative and body-based methods"(§4)(259). Chiropractic shall only be practised by those who have a diploma from a medical faculty, knowledge of chiropractic and a valid licence (259).

8.33.8 Herbal medicine/Phytotherapy

We found no direct regulation on herbal medicine/phytotherapy other than the common EU regulation of medicinal products. However this treatment may well fit into some of the CAM treatments included in the CAM act, like Traditional Chinese medicine (TCM), Ayurveda, homeopathy and other CAM systems (259).

8.33.9 Homeopathy

Homeopathy is listed as a CAM system in the CAM act(§4)(259). Homeopathy shall only be practised by those who have a diploma from a medical faculty, knowledge of homeopathy and a valid licence (259).

In June 2008 the Medical Chamber of Slovenia introduced an article in the Medical Doctors Service Act (Official Gazette of the Republic of Slovenia, No. 58/2008) to strictly prohibit medical doctors from practising homeopathy (28). As we understand it is the intention of the Slovene Medical Chamber to take the licence to practise away from those who practise homeopathy (260, 261). If implemented, the Medical Chamber may never issue a first licence or may withdraw the medical doctor's licence either temporarily or permanently and she/he will be struck off from the Register of medical doctors (28).

8.33.10 Massage

Massage is included in the CAM act(§4) as "other CAM systems" (259). We found one professional massage title registered in the EU regulated professions register.

Massage is registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title "**Maser v zdravstveni dejavnosti** " (Masseur in health sector (EN)) recognized under Directive 2005/36/EC (5), ID 6592. General system of recognition – primary application. All regions. Qualification level: SEC - Certificate attesting the completion of a secondary course, Art. 11 b (7).

8.33.11 Naprapathy

We found no direct regulation of naprapathy. Probably this treatment may fit into some of the "other CAM systems" mentioned in the CAM act (259).

8.33.12 Naturopathy

We found no direct regulation of naturopathy. Probably this treatment may fit into some of the "other CAM systems" mentioned in the CAM act (259).

8.33.13 Neural therapy

We found no direct regulation of neural therapy. Probably this treatment may fit into some of the "other CAM systems" mentioned in the CAM act (259).

8.33.14 Osteopathy

Osteopathy is listed within "other CAM systems", a method defined within "manipulative and body-based methods"(§4)(259). Osteopathy shall only be practised by those who have a diploma from a medical faculty, knowledge of osteopathy and a valid licence (259).

8.33.15 Traditional Chinese Medicine (TCM)

Traditional Chinese Medicine (TCM) is listed in the CAM act §4 as a CAM system that may be used when carrying out CAM practices (259). The CAM act enables practitioners of TCM to be registered if they have at least a secondary education in the domain of healthcare or a

secondary education and a knowledge test in healthcare, plus a valid licence (details in §39)(259).

8.33.16 Other treatments (mentioned if found in legislation)

Physiotherapy in Slovenia is a regulated profession with the title "**diplomirani fizioterapevt**". The title and the professional activity are protected by the state, and the rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise. The Slovenian Association of Physiotherapists has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Slovenia is the Ministry of Health (262).

Physiotherapy is registered in the EU regulated professions database as follows:

Physiotherapy is a directly related regulated profession with title "**Diplomirani fizioterapevt**" recognized under Directive 2005/36/EC (5), ID 6072. General system of recognition – primary application. All regions. Qualification level: PS3 – Diploma of post-secondary level (3-4 years), Art.11 d (7).

8.34 Spain

Spain is a member of the European Union since 1986 (11) and a member of the Council of Europe since 1977 (12).

8.34.1 The legal and regulatory status of CAM and CAM practices

Health care is provided by the Regional Governments in Spain, and national health regulations are consequently implemented by the regional governments (263).

CAM in general is not regulated in Spain (43, 106). The Congress adopted 29 September 2009 a proposal forwarded by the Committee on Health and Consumer Affairs of the Spanish Parliament on a new act recognizing some CAM treatments (acupuncture, homeopathy and natural medicine) as a medical act (28, 263). The law was planned to come into force in 2011 (263). CAM practices provided by medical doctors are regulated within the authorization system for health care services and centers (263).

WHO reported in 2005 that “Spain does not have a national policy, laws, regulations, a national programme, a national office ... nor are there currently any plans to establish these”(59). According to the Royal Decree 3166/1966 only authorized health care professionals are allowed to perform medical acts. Licensed paramedics are allowed to perform medical acts only under the supervision of an allopathic physician (43).

The Royal Decree (RD) 1277/2003 (10 October) regulates the health care services and centers (public or private)(264). Within the integrated care units in healthcare facilities, the so called U.101 units “Terapias no convencionales”(unconventional therapies) may be found (263). The U.101 unit is a “health care unit where a **medical doctor (MD)** is responsible for making treatment through natural medicine, homeopathic medication or using techniques for peripheral stimulation with needles, or any other treatments that demonstrate efficacy and safety”(263). It needs no specific requirement other than those given in RD 1277/2003 (263). The regional governments authorize the installation, operation, modification and closure when required of health care services, facilities and units located in its territory (263).

Consequently, the centers for non-conventional therapies are considered as **health centers (public or private)** if the person performing the **acupuncture, homeopathy or herbal medicine** is a **MD** and are subject to prior approval by the regional regulations (263).

Most of the centers that provide CAM in Spain are not health centers according to the law, but “**non-sanitary centers**” or “**parasaniatary centers**” where there is no need of a MD providing therapies (263).

There is no specific regulation regarding the training and qualifications of CAM providers in Spain. To conduct their business activity in these areas, undergraduate providers (non-MDs) are classified in group 841 of activities related to **paramedical professionals (naturopaths, acupuncturist and other paramedical professionals)**, professional activity described in RD 1175/1990, (28 September), "Agrupación 84.- Profesionales relacionados con Actividades Parasitarias (PARAMEDIC activities) GRUPO 841. NATUROPATAS, ACUPUNTORES Y OTROS PROFESIONALES (263, 265). The Royal Decree 127/1984 regarding medical specialties does not include CAM (43).

8.34.2 The governmental supervision of CAM Practices

The Council of Medical Colleges has been delegated the authority of supervision of physicians (43). The state authorities are tolerant to CAM as a counseling service not intruding on the health care service. According to the Penal Code intrusions made by non-medical providers are illegal (43).

8.34.3 The reimbursement status of CAM practices and medicinal products

CAM treatment is not reimbursed in the public insurance system. Under Article 94 of Law 26/1990 of 20 December 1990 there is no justification for homeopathic products to be funded through the State insurance system, INSALUD (44). Some insurance companies provide coverage for CAM (43, 44). Acupuncture treatment is covered by the national health insurance system in one region (106).

8.34.4 Acupuncture

The Congress adopted 29 September 2009 a proposal forwarded by the Committee on Health and Consumer Affairs of the Spanish Parliament on a new act recognizing acupuncture as a medical act (28, 263). The law is planned to come into force in 2011 (263). Acupuncture treatment as a medical act can only be legally practised by medical doctors (263).

Acupuncture is regulated by the government to be **provided only by medical doctors (MDs)**(106). Acupuncture treatment may be provided at **health centers (public or private)** if the person performing the acupuncture is a **MD** and the center is approved by the regional regulations as appropriate (263). Statutory regulation and issuing of diplomas of medical acupuncturists is approved by the Medical Association Council (106). Undergraduate and postgraduate acupuncture training is offered at universities (106).

8.34.5 Anthroposophic medicine

Courses in anthroposophic medicine are offered at universities and medical schools as an optional part of the medical undergraduate curriculum. Postgraduate medical training courses in anthroposophic medicine are provided at private teaching centers (106).

The national association of anthroposophic doctors issues diplomas, recognized by the national medical association council (106).

8.34.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.34.7 Chiropractic

No specific regulation has been found on chiropractic.

8.34.8 Herbal medicine/Phytotherapy

The Congress adopted 29 September 2009 a proposal forwarded by the Committee on Health and Consumer Affairs of the Spanish Parliament on a new act recognizing natural medicine as a medical act (28, 263). The law was planned to come into force in 2011 (263). Nature medicine as a medical act can only be legally practised by medical doctors (263).

8.34.9 Homeopathy

The Congress adopted 29 September 2009 a proposal forwarded by the Committee on Health and Consumer Affairs of the Spanish Parliament on a new act recognizing homeopathy as a medical act (28, 263). The law was planned to come into force in 2011 (263). Homeopathy as a medical act can only be legally practised by medical doctors (28).

Homeopathy is recognized as a medical act by the Committee on Health and Consumer Affairs of the Spanish Parliament, Act dated 29 September 2009 (28). The act urges the governments to “take the measures necessary for the exercise of homeopathy exclusively by graduates in medicine and surgery”(28). The Spanish Medical Council (Consejo General de Colegios Oficiales de Médicos) passed 17 December 2009 a resolution that recognized the practice of homeopathy as a medical act (28).

The Spanish Medical Association Council supports homeopathy, provided it is practised by physicians. Homeopathy training is offered as postgraduate medical studies at the university level (60). Postgraduate homeopathy training for doctors is provided at universities in Spain (106). Homeopathy treatment is provided in two hospitals in Spain (106).

8.34.10 Massage

No specific regulation has been found on massage.

8.34.11 Naprapathy

No specific regulation has been found on naprapathy.

8.34.12 Naturopathy

No specific regulation has been found on naturopathy.

8.34.13 Neural therapy

No specific regulation has been found on neural therapy.

8.34.14 Osteopathy

No specific regulation has been found on osteopathy.

8.34.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.34.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Spain with the title "**Fisioterapeuta**". The title and the professional activity is protected by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise. Spain has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Spain is "Ministerio de Educacion, Cultura y Deporte" (266).

Physiotherapy is registered in the EU regulated professions database as follows: **Physiotherapist** is a directly related regulated profession with title "**Fisioterapeuta**" recognized under Directive 2005/36/EC (5), ID 460. General system of recognition- primary application. All regions. Qualification level: PS3- Diploma of post-secondary level (3-4 years), Art.11d (7).

8.35 Sweden

Sweden has been a member of the European Union since 1995 (11), and a founding member of the Council of Europe since 5 May 1949 (12).

8.35.1 The legal and regulatory status of CAM and CAM practices

The health and medical services in Sweden are regulated by two main acts; Hälso-och sjukvårdslagen (1982:763) (The Health and Medical Service Act), that has been amended to Svensk förfatningssamling (SFS) 2010:1314 (267) and Patientsäkerhetslagen (2010:659) (The Patient Safety Act), as of January 1, 2011 (268). These acts define which professionals are to be considered health professionals and what responsibilities they have.

The Patient Safety Act (268) defines twenty-one professional titles as registered health care professionals, including **Pharmacists, Occupational therapists, Dietitians, Chiropractors, Physicians, Naprapaths, Nurses, Physiotherapists, Psychologists**. In general, CAM professionals are not included in the definition of health professionals according to this act.

The Patient Safety Act, chapter 6, §1 defines that registered health care professionals shall practise according to “science and tested experience” (268). In practice, this means that registered health care professionals are not allowed to use or recommend any CAM that is not evidence-based. As Knox et al. (269) write “there is a small exception to this rule: registered health care providers may be permitted to practise CAM on the rare occasion when a patient request for it, no alternative conventional treatment options exist, and the treatment is given in conjunction with conventional care”. Also, the CAM treatment must be documented as safe (269). However, with the new Patient Safety Act (268) these conditions may have shifted towards a stronger focus on patient safety and patient preference. In a recent court case, the highest court acquitted a medical doctor who had prescribed homeopathic remedies to his patients. The basis for this decision were:

- 1) The homeopathic remedies that were described had not been a threat to the patients’ safety.
- 2) Patients themselves had asked for homeopathic treatment.
- 3) Conventional treatment was given in parallel to the homeopathic remedies (270, 271).

This court case may be seen as establishing a precedent for other cases involving the prescription or practice of CAM services by registered health care professionals.

CAM professionals are not governed by any explicit law or regulation other than their own professional rules of conduct. However, the Patient Safety Act, Chapter 5 (268), provides limitations for individuals other than registered health professionals (i.e. CAM professionals)

to offer any services to patients for prevention, cure or symptom relief in association with the following conditions:

- Contagious diseases obliged to be reported.
- Cancer, other malignant tumors, diabetes, epilepsy or illness symptoms in association with pregnancy and delivery.
- Examination or treatment of patients undergoing anaesthesia or hypnosis.
- Treatment using radiology.
- Without personal examination, give written advice or recommendations for treatment.
- Examination or treatment of children under the age of eight.
- Adjust contact lenses.

WHO reports in 2005 that “Sweden does not have national policy, laws, regulations or a national programme on TM/CAM, and there are no plans to establish them” (59).

With the exception of herbal medicinal products, Naprapathy, Chiropractic and Anthroposophic care at the Vidar Clinic hospital, a hospital with special research and development status- no CAM practice is explicitly mentioned in the Swedish health care laws.

8.35.2 The governmental supervision of CAM Practices

The Public Health Care Services (including registered health care professionals) are supervised by “Socialstyrelsen” according to The Patient Safety Act, chapter 7, §1 (268).

8.35.3 The reimbursement status of CAM practices and medicinal products

CAM treatments provided by non-registered health care professional are not covered by the official Swedish health insurance system. Herbal products registered as Herbal medicinal products except traditional herbal medicinal products are covered by the official reimbursement system like other medicinal products.

Acupuncture is covered by national health insurance when practised by registered health care professionals, primarily for the treatment of pain and nausea (106). When acupuncture is practised by non-registered health care professionals it is not covered by the national health insurance.

Anthroposophic care given under the supervision of the Vidar Clinic (see description below) is covered by the national health insurance system (60, 106).

8.35.4 Acupuncture

Acupuncture is covered by national health insurance when practised by registered health care professionals, primarily for the treatment of pain and nausea (106). When acupuncture is practised by non-registered health care professionals it is not covered by the national health insurance.

8.35.5 Anthroposophic medicine

The Vidar hospital near Stockholm is an anthroposophic hospital. The hospital is also a research center for anthroposophic medicine (60). The “Vidar Clinic” hospital has a permit from the Minister of Social affairs (60) and is the only hospital with authorization to practise anthroposophic medicine in Sweden (106). Medical doctors are only allowed to practise anthroposophic medicine within the Vidar clinic authorization (106).

8.35.6 Ayurveda

No specific regulation has been found for Ayurvedic medicine.

8.35.7 Chiropractic

Chiropractors are classified as a regulated health care profession in Sweden from 1989 (106) and listed as health professionals in the Patient Safety Act, Chapter 4, §1 and §5 (268). Educational and occupational regulations can be found in the bylaw (268).

Chiropractor is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title “**Kiropractor**” recognized under Directive 2005/36/EC (5), ID 15605. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.35.8 Herbal medicine/Phytotherapy

No specific regulation has been found on Phytotherapy treatment.

8.35.9 Homeopathy

Homeopathy is allowed to be practised by non-medically qualified practitioners outside the healthcare system (28). Professionals (non-medical homeopaths) may practise on completion of 600 hours of training (60).

A high court case from 2011 must be seen as precedential for allowing the prescription or practice of CAM services by medical doctors and other registered health care professionals (272).

8.35.10 Massage

No specific regulation has been found for massage.

8.35.11 Naprapathy

Naprapaths are classified as a regulated health care profession in Sweden and listed as health personnel in the Patient Safety Act, chapter 4, §1 and §5 (268). Educational and occupational regulations can be found in the bylaw (268).

Naprapath is registered under title **chiropractor** in the EU regulated professions database: Naprapath is a directly related regulated profession with title "Naprapat" recognized under Directive 2005/36/EC (5), ID 15606. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.35.12 Naturopathy

No specific regulation has been found for naturopathy.

8.35.13 Neural therapy

No specific regulation has been found for neural therapy.

8.35.14 Osteopathy

No specific regulation has been found for osteopathy.

8.35.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found for traditional Chinese medicine (TCM).

8.35.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a regulated profession in Sweden with the title "**Registered Physical Therapist**". The title is protected by the state, but the professional activity is not. The rules of professional conduct are determined directly by the state through national legislation. The physical therapist must be state-registered and obtain a licence to practise. The Swedish physiotherapy association has established a code of ethics for physical therapists. The national authority responsible for the physiotherapy profession in Sweden is "The National Board of Health and Welfare"(273).

Physiotherapy is registered in the EU regulated professions database as follows: "**Physiotherapist**" is a directly related regulated profession with title "**Sjukgymnast**" recognized under Directive 2005/36/EC (5), ID 2492. General system of recognition- primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.36 Switzerland

Switzerland is a Federal State composed of the federal level, 26 Cantons and the municipalities (274). Switzerland is an EFTA member state since 1966 with bilateral agreements to EEA (215) and joined the Council of Europe in 1963 (12).

8.36.1 The legal and regulatory status of CAM and CAM practices

Regulation of the Swiss healthcare system is decentralized (274) and the legislative authority in the cantons is a unicameral parliament (275). In principle, each Canton has its own regulations for health practice, but there are some federal regulations (276).

Complementary medicine is included in the Federal Constitution of the Swiss Confederation Art. 118a 52 since 2009; "The Confederation and the Cantons shall within the scope of their powers ensure that consideration is given to complementary medicine" (277).

The cantons have a high degree of independence regarding licensing of the health professions, authorizations to open a medical practice or pharmacy and the structure of healthcare services (275). The regulatory power of the federal government over the health care system is increasing. The Federal Health Act became effective on 1 January 1996 (278) and from 18 April 1999 the new federal constitution confirmed the federal responsibility for the training of health-related professionals other than doctors (275).

By definition, Swiss CAM is divided in two terms: Complementary Medicine (CM) is reserved for Medical Doctors' (MD's) practices, whereas Alternative Medicine (AM) dominates non-medically trained practitioners' practices (276).

Federal law defines criteria for a medical profession. (Updated Federal Law on Medical Professions (MedBG) is expected in 2012). Regulations include MD's and non-medically trained practitioners' education, training, certification, and Continuous Medical Education (CME). For MDs, the latter is delegated to the Swiss Association of Medical Doctors („Foederatio Medicorum Helveticorum“, FMH), for CM it is delegated to the respective CM associations. Most insurance companies delegate non-medically trained practitioners' certification to a private registry of experience medicine ("Erfahrungsmedizinisches Register", EMR).

Practice establishment is regulated by the Cantons for both, MDs, and non-medical practitioners (276).

8.36.2 The governmental supervision of CAM Practices

Licensed CM practice by MDs is restricted to certified MDs with an additional and certified CM qualification, to be renewed (CME) every 3 years (106, 276).

Registered non-medical professionals' practice will be regulated in 2013. Currently, in 6 Cantons there are almost no regulations at all (free setting-of practice), whereas in other Cantons (eg. Berne), strict regulations, similar to MD practices, exist.

8.36.3 The reimbursement status of CAM practices and medicinal products

The 'Gemeinsame Einrichtung KVG' (Common Institution under the Fed. Health Insurance Act) was established by the insurers when the Federal Health Act became effective on 1 January 1996(4). In 1999 compulsory health insurance (OKP) was introduced by passing The Health Insurance Law (2).

Reimbursement MD practices

Acupuncture treatment is reimbursed (included in KVG) from 1 July 1999 (279).

Five CM disciplines, practised by certified CM physicians, were included in KVG temporarily, 1 July 1999 - 30 June 2006: **Anthroposophic Medicine, Classical Homeopathy, Herbal Medicine (Phytotherapy), Neural Therapy, and non-acupuncture TCM**. In that time period cost reimbursement of these CM disciplines was restricted to additional insurances (VVG) in a similar way as generally non-medical AM practices. Since 1 July 2011, local and segmental **Neural Therapy** is permanently included in KVG. Neural Therapy according to Huneke („Störfeldtherapie“, interference field therapy) is still restricted to additional insurances (VVG). Due to a referendum (17 May 2009) **Anthroposophic Medicine, Classical Homeopathy, Herbal Medicine (Phytotherapy) and non-acupuncture TCM**, practised by certified MDs, are again temporarily included in KVG of compulsory health insurance (OKP) in the period from 1 January 2012 up to 31 December 2017. Regulations are based on proof of efficacy as well as clinical- and cost-effectiveness (276, 279). The Physicians' association of Neural Therapy according to Huneke withdrew their attempt for temporary implementation on 4 November 2011.

Reimbursement of non-certified disciplines or practices of MDs, (partially) trained in CM or AM, are restricted to additional insurances (VVG), according to individual contracts or paid out-of-pocket (276).

Reimbursement non-medically trained professionals' practices

Cost reimbursement of most (registered) non-medical AM practices is restricted to additional insurances (VVG) according to a nation-wide registry (EMR) of disciplines and non-medical AM practitioners, and individual companies' contracts. Some insurance companies

also reimburse non-registered AM disciplines, and practices, according to individual contracts. Other non-medical AM practice is paid out-of-pocket (276).

Reimbursement medicinal products (see CAM medicinal product report)

CAM products, registered by Swiss Agency for Therapeutic Products (swissmedic) in a special list ("Spezialitäten-Liste", SL), are reimbursed by KVG, whereas others are reimbursed due to individual contracts according to VVG or out-of-pocket (276).

8.36.4 Acupuncture

Acupuncture is included in federal laws and detailed regulation is delegated to medical and non-medical associations. The medical association has recognized acupuncture as an additional medical qualification and issues diplomas of medical acupuncturists (106).

Acupuncture treatment is reimbursed and permanently covered by the health insurance act (279) (see reimbursement section).

Acupuncture is registered in the EU regulated professions database as follows:

Acupuncturist is a directly related regulated profession with title "**Akupunkteur(DE)/Acupuncteur(FR)**" recognized under Directive 2005/36/EC (5), ID 10045. System of recognition and application to be checked. Qualification level: undefined (7).

8.36.5 Anthroposophic medicine

Anthroposophic medicine is recognized by federal law as a CAM specific therapeutic system and detailed regulation and issuing of diplomas is delegated to medical and non-medical associations (106, 276).

Anthroposophic medicine is provided in some hospitals in Switzerland (106).

Anthroposophic medicine treatment is reimbursed with certain limitations (see reimbursement section). A professional chair of CAM including anthroposophic medicine exists at the University of Bern (106).

8.36.6 Ayurveda

No specific regulations have been found on ayurvedic medicine.

8.36.7 Chiropractic

Chiropractors are regulated as a conventional health profession and the Federal Law on Medical Professions (MedBG) regulates chiropractor accreditation (280).

A professional chair of chiropractic, funded by their association, exists at the University of Zürich (276).

Chiropractor is registered in the EU regulated professions database as follows:

Chiropractor is a directly related regulated profession with title "**Chiropractor(DE)/chiropracticien(FR)**" recognized under Directive 2005/36/EC (5), ID 5980. General system of

recognition- primary application. National legislation all regions: législation cantonale. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d (7).

8.36.8 Herbal medicine/Phytotherapy

Herbal medicine/Phytotherapy is included in federal laws and detailed regulation is delegated to medical and non-medical associations.

Herbal medicine/Phytotherapy treatment is reimbursed with certain limitations (see reimbursements section).

8.36.9 Homeopathy

Homeopathy is included in federal laws and detailed regulation is delegated to medical and non-medical associations. Statutory regulation has been introduced by the Swiss national medical association (106). According to ECH (28) "based on a contract between the Swiss National Medical Association FMH and the Swiss Homeopathic Medical Association SVHA/SSMH/SSMO, the FMH recognizes the qualification 'Homeopathy' - 'Fähigkeitsausweis Homöopathie' - for those medical doctors who have acquired the diploma 'physician for homeopathy SVHA'".

A professional chair of CAM including homeopathy exists at the University of Bern (106). Homeopathy treatment is reimbursed with certain limitations (see reimbursement section).

Homeopath is registered in the EU regulated professions database as follows:

"Natural health practitioner" is a directly related regulated profession with title **"Naturopathe/Homéopathe(FR)/ Naturheilpraktiker/Homöopath (DE)"** recognized under Directive 2005/36/EC (5), ID 10050. Level of recognition and application to be checked. Qualification level undefined. All regions included (7).

8.36.10 Massage

Masseur is a regulated profession in Switzerland, registered in the EU regulated professions database as follows:

Masseur/Massage therapist/Spa therapist/Masseur-Aesthetician is a directly related regulated profession with title **"Masseur médical" (Masseur (EN))** recognized under Directive 2005/36/EC (5), ID 10304. All regions. General system of recognition - level to be checked. Qualification level: undefined (7).

8.36.11 Naprapathy

No specific regulation found on naprapathy.

8.36.12 Naturopathy

Natural health practitioner is a regulated profession in Switzerland. Two different professions are registered in the EU regulated professions database as follows:

"Natural health practitioner" is a directly related regulated profession with title **"Naturopathe/Homéopathe(FR)/ Naturheilpraktiker/Homöopath (DE)"** recognized under

Directive 2005/36/EC (5), **ID 10050**. Level of recognition and application to be checked. Qualification level undefined. All regions included (7).

“**Natural health practitioner**” is a directly related regulated profession with title “**Naturopathe (de tradition Européenne)/ Traditionnelle Europäische Naturheilkunde (DE)**” recognized under Directive 2005/36/EC (5), **ID 15454**. Level of recognition and application to be checked. Qualification level undefined. All regions included (7).

A professional chair of CAM, including naturotherapy (“Naturheilkunde”) exists at the University of Zurich (276).

8.36.13 Neural therapy

Neural therapy is included in federal laws and detailed regulation is delegated to medical and non-medical associations.

Neural therapy treatment is reimbursed with certain limitations (see reimbursement section).

A professional chair of CAM including neural therapy exists at the University of Bern (276).

8.36.14 Osteopathy

In Switzerland, osteopathy is a licensed profession but is not considered as an academic program. This means that osteopathy is not offered at any state Swiss university.

“In 2007 Switzerland passed a law to regulate the practice of osteopathy, which had previously been controlled by each individual canton. Although many cantons had already fully recognized the practice of osteopathy, on 1 January 2007 the Swiss Conference of the Cantonal Ministers of Public Health published directives to the cantons on the regulation of osteopathy and set up a list of requirements to qualify for the Inter-Cantonal Osteopathy Diploma. Since 2007 these requirements have included 5 years of full-time study and a 2-year internship”. “The Swiss School of Osteopathy in Lausanne was founded in 1991, and is one of two centres training osteopaths in Switzerland. Students complete five years of full-time university training before working for two years as interns” (281).

Osteopathy is registered in the EU regulated professions database as follows:

Osteopath is a directly related regulated profession with title “**Osteopath(DE)/ Ostéopathe(FR)**” recognized under Directive 2005/36/EC (5), ID 10323. System of recognition and application level to be checked. All regions. Qualification level: undefined (7).

8.36.15 Traditional Chinese Medicine (TCM)

TCM is included in federal laws and detailed regulation is delegated to medical and non-medical associations.

TCM treatment is regulated and reimbursed with certain limitations (see reimbursement section). A professional chair of CAM including TCM/acupuncture exists at the University of Bern (276).

8.36.16 Other treatments (mentioned if found in legislation)

“Health care by gymnastics” is a Swiss regulated profession registered in the EU regulated professions database as follows:

“Health care by gymnastics” is a directly related regulated profession with title **“Gymnastique curative”** (Heilgymnastik (DE)) (recognized under Directive 2005/36/EC (5), ID 15453. System of recognition and application to be checked. Qualification level: undefined (7).

Physiotherapy is a regulated profession with the title **“Diplomierter Physiotherapeut FH (BSc)”** “The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registrated and obtain a licence to practise. Switzerland has established a code of ethics for physiotherapists”(282).

Physiotherapy is registered in the EU regulated professions database as follows: Physiotherapy is a directly related regulated profession with title **“Physiothérapeute”** recognized under Directive 2005/36/EC (5), ID 10324. System of recognition and application to be checked. All regions. Qualification level: Undefined (7).

“Alternative Care” is a regulated profession in Switzerland registered in the EU regulated professions database as follows:

“Alternative Care” is a directly related regulated professions with titles **“Thérapie respiratoire, Eurythmie curative, Shiatsu, biorésonance”** under Directive 2005/36/EC (5), ID 15458. System of recognition and application: level to be checked. All regions (7).

8.37 The Netherlands

The Netherlands was a founding member of the European Union (EU) in 1952 (11), and a founding member of the Council of Europe on 5 May 1949 (11).

8.37.1 The legal and regulatory status of CAM and CAM practices

In the Netherlands provision of alternative care is legal (283). Both medically and non-medically qualified professionals are allowed to practise CAM (106, 284). By passing amendments to the Individual Health Care Professions Act on 1.12.1997 (Beroepen in de Individuele Gezondheidszorg), practice of medicine is open to all with some limitations; some procedures may be carried out only by categories of professional practitioners authorized to do so by law (see supervision)(284).

“Professions can be regulated in two ways: by Act of Parliament (section 3 of the Individual Health Care Professions Act lays down rules governing eight) or by an Order in Council pursuant to an act (section 34 of the aforementioned legislation). Both regulations enable titles to be legally protected; the most important differences are that the government only maintains a register for the professions covered by section 3, and that the government regulates the disciplinary procedures applying to practitioners of these professions”(284).

The act introduced a system to protect the titles of a limited number of professional groups. Persons practising a regulated profession may use a professional title, protected under public law, if they are registered in the legal status register (284). They must meet a number of statutory requirements, the most important of which are of an educational nature (284). The eight health professions regulated by Section 3 of the Individual Health Care Professions Act are: **doctor, dentist, pharmacist, health care psychologist, psychotherapist, physiotherapist, midwife, nurse**. The new registration and title protection of these professions started 1 December 1997. At the same time professions not governed by law but by an Order in Council (regulations based on section 34, applying mainly to paramedical professions) will likewise enjoy title protection (284).

The criteria applicable to **a profession under section 34** are the need for public information (protected title), the need for a regulation to govern the independent carrying out of reserved procedures in practice, and the need for a legal regulation to govern training.

The declaration of professional competence and registration of persons with foreign qualifications who wish to practise their profession in the Netherlands is regulated in the Individual Health Care Professions Act (284).

In 2008 the Minister of Health, Welfare and Sport announced that he intended to investigate a further regulation and restriction of alternative treatments (283, 285).

8.37.2 The governmental supervision of CAM Practices

According to the Individual Health Care Professions Act, the performance of certain medical procedures are limited to categories of professional practitioners authorized to do so by law (284). Performance of such a procedure by an unauthorized practitioner is a criminal offence. The procedures specified are: surgical procedures, obstetric procedures, catheterizations and endoscopies, punctures and injections, general anaesthetics, procedures involving the use of radioactive substances and ionizing radiation, cardio version, defibrillation, electroconvulsive therapy, lithotripsy, artificial insemination (3).

8.37.3 The reimbursement status of CAM practices and medicinal products

A new health insurance system was introduced in 2006 (283). CAM treatments are not covered by basic health insurance, but health insurers cover alternative treatment as either additional “free” benefits or covered by complementary Voluntary Health Insurance (VHI)(283).

Acupuncture treatment, fees for consultation with an anthroposophic physician and anthroposophic medicines are partially covered by private insurance companies (106). Homeopathy treatment and homeopathic medicines are covered by private insurance companies (106). Chiropractic treatment is covered by private insurance if the chiropractor is connected with a professional body such as De Nederlandse Chiropractoren Associatie (NCA) and that he/she is registered at the Netherlands Foundation for Chiropractic (SCN)(286).

If osteopathy treatment is offered by an osteopath registered in the Nederlands Register voor Osteopathie (NRO) all health insurers reimburse all or part of osteopathic consultation under the supplementary package. Most insurers require no referral from a doctor to osteopathic treatment (287).

8.37.4 Acupuncture

Some acupuncture training is offered in the CAM courses provided in the medical undergraduate curriculum (106). The medical acupuncturists’ associations require a defined amount of Continuous Medical Education (CME)(106).

8.37.5 Anthroposophic medicine

There is no statutory regulation of anthroposophic medicine in the Netherlands, and diplomas in anthroposophic medicine are not recognized by the medical associations (106).

Anthroposophic medicine is offered in several hospitals in the Netherlands, and postgraduate training is offered by private teaching centres (106). The national association of anthroposophic doctors requires their members to complete a defined amount of CME in anthroposophic medicine (106).

8.37.6 Ayurveda

No specific regulation has been found on ayurvedic medicine.

8.37.7 Chiropractic

In the Netherlands chiropractic is a profession that falls under the heading of "alternative or complementary medicine" and to date the profession is not officially recognized and regulated by the government (286). The Foundation for Chiropractic Netherlands (SCN) is an independent institute for quality promotion and monitoring of the performance of chiropractic in the Netherlands. They work towards recognition of work requirements for chiropractic treatment under the Individual Health Care act (BIG)(286). The chiropractic discipline has been made more transparent for patients and healthcare professionals by these quality descriptions. The quality of registered chiropractors in the SCN by the Netherlands Foundation for Chiropractic is periodically checked. The re-registration period is a period of five years (286).

The "Nederlandse Chiropractoren Associatie" is a member of the European chiropractors' association (286).

8.37.8 Herbal medicine/Phytotherapy

No specific regulation has been found on herbal medicine/phytotherapy treatment.

8.37.9 Homeopathy

There is no statutory regulation of homeopathy in the Netherlands (106).

Optional courses in homeopathy are offered in the medical undergraduate curriculum at most of the universities in the Netherlands. The national association of homeopathic doctors requires their members to complete a defined amount of CME in homeopathy (106).

8.37.10 Massage

No specific regulation has been found on massage.

8.37.11 Naprapathy

No specific regulation has been found on naprapathy.

8.37.12 Naturopathy

No specific regulation has been found on naturopathy.

8.37.13 Neural therapy

No specific regulation found on neural therapy.

8.37.14 Osteopathy

“The Stichting Nederlands Register voor Osteopathie (NRO) is the executive and supervising organ for the registered rules for the profession of osteopathy in the Netherlands” (287). “The Nederlandse Vereniging voor Osteopathie (NVO) promotes the interests of the osteopath and the client in general” (287).

By specifying the professional profile and code of osteopathy, including the recognition criteria of training, the College voor Osteopathie determines the requirements for the registration in the Registry NRO (287).

In the Netherlands the following authorities for osteopathy are active: College voor Osteopathie (CvO), Stichting Nederlands Register voor Osteopathie (NRO), Nederlandse Vereniging voor Osteopathie (NVO)(287). The College voor Osteopathie (CvO) is an independent council whose responsibility is the promotion of the quality of the osteopath profession (287).

8.37.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM.

8.37.16 Other treatments (mentioned if found in legislation)

Physiotherapist is a regulated profession in the Netherlands according to section 3 in the Individual Healthcare Professions Act (284). The title “**Physical therapist Bachelor**” is protected through state legislation, but not the professional activity. The rules of professional conduct are determined by the association. The physiotherapist must be state registered and obtain a licence to practise. The association has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in The Netherlands is the "Department of Health Care" (288).

Physiotherapy is registered with three titles in the EU regulated professions database:

Physiotherapy is a directly related regulated profession with the title “**Fysiotherapeut**” recognized under Directive 2005/36/EC (5), ID 815 General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

Physiotherapy is a directly related regulated profession with the title “**Oefentherapeut-cesar**” recognized under Directive 2005/36/EC (5), ID 3167 General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

Physiotherapy is a directly related regulated profession with title “**Oefentherapeut-mensendieck**” recognized under Directive 2005/36/EC (5), ID 3211 General system of recognition- primary application. All regions. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7).

8.38 Turkey

Turkey is a candidate country for European Union (EU) membership. On 18 February 2008 the Council adopted a revised Accession Partnership with Turkey (11). The EU established a Customs Union with Turkey in 1995 (11). Turkey became member of the Council of Europe on 9 August 1949 (12).

8.38.1 The legal and regulatory status of CAM and CAM practices

There is no general legislation or regulations on Traditional, Complementary and Alternative Medicine (CAM) in Turkey (289). Physicians preserve the right to treat their patients with all approaches, including the use of CAM (289). Consequently CAM therapy is recognized in Turkey as approved directly by the Ministry of Health (MOH)(290). In 1991 and 2002 by-laws on acupuncture were approved by the MOH (290-292).

Laws and regulations on Herbal Medical Products were issued in 1985 in the “Permanent Notice concerning Shops, Spice Shops and Similar Stores”, at the same time as the Expert committee for Licensing Herbal Medicinal Products was established (59) http://www.iegm.gov.tr/Default.aspx?sayfa=gel_bit_tib_urun&lang=tr-tr. Turkey has a long cultural tradition of self-medication and common folk medicine uses herbal medicines and CAM treatments. However, among physicians the knowledge and provision of CAM treatment is low (293). In 2002 WHO reported that the regulation of the pharmaceutical and herbal medicine sector needed improvements (294).

Since Turkey is a candidate country and not a member state of the EU, no CAM professions are registered in the EU regulated professionals’ database.

In Turkey CAM training has not been mandatory in the medical curriculums, but recently some universities, medical schools and hospitals have started to offer lectures or training courses in CAM (291, 293).

8.38.2 The governmental supervision of CAM Practices

On 2 November 2011, the Ministry of Health used the term ‘CAM’ for the first time and stated that Traditional, Alternative and Complementary Medicine regulations, treatment approvals and inspection tasks belongs to the General of Health Services Directorate (295).

In the ninth development plan (2007-2013) Turkey has developed a patient-oriented health system with legal regulations set up to prevent malpractice in medicine and the regulatory

and supervisory role of the Ministry of Health (MOH) has been strengthened (296, 297). The Communication report from **The European Commission on enlargement challenges 2011-2012** concludes that Turkey has not yet completed the improvement process on health legislation and safety status of the population (298).

Due to the strong tradition of self-medication and use of herbal medicine in Turkey, health personnel (physicians) must be aware of possible harmful side-effects and possible negative drug-herb interactions (293). The Ministry of Health of Turkey, General directorate of pharmaceuticals and pharmacy, has aimed at harmonizing their new legislation on medicinal products with the EU Directives.

<http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=11>

8.38.3 The reimbursement status of CAM practices and medicinal products

CAM therapy treatment or CAM medicinal products are not covered by any insurance in Turkey (291).

Some CAM therapies are available through physiotherapy and pain clinics, but the vast majority of CAM provision in Turkey is within the private sector. None of the private health insurance companies cover CAM treatments in their policies. Even if acupuncture is regulated it is not covered by the private insurance companies in Turkey.

8.38.4 Acupuncture

Acupuncture is regulated by the Ministry of Health in 1991/2002 (290). By the regulation in 1991 MOH established the “Higher Acupuncture Commission” under the Ministry of Health in order to “decide who and under which circumstances they can treat various diseases and give the necessary education for the acupuncture treatment together with a certificate” (290).

Acupuncture can only be **applied by physicians**. To get the Authorization of Acupuncture Treatment Application the provider must have a medical degree according to the law numbered 1219, concerning the Art of Medication and Treatment applications (290).

Physicians who want to apply acupuncture treatment must have completed the courses that are affiliated with the Ministry of Health. These courses are given by the 3 universities approved by the Ministry of Health. There are 4 societies for Acupuncture. Acupuncture treatment rooms and other aspects of the physical environment are strictly described by the Ministry of Health and regularly controlled by the regional agencies of Ministry of Health. Acupuncture courses are integrated in a few medical undergraduate curriculums (like Yeditepe University), and a professional chair of acupuncture exists at Yeditepe and Gazi Universities (291).

Physiotherapy and Rehabilitation is a 4-year residency program for medical doctors. If these doctors have a Ministry of Health affiliated course for acupuncture during or after their residency education they can apply acupuncture in physiotherapy, rehabilitation and pain clinics. If an anesthesiologist has the same certificates then he or she can also apply acupuncture in the pain clinics (289).

Additionally acupuncture treatment can be applied by physicians;

- a) If holding a certificate received abroad that is regarded as appropriate and confirmed by the Higher Commission,
- b) and successfully pass a course offered by the Acupuncture Higher Commission (292).

There are clinics of acupuncture in some faculties of medicine and teaching and research hospital (291).

8.38.5 Anthroposophic medicine

No specific regulation found on anthroposophic medicine (291). Medical doctors with an additional qualification may practise anthroposophic medicine.

8.38.6 Ayurveda

No specific regulation found on ayurvedic medicine (291). Medical doctors with an additional qualification may practise ayurvedic medicine.

8.38.7 Chiropractic

No specific regulation found on chiropractic (291). Medical doctors with an additional qualification may practise chiropractic medicine.

The Turkish Chiropractic Spinal Health Association was founded in 2007 (291).
<http://www.kayropraktikdernegi.org/en/about-kosd/about>

8.38.8 Herbal medicine/Phytotherapy

No specific regulation found for therapists or medical doctors' clinical use of herbal medicine/phytotherapy (291). Medical doctors with an additional qualification may practise herbal medicine/phytotherapy. Laws and regulations on Herbal Medicinal Products were issued in 1985 in the "Permanent Notice concerning Shops, Spice Shops and Similar Stores", at the same time as the Expert committee for Licensing the Herbal Medicinal Products was established (59).

At 2 November 2011, the Ministry of Health stated that Traditional, Alternative and Complementary Medicine (and thereby herbal medicine) regulations, treatment approvals and inspection tasks belongs to the General of Health Services Directorate (295).

There are courses and Master programs of Phytotherapy offered at some universities (like Yeditepe University). Phytotherapy courses are integrated in a few medical undergraduate curriculums (like Yeditepe University), and a professional chair of phytotherapy exists at some universities (like Yeditepe University)(291).

8.38.9 Homeopathy

As there is no general CAM or specific homeopathic regulation in Turkey, homeopathy is not legally recognized. Physicians preserve the right to treat their patients with all means, including the use of homeopathy (289). The inaccessibility of homeopathic remedies and homeopathic text books in Turkish is a great obstacle for homeopathy practitioners in Turkey (289).

The Turkish Classical Homeopathy Association, www.turkiyehomeopati.com, established in 2003, is a full member of the international homeopathic medical society (Liga Medicorum Homoeopathica Internationalis (LMHI))(289). In 2008 they had a goal of joining the European Committee for Homeopathy (ECH)(289). The association consists of about 90 medical doctors, dentists and veterinarians with diverse training in classical homeopathy. They collaborate with InHom (European Institute of Homeopathy) for courses and training. In 2008, nine medical doctors had completed proper training and were full-time practicing classical homeopaths (289).

The association offers guidance for the recognition and regulation of classical homeopathy in Turkey and had in 2008 (289) forwarded suggestions of laws and by-laws to the MOH (289).

8.38.10 Massage

The first legal regulation was declared on 25 July 2010. 520 hours of education which is approved by Ministry of Education is needed in order to practice (291, 299).

8.38.11 Naprapathy

No specific regulation has been found on naprapathy treatment (291). Medical doctors with an additional qualification may practise naprapathy.

8.38.12 Naturopathy

No specific regulation has been found on naturopathy treatment (291). Medical doctors with an additional qualification may practise naturopathy.

8.38.13 Neural therapy

No specific regulation has been found on neural therapy. Medical doctors with an additional qualification may practise neural therapy.

The National Society for Neural Therapy was founded on 1 December 2004. Only physicians and dentists are accepted in the society, and courses of 120 hours are offered (291).

8.38.14 Osteopathy

No specific regulation has been found on Osteopathy treatment. Medical doctors with an additional qualification may practise osteopathic medicine.

The Turkish Institute for Adapted Osteopathy was founded in 2009, and 47 candidates have graduated from their courses (291).

8.38.15 Traditional Chinese Medicine (TCM)

No specific regulation has been found on TCM treatment except for acupuncture (291). Medical doctors with an additional qualification may practise TCM.

8.38.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a **regulated profession** in Turkey. The law on practice of medicine states; "b) the physiotherapist, physiotherapy undergraduate education in the field belong to a faculty or Graduate schools graduated from the medical profession"(300). In 1994, with the decision of the Council of Ministers, the "Physiotherapists Association of Turkey" and the ethical principles of the profession of physiotherapy was approved (300).

Physiotherapist and **Physiotherapist doctor** are completely different terms for Turkey. Physiotherapists have 2 years of education after high school and they cannot apply acupuncture. Physiotherapy and Rehabilitation is a 4-year residency program for medical doctors (289).

8.39 The United Kingdom (UK)

The United Kingdom (UK) entered the European Union in 1973 (11) and consists of England, Wales, Scotland (who together make up Great Britain) and Northern Ireland (11). UK became a founding member of the Council of Europe from 5 May 1949 (12).

8.39.1 The legal and regulatory status of CAM and CAM practices

Under Common Law all practitioners have a duty of care towards their patients, and non-medically qualified individuals are prohibited from curing or treating specific illnesses and medical conditions, for example cancer and venereal disease (301). The Health and Safety at work Act 1974 places a statutory duty of employers to ensure the health and safety of people affected by the various activities undertaken on their premises (301). According to the House of Lords' report 2000 5.9.(301). "The Common Law right to practise medicine means that in UK anyone can treat a sick person even if they have no training in any type of healthcare whatsoever, provided that the individual treated has given informed consent".

Osteopathy and chiropractic are statutorily regulated while acupuncture and other CAM treatments are voluntarily regulated (or not) depending on the associations/groups (234). The UK Government has announced that it is planning to statutorily regulate practitioners supplying unauthorized herbal medicines on a one-to-one basis (after an individual consultation) under the aegis of the Health Professions Council. Both statutory and voluntary regulations are based on minimum standards for practices. However, for voluntary self-regulated practitioners there are no legal sanctions against practitioners who fail to meet these standards (302).

The Government's Command Paper Enabling Excellence (February 2011) stated that the Council for Healthcare Regulatory Excellence (CHRE) was to be given new powers to accredit voluntary registers of health professionals who are currently not regulated by statute. These powers will be enacted when the Health and Social Care Bill becomes law, and the CHRE is expected to commence the implementation scheme in the autumn of 2012 (303).

On 1 March 2012 the Law Commissions of Scotland, England & Wales, and Northern Ireland published a joint consultation "REGULATION OF HEALTH CARE PROFESSIONALS", seeking views on how the regulation of health care professionals in the UK and social workers in England can be made clearer, simpler, more modern and more consistent. Chiropractic and osteopathy are listed among the regulated professions in question (304).

Non-medically trained homeopaths, acupuncturists, and herbal medicine practitioners are all registered and self-regulated in their own individual councils. A number of other disciplinary groups of non-medically trained CAM practitioners are registered under the banner of the

Complementary and Natural Healthcare Council (CNHC). CNHC has put into place the policies and procedures necessary for an effective running of a regulatory body, including an on-line multi-disciplinary register that opened in January 2009 (305).

8.39.2 The governmental supervision of CAM Practices

In England the Care Quality Commission, established under the Health and Social Care Act of 2008, regulates health and adult social care under the Care Standards Act 2003 (302). Similar inspectorates are established for the other UK states, but they do not regulate CAM services under current legislation (302).

Anyone may practise and provide various CAM treatments as long as they do not claim to be a medical practitioner registered under the Medical Act or claim to cure diseases as proscribed by the law (301). The above mentioned groups fall outside the governmental health supervision systems.

8.39.3 The reimbursement status of CAM practices and medicinal products

A number of private health insurance companies cover some CAM treatments in their policies but many private insurance companies will only reimburse treatments carried out by statutorily regulated practitioners. Some acupuncture treatments (largely for pain) is covered mainly by private insurance companies in the UK (106). Some acupuncture, anthroposophic medicine and homeopathy treatments are also provided by the NHS (60, 106). Some therapies are available through the NHS in pain clinics and terminal care environments but the vast majority of CAM provision in the UK is within the private sector and is not covered by medical insurance.

8.39.4 Acupuncture

Most UK acupuncturists are not statutorily regulated. As a member of the British Medical Acupuncture Society (BMAS) healthcare professionals subject to statutory regulation are offered training in Western medical acupuncture up to full accreditation status with the Diploma of Medical Acupuncture (Dip Med AC). Professionals included are doctors, dentists, nurses, midwives, health visitors, physiotherapists, osteopaths, chiropractors, and podiatrists (306). The Acupuncture Association of Chartered Physiotherapists (AACP) offers training courses for registered physiotherapists (307). The British Acupuncture Council (BAcC) is a self-regulating body for the practice of traditional acupuncture and represents most of the non-medically qualified acupuncturists (308). The Local Government Act 2003

(similar laws in Wales, Scotland, Northern Ireland) gives local authorities specific powers to regulate acupuncture practices (302).

8.39.5 Anthroposophic medicine

In the UK anthroposophic medicine is not regulated as a distinct therapeutic system and diplomas in anthroposophic medicine are not recognized. However, anthroposophic medicinal products are regulated (106) (see report WP2: CAM medicinal products). Anthroposophic medicine is provided in some hospitals in the UK (106). Five bodies represent different categories of statutory regulated practitioners providing anthroposophic medicine in the UK; a medical association, a nursing association, an art therapists association, a movement therapists association, while the last represents massage (301).

8.39.6 Ayurveda

Ayurvedic medicine is not statutorily regulated in the UK but ayurvedic practitioners supplying unlicensed herbal medicines on a one-to-one basis are set to be statutorily regulated under the Health Professions Council along with other traditional or herbal medicine practitioners. There are approximately 200 qualified Ayurvedic practitioners in the UK most of whom are registered with one of the two existing voluntary regulation bodies: either with the Ayurvedic Practitioners Association (APA) or the British Association of Accredited Ayurvedic Practitioners (BAAAP). The only currently existing training course is the 4-year integrated MSc programme offered by the College of Ayurveda in conjunction with Middlesex University. Middlesex University has re-validated this programme for another 5 years in 2011 and intends to accredit the course through the EHTPA Accreditation Board before statutory regulation commences in 2013 (309).

8.39.7 Chiropractic

The Chiropractors Act of 1994 established The General Chiropractic Council (GCC) with a statutory register for chiropractors (310). The title “chiropractor” is protected, and GCC regulates and develops the chiropractic profession. It is a criminal offence to claim to be chiropractor if not registered with the GCC (311, 312).

Chiropractic in the UK is registered in the **EU regulated professions database** as follows:

Chiropractor is a directly related regulated profession with the title “Chiropraktor” recognized under Directive 2005/36/EC (5), ID 3762. General system of recognition - application (primary or secondary to be defined). Qualification level: PS4- Diploma of post-secondary level (exactly 4 years)(7).

8.39.8 Herbal medicine/Phytotherapy

Regulation of herbal medicine practitioners in the UK is currently voluntary. Most herbalists are registered in one or more of a number of professional associations on a voluntary basis (302). However in February 2011, the UK Government announced that it intends to statutorily regulate practitioners supplying unlicensed herbal medicines on a one-to-one basis (after an individual consultation) under the aegis of the Health Professions Council (313).

8.39.9 Homeopathy

Homeopathy practices are not statutorily regulated in the UK (60) and registration is not compulsory. There are three major professional associations that between them regulate some 2500 non-medical practitioners. Homeopathy has been recognized by law as a distinct therapeutic system for doctors since the Faculty of Homeopathy in the UK was established by the Faculty of Homeopathy Act of 1950 (314). The faculty offers homeopathy training courses to statutorily registered healthcare professionals like dentists, doctors, nurses, midwives, osteopaths, pharmacists, podiatrists and veterinary surgeons (314). At some universities optional CAM courses including homeopathy are offered but not as part of normal medical training (106). Within the NHS in the UK there are 3 homeopathic hospitals, 7 NHS referral clinics and in many areas GPs integrate homeopathy in their primary care practice (106, 309).

8.39.10 Massage

Massage is not statutorily regulated in the UK (301).

8.39.11 Naprapathy

No specific regulation has been found on naprapathy treatment.

8.39.12 Naturopathy

Naturopathy treatment is not statutorily regulated in the UK.

8.39.13 Neural therapy

No specific regulation has been found on neural therapy.

8.39.14 Osteopathy

The Osteopaths Act of 1993 (315) established the General Osteopathic Council (GOC) with the UK Statutory register of Osteopaths (316). The title 'osteopath' is protected by law and it is a criminal offence to claim to be an osteopath if not registered with GOC (316).

Osteopathy in the UK is registered in the **EU regulated professions database** as follows:

Osteopathy is a directly related regulated profession with the title "Osteopath" recognized under Directive 2005/36/EC (5) ID 4381. General system of recognition - application (primary or secondary) to be defined. All regions. Qualification level: PS4 - Diploma of post-secondary level (exactly 4 years), Art. 11e (7).

8.39.15 Traditional Chinese Medicine (TCM)

A TCM practitioner in the UK may currently register voluntarily with a professional body (302). However, the UK Government has announced that it is to statutorily regulate those prescribing Chinese herbal medicines on a one-to-one basis (after an individual consultation) under the aegis of the Health Professions Council.

8.39.16 Other treatments (mentioned if found in legislation)

Physiotherapy is a **regulated health profession** in the UK. The title 'Physiotherapist' is protected by the state, regulated by the Health Professions Council (HPC). Physiotherapists

must be registered with the HPC and obtain a licence to practise. Legislation also requires that they meet the HPC's generic standards of proficiency, conduct and performance. The Chartered Society of Physiotherapy has established a code of professional values and the CSP standards (317).

Physiotherapy in the UK is registered in **the EU regulated professions database** as follows:

Physiotherapy is a directly related regulated profession with title "Physiotherapist" recognized under Directive 2005/36/EC (5), ID 1180. General system of recognition - primary application. Qualification level: PS3 - Diploma of post-secondary level (3-4 years), Art. 11d (7)

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Attachment 1: European CAM associations:

ANME (Association of Natural Medicine in Europe)

CAMDOC Alliance (alliance of the four major European medical CAM umbrella organizations ECH, ECPM, ICMART and IVAA)

ECCH (European Central Council of Homeopaths)

ECH (European Committee for Homeopathy)

ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.)

ECPM (European Council of Doctors for Plurality in Medicine)

EFCAM (European Forum for Complementary and Alternative Medicine)

EHTPA (European Herbal and Traditional Medicine Practitioners' Association)

EICCAM (European Information Centre for Complementary and Alternative Medicine)

ELIANT (European Alliance for Applied Anthroposophy)

EPHA (European Public Health Association)

ICMART (International Council of Medical Acupuncture and Related Techniques)

IVAA (International Federation of Anthroposophic Medical Association)

KB (Kneipp-Bund eV)

Attachment 2: Directive 2005/36/EC

30.9.2005 EN Official Journal of the European Union L 255/31

TITLE III FREEDOM OF ESTABLISHMENT CHAPTER I**General system for the recognition of evidence of training****Article 10 Scope**

This Chapter applies to all professions which are not covered by Chapters II and III of this Title and in the following cases in which the applicant, for specific and exceptional reasons, does not satisfy the conditions laid down in those Chapters:

- (a) for activities listed in Annex IV, when the migrant does not meet the requirements set out in Articles 17, 18 and 19;
- (b) for doctors with basic training, specialised doctors, nurses responsible for general care, dental practitioners, specialised dental practitioners, veterinary surgeons, midwives, pharmacists and architects, when the migrant does not meet the requirements of effective and lawful professional practice referred to in Articles 23, 27, 33, 37, 39, 43 and 49;
- (c) for architects, when the migrant holds evidence of formal qualification not listed in Annex V, point 5.7;
- (d) without prejudice to Articles 21(1), 23 and 27, for doctors, nurses, dental practitioners, veterinary surgeons, midwives, pharmacists and architects holding evidence of formal qualifications as a specialist, which must follow the training leading to the possession of a title listed in Annex V, points 5.1.1, 5.2.2, 5.3.2, 5.4.2, 5.5.2, 5.6.2 and 5.7.1, and solely for the purpose of the recognition of the relevant specialty;
- (e) for nurses responsible for general care and specialised nurses holding evidence of formal qualifications as a specialist which follows the training leading to the possession of a title listed in Annex V, point 5.2.2, when the migrant seeks recognition in another Member State where the relevant professional activities are pursued by specialised nurses without training as general care nurse;
- (f) for specialised nurses without training as general care nurse, when the migrant seeks recognition in another Member State where the relevant professional activities are pursued by nurses responsible for general care, specialised nurses without training as general care nurse or specialised nurses holding evidence of formal qualifications as a specialist which follows the training leading to the possession of the titles listed in Annex V, point 5.2.2;
- (g) for migrants meeting the requirements set out in Article 3(3).

Article 11

Levels of qualification

For the purpose of applying Article 13, the professional **qualifications are grouped under the following levels** as described below:

(a) an attestation of competence issued by a competent authority in the home Member State designated pursuant to legislative, regulatory or administrative provisions of that Member State, on the basis of:

(i) either a training course not forming part of a certificate or diploma within the meaning of points (b), (c), (d) or (e), or a specific examination without prior training, or full-time pursuit of the profession in a Member State for three consecutive years or for an equivalent duration on a part-time basis during the previous 10 years,

(ii) or general primary or secondary education, attesting that the holder has acquired general knowledge;

(b) a certificate attesting to a successful completion of a secondary course,

(i) either general in character, supplemented by a course of study or professional training other than those referred to in point (c) and/or by the probationary or professional practice required in addition to that course,

(ii) or technical or professional in character, supplemented where appropriate by a course of study or professional training as referred to in point (i), and/or by the probationary or professional practice required in addition to that course;

(c) a diploma certifying successful completion of

(i) either training at **post-secondary level other than that referred to in points (d) and (e)** of a **duration of at least one year** or of an equivalent duration on a part-time basis, one of the conditions of entry of which is, as a general rule, the successful completion of the secondary course required to obtain entry to university or higher education or the completion of equivalent school education of the second secondary level, as well as the professional training which may be required in addition to that post-secondary course; or

(ii) in the case of a regulated profession, training with a special structure, included in Annex II, equivalent to the level of training provided for under (i), which provides a comparable professional standard and which prepares the trainee for a comparable level of responsibilities and functions. The list in Annex II may be amended in accordance with the procedure referred to in Article 58(2) in order to take account of training which meets the requirements provided for in the previous sentence;

(d) a diploma certifying successful completion of training at **post-secondary level of at least three and not more than four years' duration**, or of an equivalent duration on a parttime basis, at a university or establishment of higher education or another establishment providing the same level of training, as well as the professional training which may be required in addition to that post-secondary course;

(e) a diploma certifying that the holder has successfully completed a **post-secondary course of at least four years' duration**, or of an equivalent duration on a part-time basis, at a university or establishment of higher education or another establishment of equivalent level and, where appropriate, that he has successfully completed the professional training required in addition to the post-secondary course.



The Roadmap for
European CAM Research

A pan-European research network for Complementary and Alternative Medicine (CAM)

Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebø)

Legal status and regulation of CAM in Europe

Part II - Herbal and homeopathic medicinal products

**Vinjar Fønnebø, Torkel Falkenberg, Gabriella Hegyi, Johanna Hök,
Paolo Roberti di Sarsina, Solveig Wiesener**

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Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebo)

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CAMbrella – A pan-European research network for Complementary and Alternative Medicine (CAM)

The goal of this collaboration project was to look into the present situation of CAM in Europe in all its relevant aspects and to create a sustained network of researchers in the field that can assist and carry through scientific endeavours in the future. Research into CAM – like any research in health issues – must be appropriate for the health care needs of EU citizens, and acceptable to the European institutions as well as to national research funders and health care providers. It was CAMbrella's intention to enable meaningful, reliable comparative research and communication within Europe and to create a sustainable structure and policy.

The CAMbrella network consists of academic research groups which do not advocate specific treatments. The specific objectives were

- To develop a consensus-based terminology widely accepted in Europe to describe CAM interventions
- To create a knowledge base that facilitates our understanding of patient demand for CAM and its prevalence
- To review the current legal status and policies governing CAM provision in the EU
- To explore the needs and attitudes of EU citizens with respect to CAM
- To develop an EU network involving centres of research excellence for collaborative research.

Based on this information, the project created a roadmap for research in CAM in Europe. The roadmap sums up and streamlines the findings of the whole project in one document that aims to outline the most important features of consistent CAM research at European level.

For other reports of the CAMbrella project which are also available on <https://phaidra.univie.ac.at/> see the additional information on the description data (meta-data) of this report.

Foreword

CAMbrella Work Package 2 (WP2) - Legal Status and regulation of CAM in Europe

This report is developed by WP2 in the CAMbrella consortium in the period January 1, 2010 to April 30, 2012, and has been updated in the period from May to October 2012. The present report represents the updated version from November 5, 2012.

The aim of this work package was to review and describe in all 27 EU member states as well as 10 associated states (later expanded with two additional countries):

- The legal status of CAM
- The regulatory status of CAM practices
- The governmental supervision of CAM practices
- The reimbursement status of CAM practices and medicinal products
- The regulation of CAM medicinal products

An additional aim was to review at the EU level:

- The status of EU-wide regulation of CAM practices and medicinal products
- The potential obstacles for EU-wide regulation of CAM practices and medicinal products

The country-specific status has been described on the basis of publicly available legal and regulatory documents supplemented by personal visits to a purposive sample of countries. The status with regard to regulation of CAM medicinal products and the EU-wide regulation of CAM has been described on the basis of publicly available legal and regulatory documents only.

The work of WP2 **Legal status and regulation of CAM in Europe** is presented in **three separate reports**:

1. Part I - CAM regulations in the European countries
2. **Part II - Herbal and homeopathic medicinal products** (present report)
3. Part III - CAM regulations in EU/EFTA/EEA

All reports are available on <https://phaidra.univie.ac.at/>.

Tromsø, Norway, November 5, 2012

On behalf of WP2 in CAMbrella,

Solveig Wiesener and Vinjar Fønnebø

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Summary

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level. The individual state within the EU/EEA area are therefore no longer free to uphold deviating national regulation of medicinal products in violation of the following three EU directives:

1. *Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001* (on the Community code relating to medicinal products for human use).
2. *Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004* (amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use 2001/83/EC).
3. *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004* (amending Directive 2001/83/EC on the Community code relating to medicinal products for human use).

Other amendments on specific topics applicable to all medicinal products have been made in 2003, 2010 and 2011:

* *Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components* and amending Directive 2001/83/EC.

* *Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards **pharmacovigilance**, Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

* *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the **prevention of the entry into the legal supply chain of falsified medicinal products**.*

Herbal medicinal products marketed without authorization before Directive 2004/24/EC came into force could continue to be marketed until April 30 2011 under transitional measures defined in this directive. After the expiration of this time limit, all previously unauthorized herbal medicinal products must have a registration or marketing authorization according to directive 2001/83/EC - and amended by Directives 2004/27/EC and 2004/24/EC - before they can be marketed in the EU/EEA states.

Registrations or marketing authorizations for herbal and homeopathic medicinal products are always given at the national level, but a mutual recognition procedure can be used in some cases. Herbal and homeopathic medicinal products are subject to the same requirements as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements with the possible exception of

documentation of efficacy. There are five administrative procedures that can be followed to obtain a registration or a marketing authorization for these products: Standard marketing authorization, Well-established use authorization (for herbal medicinal products only), two Simplified registration procedures (one for homeopathic medicinal products and the other for traditional-use registration of herbal medicinal products) and a national registration procedure for homeopathic medicinal products. The simplified registration procedures and the national registration procedure for homeopathic medicinal products allow alternative documentation of efficacy.

Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993 and herbal medicinal products already authorized in accordance with Regulation (EEC) No 2309/93 or supplied in response to a bona fide unsolicited order can be marketed irrespective of the two directives.

These uniform regulations aim to supply citizens with a predictable standard of all medicinal products (including herbal and homeopathic) across Europe. Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without access to beneficial products and the establishment of unnecessary additional regulatory bureaucracy around well-known medicinal products with a long tradition and a well-known safety profile.

In general, the European legal system for herbal and homeopathic medicinal products differs from the legal system surrounding all other aspects of CAM practice. The regulation of clinical practice and practitioners appears to be as diverse as possible in Europe. At the same time the medicinal products these practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This appears to be inconsistent and European politicians at both the national and EU level need to closely consider whether regional or EU-wide harmonization of CAM practice and its medicinal products could further optimize the healthcare of European citizens. In the frame of free circulation within the EU, calls for these considerations have been articulated in resolutions by both the Council of Europe and the European Parliament.

1 Aim

To review at EU/EEA level:

- The status of EU/EEA-wide regulation of herbal and homeopathic medicinal products.

To review and describe in all 27 EU member states and 12 associated states:

- The extent of country-specific registration and market authorization of herbal and homeopathic medicinal products according to the EU directives.

2 Methods

As an introduction a comprehensive overview was made of matters that may influence CAM in national and EU legislation. Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary both in the European Union bodies and within the 39 countries included in this report. To address CAM-related legislation in the European countries, we included EU legislation that influences the member states' national health legislation.

A search was performed in the web sites/databases *EUROPA* and *EUR-lex* to identify EU official law documents. We searched specifically for information about EU Directives regarding herbal and homeopathic medicinal products, and their EU/EFTA/EEA implications.

In addition a personal visit was made to *the European Union offices* and *NGO bodies* in Brussels to establish firsthand updated information. Meetings were held with:

- *Counselor for health and food safety at the Mission of Norway to the EU.*

At the Mission of Norway to the European Union we received updated information mainly on the EFTA/EEA legal connection to EU legislation and the new Cross-border Healthcare Directive 2011/24/EU.

- *The European Commission Central Library.*

The library assisted in searching for CAM legislation documents.

Meetings with the following NGOs gave important additional CAM information:

- *IVAA (International Federation of Anthroposophic Medical Associations).*
- *ICMART (International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.*
- *AESGP (The Association of the European Self-Medication Industry).*

We received their information, documents, and viewpoints with regard to the EU regulation of medicinal products.

We have also collected information from *European CAM associations/coalitions* and *other CAMbrella stakeholders* (Listed in [Attachment 1](#)).

3 The EU/EFTA legal and regulative system

CAMbrella WP2 Report part I gives a detailed overview of how each state covered in these reports are legally tied to the EU (1). Twenty-seven of the states included in the three CAMbrella WP2 reports are full EU members; others are affiliated to the EU through various legislation and agreements. This can potentially determine how EU legislation and regulations influence the states' national legislation on medicinal products. This report will therefore also present a short summary of the general EU regulatory systems and how the European states are linked to those systems.

The European Union Law operates alongside the legal systems of the individual EU member states and consists of Treaties and Laws (Directives, Regulations, Decisions (Court Judgements)). The EU legislation is based on the *EU treaties* and the legislative acts are expressed through *Regulations, Directives* or *Decisions*.

3.1 The EU Treaties

The legislation of interest for this report is mainly based on the 1958 **Treaty of Rome** followed up by the *2007 Treaty of Lisbon(2) with the Four Freedoms* (the requirements that goods, services, capital and persons *are to move freely* within the EEA); article 168 includes common safety concerns and measures setting high quality standards for public health, medicinal products, quality and safety, research and cross-border areas.

The EU Treaties have repeatedly established that health policy is a national responsibility for the member states. Despite this, several EU Directives and Regulations influence how the member states organize their national health policy and services.

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level.

3.2 The Regulations, Directives and Decisions

Directives, Regulations and Decisions have effect within the EU's member states either with local adjustments to national legislation or precedence over national legislation.

EU Regulations are adopted by the Council, cover general measures that are binding for all states, and are to be seen as directly enforceable law in all member states.

EU Directives are addressed to the member states and are intended to align national legislation. How the individual member states implement the Directives in national legislation is left to the member states, but the implementation should conform to the content of the EU Directives.

EU Decisions refer to decisions taken by the European Court of Justice and address individuals. These are automatically binding upon those individuals (individuals and member states) to which they are addressed, but can have a potential influence when creating new EU legislation or modifying existing EU legislation.

EU Parliamentary non-legislative Resolutions are recommendations and political statements only.

3.3 EEA - legislation and procedures

The EEA agreement is based on the EU treaties (2), legislation (EEA relevant Regulations, Directives, Decisions) and on certain non-binding instruments adopted by the EU institutions on an on-going basis (3).

The EU "Treaty of Lisbon" with "*the four freedoms*" is included in the EEA agreement. "*The four freedoms*" aim to enable goods, services, capital and persons *to move freely* within the EEA. Education, training, employment, enterprise and civil protection are among the fields that are handled within EEA. Relevant legislation is incorporated into the EEA agreement by decisions of the *EEA Joint Committee*. The non-EU EEA member states can negotiate adaptations to EU legislation and the documents have to be amended to national legislation. For the EU member states the EU legislation is already binding.

4 EU Directives, Regulations and Decisions of importance for herbal and homeopathic medicinal products

The three directives passed in the European Union with impact on herbal and homeopathic medicinal products cover marketing authorization and registration of herbal and homeopathic medicinal products in the EU.

- *Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001 on the Community code relating to medicinal products for human use (4).*

This directive states that “No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 2309/93.” Directive 2001/83/EC has not significantly been amended for homeopathic medicinal products; for herbal medicinal products substantial amendments have been introduced in 2004 by means of:

- *Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (5).*

And:

- *Directive 2004/27/EC of the European Parliament and of the Council, of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance)(6).*

Directive 2001/83/EC with its 2004 amendment for herbal medicinal products has been actively protested from various stakeholders before its implementation (7). The objections have mainly been concentrated around the issues of continued access to well-established medicinal products and on the establishment of unnecessary additional regulatory bureaucracy around safe products. Since both directives are now fully implemented, this report will not describe in detail the pros and cons argued by various stakeholders with regard to the regulation of herbal and homeopathic medicinal products.

4.1 What constitutes a medicinal product?

Directive 2001/83/EC as amended by *Directives 2004/24/EC* and *2004/27/EC* defines a medicinal product as: “(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either

with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis” (6).

Herbal and homeopathic medicinal products constitute two subsets of medicinal products, and the EU has established special regulations for these. A herbal medicinal product is defined as “any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations” (5). A homeopathic medicinal product is defined as “Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles” (6).

It is important to realize that the EU regulation of herbal medicinal products also applies to medicinal products from anthroposophic medicine, Traditional Chinese Medicine, ayurvedic medicine or from other European or non-European medicine systems, as far as they are not homeopathically manufactured, not in form of injection and not containing other ingredients than herbals. There are no separate rules for these medicinal products.

4.2 Limitation

Food supplements are not described in this report. The EU regulation of food supplements can be found in *Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements*.

4.3 Relevant institutions regarding herbal medicinal products

- *The European Commission* is the EU's executive body. The Commission has the ultimate authority for granting marketing authorizations in the EU.
- *The European Medicines Agency (EMA)* is a decentralized agency of the European Union. The EMA is responsible for the scientific evaluation of medicines in the European Union. Specifically, the EMA is responsible for the centralized procedure and for arbitration in cases where there is a disagreement between Member States in the ‘mutual-recognition’ and ‘decentralized’ procedures (see below). Opinions and decisions made by the EMA are transmitted to the European Commission for final approval.

- *Committee on Herbal Medicinal Products (HMPC)* is one of six Scientific Committees of the EMA. The HMPC's activities aim at assisting the harmonization of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework. As part of these objectives, the HMPC provides EU Member States and European institutions its scientific opinion on questions relating to herbal medicinal products. Other core tasks include the establishment of a draft 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products', as well as the establishment of Community herbal monographs.



Figure 4.1 Relevant institutions regarding herbal medicinal products in the EU.

4.4 Relevant Institutions regarding homeopathic medicinal products

- The *Heads of Medicines Agencies (HMA)* is a network of the Heads of the National Competent Authorities whose organizations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat.
- The *Homeopathic Medicinal Products Working Group (HMPWG)* is a working group of the HMA composed of heads and staff of the regulatory department for Homeopathic Medicinal Products in the national medicines agencies; the aim of the work of this group is to harmonize the assessment of homeopathic products amongst the Member States and to create a network of assessors to facilitate cooperation in National and Mutual Recognition Procedures.

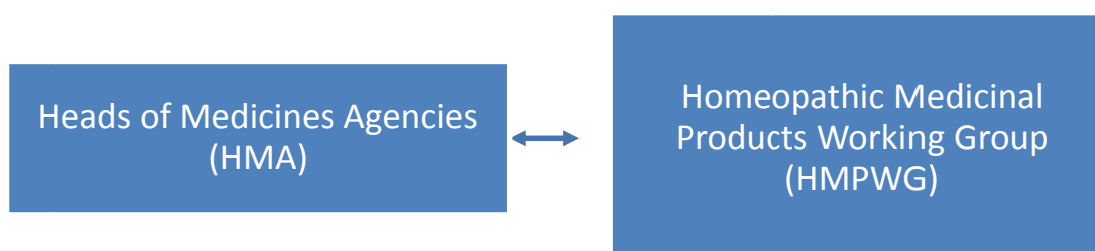


Figure 4.2 Relevant institutions regarding homeopathic medicinal products in the EU.

5 Simplified registration and marketing authorization for herbal and homeopathic medicinal products

Figure 5.1 outlines through which procedures herbal and homeopathic medicinal products can acquire an authorization to be on the market.

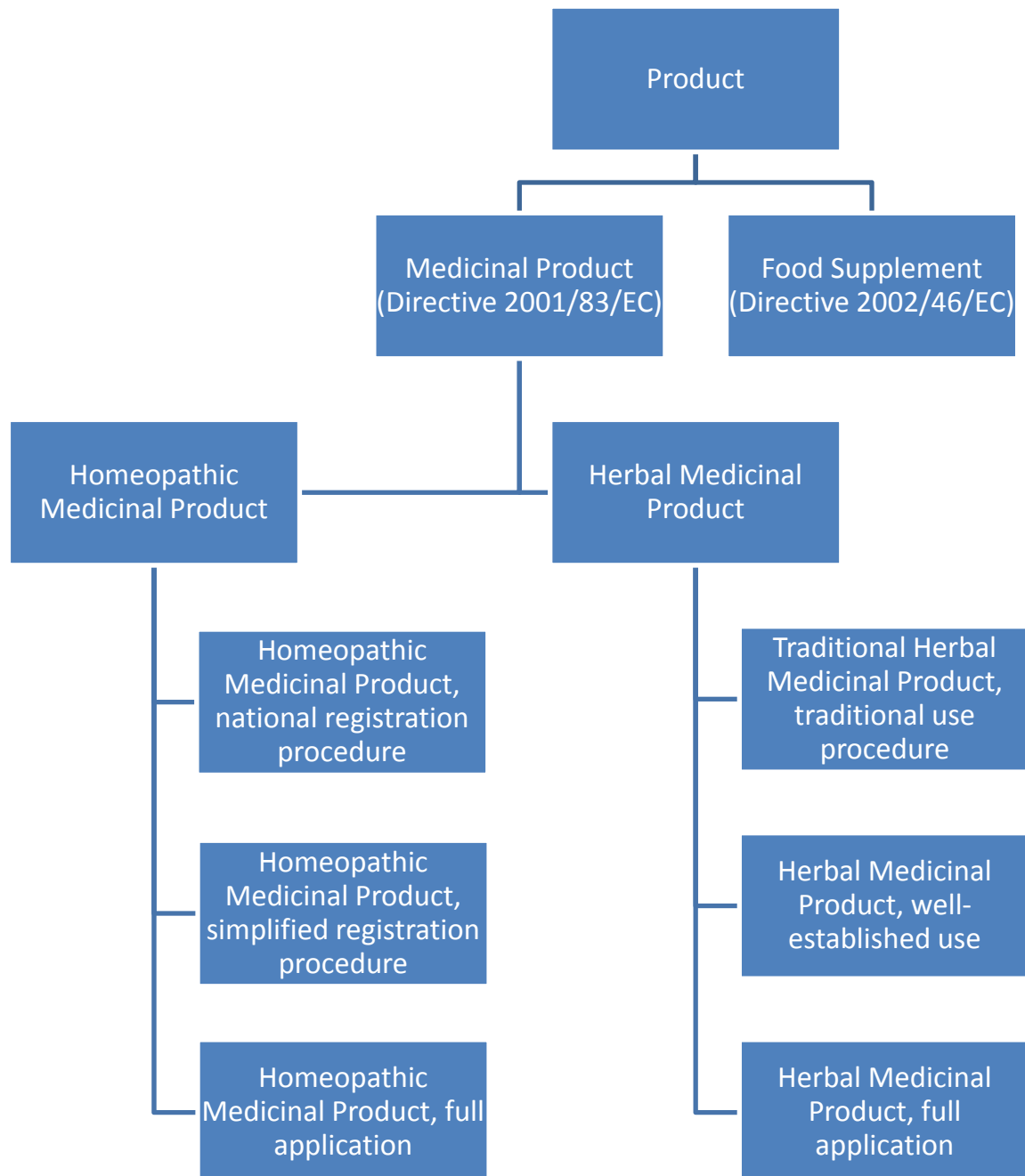


Figure 5.1 Procedures for herbal and homeopathic medicinal products in the EU.

5.1 Regulatory pathways for herbal and homeopathic medicinal products

Herbal and homeopathic medicinal products are subject to the same application procedures (Article 8 in Directive 2001/83/EC)(4) as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements with the possible exception of documentation of efficacy. The well-established use procedure (for herbal medicinal products), a simplified registration procedures (for both, herbal and homeopathic medicinal products), and the national marketing authorization based on special national rules (for homeopathic medicinal products) described below allow alternative documentation of efficacy.

5.1.1 Standard procedure (Full application)

Herbal and homeopathic medicinal products can be given a full marketing authorization through the same pathways as regular medicinal products. All quality and safety documentation has to be submitted, and the efficacy of the product must be demonstrated in clinical trials.

5.1.2 Well-established use procedure for herbal medicinal products

This procedure outlined in Article 10a in Directive 2004/27/EC(6) states that “the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in [Attachment 1](#). In that event, the test and trial results shall be replaced by appropriate scientific literature”.

Examples of herbal medicinal products that can be subject to this procedure are: St. Johns wart, Valeriana root and Horseradish seeds.

5.1.3 Simplified registration procedure for traditional-use registration of herbal medicinal products

This is a procedure described in chapter 2a in Title III of Directive 2004/24/EC(5) where bibliographic evidence of safety and efficacy can replace pre-clinical and clinical tests. There must be bibliographic evidence that the product “has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community”.

The technical quality requirements of the product are not subject to any “traditional” procedure. It needs to be documented according to article 8(3), in Directive 2001/83/EC(4) amended in Directive 2004/27/EC(6).

5.1.4 Simplified registration procedure for homeopathic medicinal products

A simplified registration procedure is described in Directive 2001/83/EC, Article 14 and 15. Implementation of this procedure is mandatory for the Member States. It is primarily intended to document that the homeopathic medicinal product is manufactured in a manner that ensures high quality, and thus is safe to use. If this is the case, and the product otherwise meets the three criteria listed below, no further evidence of efficacy is required.

Criteria for this simplified registration procedure:

1. The product is administered orally or externally only.
2. No specific therapeutic indication appears on the labeling of the medicinal product or in any information relating thereto.
3. There is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10,000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

5.1.5 National registration procedures for homeopathic medicinal products

Homeopathic medicinal products can, within the framework of specific national rules developed by a Member State, be registered according to article 16.2 in Directive 2001/83/EC(4). This article states that: “A Member State may introduce or retain in its territory specific rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practiced in that Member State.” In these cases the requirements for quality and safety of the product are as outlined in the directive, but pre-clinical tests can be country-specific. This can be exemplified by the “National Rules Scheme” in the UK (8). It gives the following requirements for pre-clinical tests of efficacy:

“... the applicant must provide one or more of the following:

- Study reports in relation to the product which is the subject of the application.
- Published scientific literature.
- Homoeopathic provings.

Whatever data is provided, it should be sufficient to demonstrate that UK homeopathic practitioners would accept the efficacy of the product for the indications sought.”

5.2 Exceptions from the current general rules for registration or marketing authorization

5.2.1 Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993

Some countries have homeopathic medicinal products registered according to the rule described in a revised article 13 in Directive 2004/27/EC(6). A Member State can exempt these products from any further procedure and leave them on the market.

5.2.2 Medicinal products already authorized in accordance with Regulation (EEC) No 2309/93

This EEC regulation is the previous regulation replaced by Directive 2001/83/EC(4). Herbal medicinal products could, of course, have been authorized in accordance with this regulation if they fulfilled the requirements of the regulation.

5.2.3 Medicinal products supplied in response to a bona fide unsolicited order

Article 5.1 of Directive 2004/27/EC(6) excludes from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorized health-care professional and for use by an individual patient under his direct personal responsibility. This makes it possible for authorized health-care professionals to supply individual patients with herbal and homeopathic medicinal products irrespective of the provisions set out in Directive 2001/83/EC and its 2004 amendments.

In the UK the Government is deliberately planning to circumvent the restrictions in the directives (9) by establishing a new category of authorized healthcare personnel, **herbalists**. This new profession will then be able to provide their patients with products without a registration or marketing authorization.

6 Where is a registration or a marketing authorization given?

In the EU/EEA, there are two "main pathways" to the market for medicinal products, national and at the EU level. Health authorities in each member state can provide a registration or marketing authorization valid in the Member State, or the EMA can provide a central marketing authorization that is valid throughout the EU/EEA-area (4).

Homeopathic and herbal medicinal products are only given a registration or marketing authorization at the national level. The procedures described under 5.1.2, 5.1.3 and 5.1.4 in this document are open for a so-called mutual recognition procedure as described in articles 27 to 29.3 of Directive 2001/83/EC (See also paragraph 6.1.1 in this report).

One of the tasks of HMPC is to develop "Community herbal monographs" and "A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products"(5). These monographs and the published list are to be used as documentation of safety and efficacy when herbal medicinal products are evaluated for traditional-use registration or marketing authorization.

The "Community herbal monographs" are relevant when registration or marketing authorization is sought according to both well-established and traditional use. When Community herbal monographs have been established, the Member States are recommended to take them into account when examining an application (5). This becomes mandatory if the monograph has been accepted by the European Commission on the herbal medicinal products list.

The list of herbal substances, preparations and combinations thereof is relevant only for registrations and marketing authorizations within the traditional-use category (5). If an herbal substance is included in this list, no further documentation of safety and traditional use is necessary and the relevant national authorities are not permitted to require additional documentation.

The "Community herbal monographs" and the HMPC draft list are published on the EMA website. The official list is published on the website of the European Commission.

6.1 Nationally

The "competent authority" of a member state can issue a registration or marketing authorization if the requirements outlined in the three directives have been fulfilled (4-6). The competent authority will normally be a Government drug agency.

6.1.1 Multiple states

Registration or marketing authorization can be applied for in several member states simultaneously (6). The applicant shall request one Member State to act as "reference Member State" and to prepare an assessment report on the medicinal product a draft summary of product characteristics and a draft of the labeling and package leaflet. Each Member State in which an application has been submitted shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labeling and package leaflet. This decision is based on a mutual agreement between the states receiving the simultaneous application.

If the medicinal product has already received a prior marketing authorization in one member state at the time of application, this member state will act as the "reference Member state", and the other concerned Member States shall recognize the marketing authorization granted by this reference Member State.

This is called a decentralized and mutual recognition procedure as described in article 27 to 29(3) of Directive 2001/83/EC(4).

6.2 Central procedure

In some cases, it is also possible to apply directly to the European Medicines Agency EMA, via the central procedure for approval of drugs (10). This applies to medicinal products other than herbal and homeopathic.

7 Herbal and homeopathic medicinal products registered or authorized according to the directive

7.1 Current herbal medicinal products registered or authorized according to the directive

The following tables give an overview as of 30 June 2011 of the uptake and implementation in EU Member States with regard to herbal medicinal product registration according to traditional and well-established use (11).

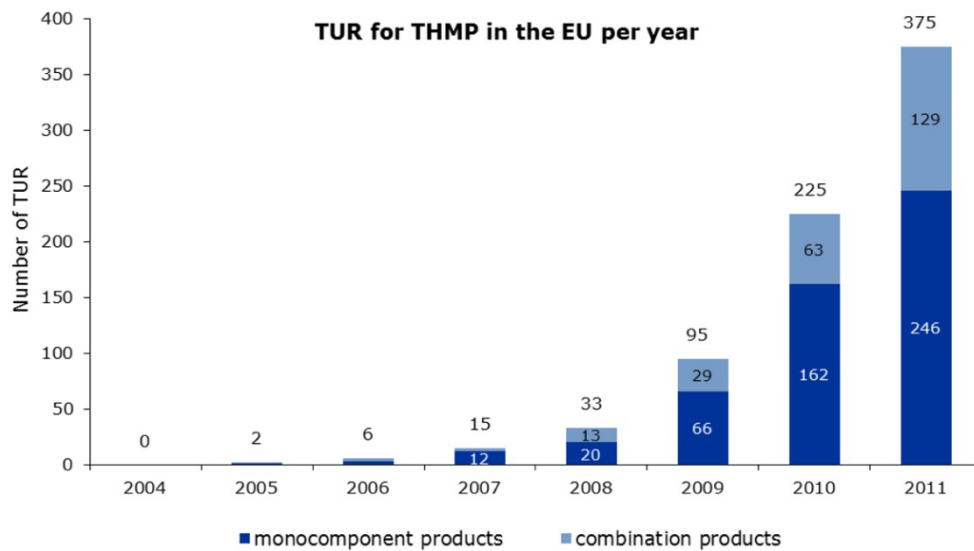


Figure 7.1 Number of traditional use registrations (TUR) for THMP in the EU grouped by year of registration for monocomponent and combination products.

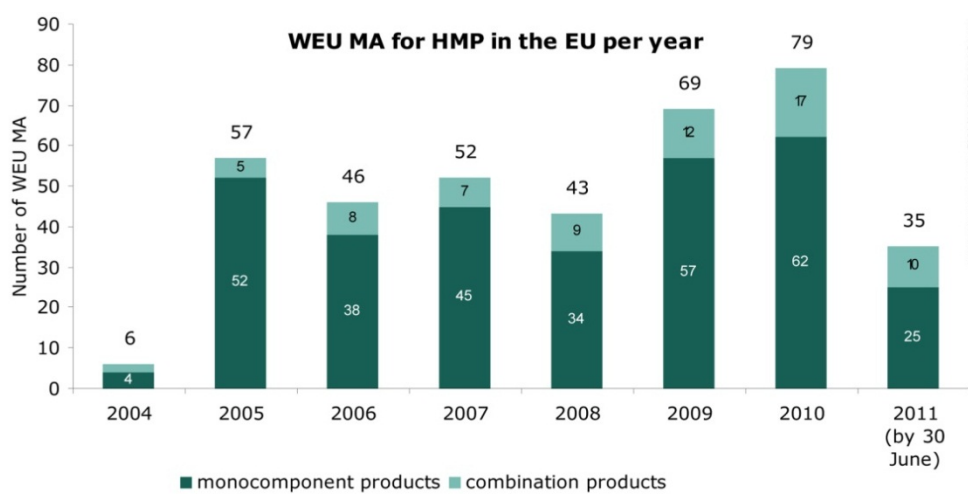


Figure 7.2 Number of well-established use marketing authorisations (WEU MA) for HMP in the EU grouped by year of registration for monocomponent and combination products.

7.2 Current homeopathic medicinal products authorized or registered according to the directive

No centralized data are available on homeopathic medicinal product registration and market authorization in EU Member States. A survey of 27 EU member states and two EFTA states in the fall of 2010 made by PricewaterhouseCoopers (PwC) on behalf of ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) yielded information from 15 countries (12). The number of homeopathic medicinal products reported on the market in these countries varied from “around 31,000” in Italy to 0 in Cyprus.

8 The eight countries that are not members of the EU or EFTA

8.1 Albania

Albania’s regulation of “herbal medicinal products for human use” follows with small variations the EU directive/amendment procedures (4-6, 13).

The regulation specifically indicates that these regulations do not include homeopathic medicinal products. We have not found any regulation of homeopathic products in Albania.

8.2 Bosnia & Herzegovina

The regulation of herbal and homeopathic medicinal products in Bosnia & Herzegovina follows with small variations the EU directive/amendment procedures (14).

8.3 Croatia

The regulation of herbal and homeopathic medicinal products in Croatia follows with small variations the EU directive/amendment procedures (15).

8.4 Israel

The regulation of herbal and homeopathic products in Israel follows the following guidelines: “The Pharmacists Regulations (Conditions for Opening and Operating of Pharmacies and Medicine Rooms) 1982 empower the Administration to regulate the marketing of traditional herbal medicinal products and homeopathic products. The regulation of these products focuses on their safety, while their efficacy is neither tested nor guaranteed by the MOH. The Department of Medicinal Herbs and Homeopathy within the Administration maintains a list of medical herbs which, for safety reasons, can only be marketed by a pharmacist, and of other herbs that are generally prohibited for sale. The manufacture and marketing of homeopathic products are regulated by guidelines published by the Administration” (16).

8.5 Montenegro

The regulation of herbal and homeopathic medicinal products in Montenegro is harmonized with the EU directive/amendment procedures (17).

8.6 Serbia

The regulation of herbal and homeopathic medicinal products in Serbia follows with small variations the EU directive/amendment procedures (18).

8.7 The former Yugoslav Republic of Macedonia

The regulation of herbal and homeopathic medicinal products in the former Yugoslav Republic of Macedonia follows with small variations the EU directive/amendment procedures (19).

8.8 Turkey

The regulation of herbal medicinal products in Turkey follows partly the EU directive/amendment procedures. There is no option of registration of a herbal product according to traditional use, and there is no regulation of homeopathic medicinal products (20).

9 Reimbursement of herbal and homeopathic medicinal products

The reimbursement of herbal and homeopathic medicinal products is considered to be an area subject to national healthcare policy, and is therefore not regulated at the EU/EEA level. This report will not describe in detail the situation in each individual country. The general European situation is, however, that reimbursement of herbal and homeopathic medicinal products in general follows the practice with regard to CAM treatments as described in WP2 Report part I (1).

10 Discussion on CAM aspects related to EU/EFTA/EEA legislation and regulation of herbal and homeopathic medicinal products

In this report we have identified and described the European Union directives governing the regulation of herbal and homeopathic medicinal products. This EU legislation i.e. the relevant directives are now all implemented in the national systems of registration or marketing authorization of herbal and homeopathic medicinal products in the 31 EU and EFTA countries. The remaining eight countries have either fully or partially adopted the EU legislation, or have their own similar regulation.

10.1 Consequences of common EU regulation of herbal and homeopathic medicinal products

Having a common set of rules throughout Europe for registration or marketing authorization of herbal and homeopathic products creates a market that is predictable for producers, importers and consumers. Consumers of these medicinal products are thereby ensured safe products with well-established documentation of effect. This common set of rules will, however, not generate a situation where all authorized products are available in all countries. This is of course due to the freedom marketers have of choosing to apply for registration or market authorization or not in each country, and the freedom of choosing to market or not, even if a registration or market authorization has been given. The important common factor is, however, that the requirements for registration or marketing authorization are the same throughout the EU/EFTA area.

10.2 Exceptions in the established common EU regulation

There are three important exceptions in the general rules for marketing authorization.

The first exception applies to homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993(6). This exception only applies to homeopathic medicinal products that have been evaluated by a national medicinal agency in the past. This previous evaluation combined with the low probability of safety concerns attached to homeopathic medicinal products should make this exception of minor concern to the citizens of Europe. It ensures that previously authorized homeopathic medicinal products are still available to practitioners and their patients.

The second exception is a general exception for all medicinal products (4) and makes it unnecessary to apply for a new marketing authorization for products that have already been legally marketed before Directive 2001/83/EC came into force. This prevents an unnecessary bureaucratic exercise in confirming previous marketing authorizations.

The third exception created to allow authorized health-care professionals to supply medicinal products in response to a bona fide unsolicited order, formulated in accordance with the specifications of and for use by an individual patient under his direct personal responsibility (6) is a necessary provision that gives authorized health-care professionals access to medicinal products currently without a registration or marketing authorization. This provision in the directive was intended to enable authorized healthcare professionals in rare cases, to provide unregistered or unauthorized medicinal products to meet an individual need. This rule of exception applies also to herbal and homeopathic medicinal products irrespective of the provisions set out in Directive 2001/83/EC and its 2004 amendments. If practiced irresponsibly this exception could pose a safety risk to the patient. The intention of this exception was not to deliberately circumvent the general authorization requirements in the directive.

This intention has recently been reaffirmed by the EU Court of Justice in a 29 March 2012 ruling (21). The case had been raised because Poland had been using the "special needs" exception to permit imports of cheap unauthorized medicinal products that contained the same active ingredients, dosage and form as drugs that were currently authorized for sale in the country. Poland had therefore been approving the import and sale of unapproved drugs which were not medically essential for a specific patient, and as a result this constituted failure to obey European law, according to the European Commission. The court added that the "special needs" exception must remain exceptional, so it is used only when completely essential and is based solely on therapeutic considerations which confirm an individual patient's requirement for treatment which is unobtainable on the national market or where there is no authorized equivalent.

It is completely up to the authorized healthcare professional to decide whether their patient has an individual need that necessitates a medicinal product (regular, herbal or homeopathic) outside of the common registration or marketing authorization scheme. The UK Government plan to establish a new category of authorized healthcare personnel (herbalists) is an interesting case. The given intent is explicitly stated as an attempt to circumvent the rules, and it will therefore be an important test case.

11 Conclusions

The EU directives regulating the registration and marketing authorization of herbal and homeopathic products are now permanently established in the EU/EEA area. From both a regulatory and patient perspective, the system aims to provide a predictable scheme of registration or marketing authorization across Europe. Citizens can relate to a uniform standard of medicinal products (including herbal and homeopathic). Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without access to beneficial products and the establishment of unnecessary additional bureaucracy around safe products.

Although uniformly regulated, the market may still appear confusing for the individual consumer due to national varieties in the number of authorized products.

The existing exceptions in the regulation may cause further confusion. The “homeopathic products” exception represents few, if any, safety concerns. While the “bona fide unsolicited order” exception is a necessary scheme to provide individual patients the appropriate therapeutic products, it may also raise safety concerns if practiced irresponsibly. It will be the responsibility of supervisory authorities in the individual country to enforce the legal requirements applicable to every health care professions group to avoid this to happen.

In general, the European legal system for herbal and homeopathic medicinal products is very different from the legal system surrounding all other aspects of CAM practice. The regulation of clinical practice and practitioners appears to be as diverse as possible in Europe. At the same time the medicinal products these practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This appears to be inconsistent and European politicians at both the national and EU level need to closely consider whether regional or EU-wide harmonization beyond medicinal products could further optimize the healthcare of European citizens. Calls for these considerations have been articulated in resolutions by both the Council of Europe and the European Parliament.

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Attachment 1: European CAM associations

ANME (Association of Natural Medicine in Europe)

CAMDOC Alliance (alliance of the four major European medical CAM umbrella organizations ECH, ECPM, ICMART and IVAA)

ECCH (European Central Council of Homeopaths)

ECH (European Committee for Homeopathy)

ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.)

ECPM (European Council of Doctors for Plurality in Medicine)

EFCAM (European Forum for Complementary and Alternative Medicine)

EHTPA (European Herbal and Traditional Medicine Practitioners' Association)

EICCAM (European Information Centre for Complementary and Alternative Medicine)

ELIANT (European Alliance for Applied Anthroposophy)

EPHA (European Public Health Association)

ICMART (International Council of Medical Acupuncture and Related Techniques)

IVAA (International Federation of Anthroposophic Medical Association)

KB (Kneipp-Bund eV)



The Roadmap for
European CAM Research

A pan-European research network for Complementary and Alternative Medicine (CAM)

Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebø)

Legal status and regulation of CAM in Europe

Part III - CAM regulations in EU/EFTA/EEA

Solveig Wiesener, Torkel Falkenberg, Gabriella Hegyi, Johanna Hök,
Paolo Roberti di Sarsina, Vinjar Fønnebø

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Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebo)

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Final report of CAMbrella Work Package 2 (leader: Vinjar Fønnebø)

CAMbrella – A pan-European research network for Complementary and Alternative Medicine (CAM)

The goal of this collaboration project was to look into the present situation of CAM in Europe in all its relevant aspects and to create a sustained network of researchers in the field that can assist and carry through scientific endeavours in the future. Research into CAM – like any research in health issues – must be appropriate for the health care needs of EU citizens, and acceptable to the European institutions as well as to national research funders and health care providers. It was CAMbrella's intention to enable meaningful, reliable comparative research and communication within Europe and to create a sustainable structure and policy.

The CAMbrella network consists of academic research groups which do not advocate specific treatments. The specific objectives were

- To develop a consensus-based terminology widely accepted in Europe to describe CAM interventions
- To create a knowledge base that facilitates our understanding of patient demand for CAM and its prevalence
- To review the current legal status and policies governing CAM provision in the EU
- To explore the needs and attitudes of EU citizens with respect to CAM
- To develop an EU network involving centres of research excellence for collaborative research.

Based on this information, the project created a roadmap for research in CAM in Europe. The roadmap sums up and streamlines the findings of the whole project in one document that aims to outline the most important features of consistent CAM research at European level.

For other reports of the CAMbrella project which are also available on <https://phaidra.univie.ac.at/> see the additional information on the description data (meta-data) of this report.

Foreword

CAMbrella Work Package 2 (WP2) - Legal Status and regulation of CAM in Europe

This report is developed by WP2 in the CAMbrella consortium in the period January 1, 2010 to April 30, 2012, and has been updated in the period from May to October 2012. The present report represents the updated version from November 5, 2012.

The aim of this work package was to review and describe in all 27 EU member states as well as 10 associated states (later expanded with two additional countries):

- The legal status of CAM
- The regulatory status of CAM practices
- The governmental supervision of CAM practices
- The reimbursement status of CAM practices and medicinal products
- The regulation of CAM medicinal products

An additional aim was to review at the EU level:

- The status of EU-wide regulation of CAM practices and medicinal products
- The potential obstacles for EU-wide regulation of CAM practices and medicinal products

The country-specific status has been described on the basis of publicly available legal and regulatory documents supplemented by personal visits to a purposive sample of countries. The status with regard to regulation of CAM medicinal products and the EU-wide regulation of CAM has been described on the basis of publicly available legal and regulatory documents only.

The work of WP2 **Legal status and regulation of CAM in Europe** is presented in **three separate reports**:

1. Part I - CAM regulations in the European countries
2. Part II - Herbal and homeopathic medicinal products
3. **Part III - CAM regulations in EU/EFTA/EEA (present report)**

All reports are available on <https://phaidra.univie.ac.at/>.

Tromsø, Norway, November 5, 2012

On behalf of WP2 in CAMbrella,

Solveig Wiesener and Vinjar Fønnebø

Acknowledgement

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Summary

This report describes legislation, Regulations and Resolutions in the European Union (EU) and the Council of Europe that may influence the professional practice of CAM, whether practised by an authorized/licensed health care provider or by a provider without such authorization/licensing. This system of European-wide legislation will also affect the conditions under which patients are receiving CAM treatment(s) in Europe.

We have found no direct EU legislation of CAM except for Directives concerning CAM medicinal products (to be described in WP2 report part II). Two Resolutions deal with non-conventional medicine:

- ***The status of “non-conventional medicine”. Resolution A4-0075/97***
The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation.
- ***A European Approach to non-conventional medicines. Resolution 1206(1999)***
The Parliamentary Assembly of the Council of Europe Resolution on non-conventional medicine.

How legislation connected to “the Four Freedoms” is handled in EU/The European Economic Area (EEA) influences the individual states’ national CAM legislation and legislation that impacts directly or indirectly on CAM. Of particular interest is how patients and health professionals are able to relate to diverse national CAM regulations. European CAM practitioners have different levels of training as a basis for their practice, whether they are formally licensed or not, and patients have varying expectations depending on experiences from their home country. This heterogeneous situation influences CAM patients’ rights, access and potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new Cross-border Healthcare Directive 2011/24/EU.

Harmonization of training and regulation of non-conventional disciplines is only marginally covered in the Directive 2005/36/EC Professional Qualifications. In many states only doctors or other health professionals are allowed to practise CAM according to national health regulation. The EU regulated professionals database includes only a few CAM professions in some member states. We have thus found that the Resolutions on the status of non-conventional medicine from 1997 and 1999 have not been followed up with harmonized CAM training or regulation.

The Council of the EU invites the Commission to integrate gender aspects in health policy and research. Research confirms gender-related differences in health and the use of CAM treatments. Further analyses on those aspects are needed to develop knowledge-based CAM regulation in the EU.

The European Parliament Resolution on non-conventional medicine from 1997 stated that non-conventional medicine disciplines should be clearly identified and defined. We have found few overall clear distinctions between conventional and non-conventional medicine in the EU legislation. An adequate regulation and supervision of CAM professionals and CAM therapies will require special knowledge in the CAM field to take into account the special features of this field of health care. Developing the European legislation of CAM by simply adapting the criteria of conventional medicine will probably be inadequate for regulation of the CAM field.

The most important obstacles that hinder the European Parliament Resolution call for “a process of recognizing non-conventional medicine” are the Treaties of Rome and Lisbon clearly stating that the individual member state has the responsibility for “the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them”. This legitimizes and sustains the wide variations in CAM regulation across Europe.

Another obstacle is the unwillingness of the individual European country to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a larger degree, both patients and providers would be able to benefit from both “The right to move and reside freely” Directive, “The Professional Qualifications” Directive “The Cross-Border Healthcare Directive”, as well as the Services and the Social Security Directives.

The European Parliament Resolution on non-conventional medicine from 1997 stated that non-conventional medicine disciplines should be clearly identified and defined. The Resolution also calls on the Commission “to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees”.

In contrast to this, the EU treaties have repeatedly established that health policies are a national responsibility for the member states even if several EU Directives, Regulations and Resolutions increasingly impact on how member states organize their national health policy and services.

The Cross-border Healthcare Directive, in particular, respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedoms that enable patients from one EU member state to choose to seek treatment in another EU member state and clarifies the responsibilities of EU member state health systems as providers to patients crossing borders. Regional collaboration between providers, purchasers and regulators from the different member states can ensure safe, high-quality and efficient cross-border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to potentially facilitate cross-border opportunities in the CAM area more than EU-wide Directives, Regulations and Decisions.

We think it is important to encourage individual states within culturally similar regions to voluntarily harmonize their CAM legislation and regulation. If this does not happen, and the EU sees such harmonization as valuable it might need to reconsider its general respect for member states' health care organizational diversity.

1 Introduction

The present report constitutes one part of the CAMbrella Work Package (WP) 2 Reports labelled under the superordinate “Legal status and regulation of CAM in Europe”(1). The present part III provides an overview on “**CAM regulations in EU/EFTA/EEA**” and describes the status and potential obstacles for EU-wide regulation of CAM. EU-wide regulation of *CAM medicinal products* is included in *WP2 Report part II* on regulation of medicinal products. This is due to the close connection between the EU-wide regulation and country-specific regulations of medicinal products (1).

Of special interests are how CAM-related issues are regulated at the EU/EFTA/EEA level and how those regulations influence national health legislation and regulation. Findings of national CAM legislation is described in the WP2 Report part I – legislation of CAM in 39 European countries.

At the EU/EFTA/EEA level CAM is only regulated indirectly through legislation affecting health-care related issues. This report will therefore make a comprehensive review of this general legislation and regulations. Some of the states included in the three CAMbrella WP2 reports are full EU members; others are affiliated to the EU through various legislation and agreements. This will determine how EU legislation and regulations influence the states’ national legislation. This report will therefore present a short summary of the general EU regulatory systems and how the European states are linked to those systems.

2 Aim

The objectives covered in this report are to review at EU level:

- The status of EU-wide regulation of CAM practices.
- The potential obstacles for EU-wide regulation of CAM practices.

3 Methods

As an introduction we made a comprehensive overview of matters that may influence CAM in the European legislation. Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary both in the European Union bodies and within the 39 countries included in this report. To address CAM-related legislation in the EU, we included both the EU legislation that influences the member states’ national health legislation and various aspects of EU regulation of conventional medicine.

A search was performed in the web sites/databases **EUROPA and EUR-lex** to identify the European Union official law documents. We searched for information about EU Directives and Regulations regarding CAM, and their EU/EFTA/EEA implications. We also included items on other health issues, including legislation in progress, relevant for CAM. In addition we searched for Decisions, News, Resolutions and relevant Information from the European Commission, the European Parliament and the Council of Europe.

A personal visit was made to **the European Union offices and NGO bodies in Brussels** to establish firsthand, updated information and perform a quality check on the findings from the literature search. Meetings were held with:

- Counsellor for health and food safety at the Mission of Norway to the EU.
- The European Commission Central Library.

At the Mission of Norway to the European Union we received updated information mainly on the EFTA/EEA legal connection to EU legislation and the new Cross-border Healthcare Directive 2011/24/EU. The European Union Commission Library assisted in searching for CAM legislation documents.

Meetings with the following NGOs gave important additional CAM information:

- **IVAA** (International Federation of Anthroposophic Medical Associations) and **ICMART** (International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.
- **AESGP** (The Association of the European Self-Medication Industry).

At AESGP we received information about the EU regulation of medicinal products. Regulation of CAM medicinal products will be reported in the CAMbrella project WP2 Report No. 2.

We have also collected information from the **European CAM associations/coalitions** and other **CAMbrella stakeholders** (Listed in [Attachment 1](#)).

3.1 Countries included in the report and their legal connection to EU

This report covers 27 EU member states as well as 12 associated states. Each state is influenced by the EU legislation and has adjusted their national legislation depending on their connection to EU.

3.1.1 The European Union includes 27 member states

12 states became members in 1993 (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, United Kingdom).

3 states left EFTA and became members of EU in 1995 (Austria, Finland, Sweden).

10 states became members of EU in 2004 (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia).

2 states became members of EU in 2007 (Bulgaria, Romania).

It is of special interest to know if and how national CAM-related legislation has changed in the 12 member states joining EU in 2004 and 2007 in response to health- and medicinal-related Directives and Regulations in the EU. It is also of interest to see if the original EU member states have a more homogenous CAM legislation than the new EU member states (described in WP2 report part I).

3.1.2 EFTA - The European Free Trade Association includes 4 states

In 2011 EFTA includes Iceland, Liechtenstein, Norway and Switzerland.

Most important for the CAM legal and regulatory area is that EFTA and the EFTA member states amend their national legislation in accordance with EU legislation to a certain extent. However, most of the EU legislation of interest for CAM is approved unchanged in the EEA legislative system. Since all the EFTA countries except Switzerland have joined EEA, the specific EFTA legislation will not be reviewed in this report. For EEA details, see below.

3.1.3 EEA - The European Economic Area

EEA unites the **27 EU member states** and **3 of the 4 EFTA States** (Iceland, Liechtenstein and Norway) in an Internal Market. Switzerland (EFTA member state) enters into bilateral agreements with EEA in some areas. Free trade agreements have been signed between EFTA/EEA and Turkey, Israel, Macedonia, Croatia, Albania and Serbia (among others).

3.1.4 The European Commission Seventh Framework Programme (FP7) (8 states)

The following **8 additional countries** are included in this report since they are connected to the FP7 research programme by the following **third country agreements**:

- **Israel (EC)** – the Science and Technology Agreement 2007

- **Croatia, the Former Yugoslav Republic of Macedonia, Montenegro*** and **Turkey** (EC)/candidate countries, “Memorandum of understanding”
- **Albania, Bosnia & Herzegovina, Serbia** (EC)/potential candidate countries, “Memorandum of understanding”

*Montenegro was at the starting time of CAMbrella a potential candidate country.

Note:

The EFTA countries **Iceland, Liechtenstein and Norway** are connected to FP7 through - Article 1 of protocol 31 of the **EEA agreement** amended on 15 June 2007 by a decision of the EEA Joint Committee.

The EFTA country **Switzerland** is connected to the FP7 programme with the following agreement: (European Commission (EC) and Euratom (nuclear weapon)) The Science and Technology Agreement.

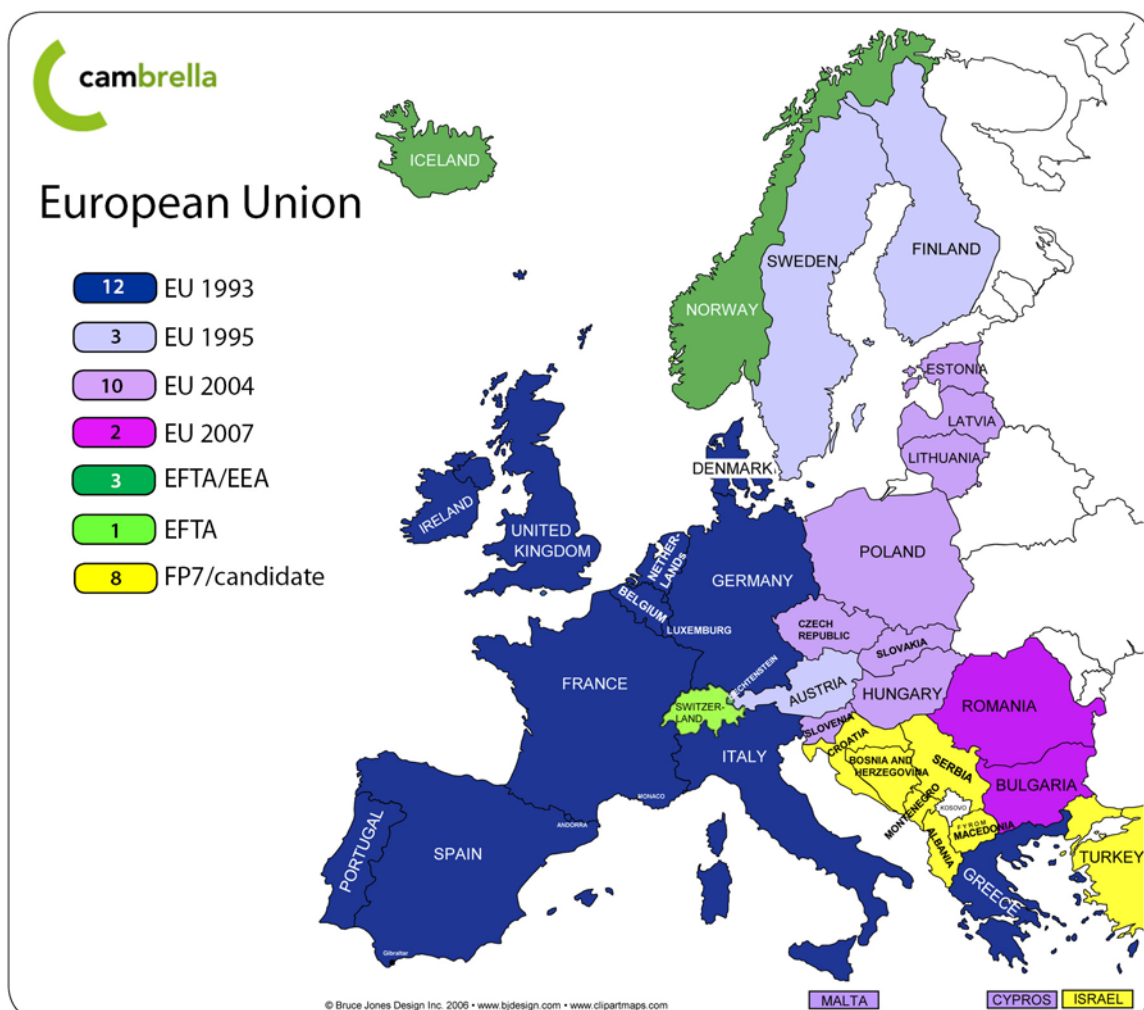


Figure 3-1 Country relationship to the European Union

Table 3-1: Country membership (X) to EU/EEA/EFTA, Council of Europe and FP7 (Seventh Framework Programme)

| Countries | EU | EEA | EFTA | Schengen | The Council of Europe |
|------------------------|--------------------------|----------------------|-----------------|----------|-----------------------|
| Albania | Potential candidate, FP7 | | Trade agreement | | X |
| Austria | X 1995 | X | | X 1997 | X |
| Belgium | X | X | | X 1995 | Founding member (FM) |
| Bosnia and Herzegovina | Potential candidate, FP7 | | | | X |
| Bulgaria | X 2007 | X | | | X |
| Croatia | Candidate, FP7 | | Trade agreement | | X |
| Cyprus | X 2004 | X | | | X |
| Czech Republic | X 2004 | X | | X 2007 | X |
| Denmark | X | X | | X 2001 | FM |
| Estonia | X 2004 | X | | X 2007 | X |
| Finland | X 1995 | X | | X 2001 | X |
| France | X | X | | X 1995 | FM |
| Germany | X | X | | X 1995 | X |
| Greece | X | X | | X 2000 | X |
| Hungary | X 2004 | X | | X 2008 | X |
| Iceland | Candidate, FP7 | X | X | X 2001 | X |
| Ireland | X | X | | | FM |
| Israel | FP7 | | Trade agreement | | - |
| Italy | X | X | | X 1997 | FM |
| Latvia | X 2004 | X | | X 2007 | X |
| Liechtenstein | FP7 | X | X | | X |
| Lithuania | X 2004 | X | | X 2007 | X |
| Luxembourg | X | X | | X 1995 | X |
| Macedonia | Candidate, FP7 | | Trade agreement | | X |
| Malta | X 2004 | X | | X 2007 | X |
| Montenegro | Candidate, FP7 | | | | X |
| Netherlands | X | X | | X 1995 | FM |
| Norway | FP7 | X | X | X 2001 | FM |
| Poland | X 2004 | X | | X 2007 | X |
| Portugal | X | X | | X 1995 | X |
| Romania | X 2007 | X | | | X |
| Serbia | Potential candidate, FP7 | | Trade agreement | | X |
| Slovakia | X 2004 | X | | X 2007 | X |
| Slovenia | X 2004 | X | | X 2007 | X |
| Spain | X | X | | X 1995 | X |
| Sweden | X 1995 | X | | X 2001 | FM |
| Switzerland | FP7 | bilateral agreements | X | X 2008 | X |
| Turkey | Candidate, FP7 | | Trade agreement | | X |
| United Kingdom | X | X | | | FM |

4 The EU/EFTA legal and regulative system

The European Union Law operates alongside the legal systems of the individual EU member states and consists of Treaties and Laws (Directives, Regulations, Decisions (Court Judgments)). The EU legislation is **based on the EU treaties** and the **legislative acts** are expressed through **Regulations, Directives or Decisions**.

The EU and EFTA countries (including candidate countries) relate to these levels of legislation that may influence CAM¹ (Complementary and Alternative Medicine) in addition to national legislation.

4.1 The EU Treaties

The legislation of interest for this report is mainly based on the 1958 Treaty of Rome followed up by **the 2007 (Entered into force December 1, 2009) Treaty of Lisbon with the Four Freedoms** (the requirements that goods, services, capital and persons **are to move freely** within the EEA); article 168 includes common safety concerns and measures setting high quality standards for public health, quality and safety for medicinal products and devices for medical use, research and cross-border areas.

The EU Treaties have repeatedly established that health policy is **a national responsibility** for the member states. This is adjusted and confirmed in the Lisbon Treaty² (2) in TITLE XIV Public Health Article 168 number 7:

“7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.”

This statement is important to keep in mind when describing legislation and regulation of CAM in the European Union. Despite this statement, several EU Directives and Regulations do influence how the member states organize their national health policy and services.

¹ EU uses the notion “non-conventional medicine”

² OJ C 306 17.12.2007, p. 01

4.2 The Regulations, Directives and Decisions

Directives, Regulations and Decisions have effect within the EU's member states either with local adjustments to national legislation or precedence over national legislation. The EU Parliament non-legislative Resolutions are recommendations and political statements only.

EU Regulations are adopted by the Council and considered as directly enforceable law in all the member states. Regulations do not need to be implemented into national legislation, because they come into force immediately on publication. They cover general measures that are binding for all states. (Note: National regulations within the member states are not the same as EU Regulations).

EU Directives are addressed to the member states and are intended to align national legislation. How the individual member states implement the Directives in national legislation is left to the member states.

EU Decisions refer to decisions taken by the European Court of Justice and address individuals. These are automatically binding upon those individuals (individuals and member states) to which they are addressed, but can have a potential influence in creating new EU legislation or modifying existing EU legislation.

Of interest for CAM is how the different implementations of EU legislation both in time and content influence variations in regulation of CAM practices and patients' rights and safety in the member states.

4.3 EEA - legislation and procedures

The EEA agreement is based on the EU treaties (e.g. Treaty of Rome, Treaty of Lisbon), legislation (EEA relevant Regulations, Directives, Decisions) and on certain non-binding instruments adopted by the EU institutions on an on-going basis)(3).

The EU "Treaty of Lisbon" with "**the four freedoms**" is included in the EEA agreement. "**The four freedoms**" aim to enable goods, services, capital and persons **to move freely** within the EEA. **Education, training, employment, enterprise and civil protection** are among the fields that are handled within EEA. Relevant legislation is incorporated into the EEA agreement by decisions of the **EEA Joint Committee**. The non-EU EEA member states can negotiate adaptations to EU legislation, while for the EU countries the EU legislation is already binding.

The non-EU EEA member states have not transferred national legislative competences to the EEA institutions. Consequently, Iceland, Liechtenstein and Norway amend the EU/EEA Directives to national legislation in the same manner as the EU member states. Regulations and Decisions are automatically binding for the EU member states and individuals without

national legal amendments. However, for the non-EU EEA member states such documents have to be amended to national legislation.

Of interest for CAM is how “the four freedoms” are handled in EEA and whether the Regulations, Directives and Decisions influence the member states’ national CAM-related legislation differently. WP reports part I and II give an overview on potential national legislation regarding CAM practices, treatments, medicinal products and patients’ rights and safety, which is connected to or based on EU legislation.

4.4 EU Directives, Regulations and Decisions of importance for CAM

In this chapter we will list the legal documents passed in the European Union with potential impact on CAM legislation in EU/EFTA/EEA. The content of each document is thereafter described from a CAM perspective.

- **“The Schengen Agreements”. DIRECTIVE 2004/38/EC³ (4)**
of the European Parliament and of the Council of 29 April 2004: on the right of citizens of the Union and their family members to move and reside freely within the territory of the member states.
- **Social security, REGULATION (EC) No 883/2004⁴ (5)**
of The European Parliament and the Council of the European Union of 29 April 2004 on the coordination of social security systems.
- **“The Service Directive”, DIRECTIVE 2006/123/EC⁵ (6)**
of the European Parliament and of the Council of 12 December 2006: on services in the internal market.
- **Professional Qualifications, Directive 2005/36/EC⁶ (7)**
of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance). The Directive included in this report is **amended up to 24 March, 2011⁷(8)**.
- **The Cross-border Healthcare Directive 2011/24/EU⁸ (9) (“The Patient Rights Directive”)**
of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare.

³ OJ L 158, 30.4.2004, p.77-123

⁴ OJ L 166, 30.4.2004, p.1

⁵ OJ L 376, 27.12.2006, p.36

⁶ OJ L 255, 30.9.2005, p.22

⁷ 2005L0036 — EN — 24.03.2011 — 006.001 — 1

⁸ OJ L 88, 04/04/2011, p. 0045 – 0065

4.5 The right to move and reside freely- Directive 2004/38/EC⁹(4)

The Directive 2004/38/EC(4) was brought into force within the member states by 30 April 2006 and gives detailed regulations of the right to move and reside freely in the EU.

Free movement of individuals and family members within the member states is one of the 4 pillars of the EU and is a fundamental right of EU citizens. They can stay in another country for 3 months unconditionally. The right is conferred directly by the Treaty, and is not dependent upon administrative procedures. After 5 years of staying in another EU country they can acquire the right of permanent residence. Workers or self-employers have the right to stay up to 5 years when employed or self-employed.

Citizens from other member states shall be given access to equal treatment as nationals in areas covered by the Treaty and secondary legislation. The right of free movement implies that individuals observe the laws of their host country, and restrictions can be given on grounds of public security or public policy. Persons who commit crimes in the host member state are subject to the same consequences as the citizens of that member state.

Of interest for CAM is how patients and health professionals are informed of and able to adjust to the national CAM regulations in the EU member states when moving to or travelling between countries in Europe. Practitioners will have different CAM training as a basis for their formal professional licence, and patients will have different expectations depending on what they are accustomed to in their home country. This may influence CAM practices and patients' treatment services. Because of the heterogeneity of the legal situation facing CAM in EU member states it is currently not possible for CAM practitioners to move freely between member states in order to practise professionally.

4.6 Professional Qualifications, Directive 2005/36/EC¹⁰ (7)

The Directive 2005/36/EC came into force in 2007. Included in this report are amendments **up to 24 March, 2011¹¹(8)**. The Directive is an important legal basis for free movement of professionals in Europe. A profession is considered regulated when access to it and the exercise of it are subject to the acquisition of a specific professional qualification.

Chapter I of Title III of Directive 2005/36/EC sets out the general system for the recognition of documentation of training for the purpose of establishment in the host country (10). Professional qualifications are grouped into five levels (see Article 11). Under certain

⁹ OJ L 158, 30.4.2004, p. 77–123

¹⁰ OJ L 255, 30.9.2005, p.22

¹¹ 2005L0036 — EN — 24.03.2011 — 006.001 — 1

restricted conditions (see Article 14), the host country may impose compensation measures, i.e. an adaptation period of up to three years or an aptitude test (10).

Substantial differences between countries regarding training requirements for a given profession can be compensated for if the professional meets a set of qualification criteria known as a 'common platform'. No common platform has been adopted yet (10).

The European Commission database of regulated professions in the EU Member States, EEA countries and Switzerland is covered by Directive 2005/36/EC. The database includes among others the professions falling under the "General System" of mutual recognition of professional qualifications and the "Sectorial professions" benefiting from automatic recognition on the basis of harmonization of minimum training conditions: doctors, nurses, midwives, pharmacists, dentists, veterinary surgeons and architects (10). The database contains professions regulated in the Member States. Detailed conditions for recognition of professional qualifications are found in the Directive 2005/36/EC and its annexes.

Some of the member states have a few CAM professions registered in the EU regulated professions database. Details are described in WP2 Report part I concerning each state's national CAM legislation.

Of special interest for CAM is that we have not found that harmonization of training for CAM professionals constitutes a special focus in the Directive 2005/36/EC Professional Qualifications (7). According to the national health regulation, several member states only permit doctors or other health professionals to practise CAM. Other member states have unilaterally introduced legislation regulating CAM practice by non-licensed health practitioners. We have not found that the Resolution on status of non-conventional medicine from 1997 has been followed up with harmonized training in CAM. See further comments below.

4.7 Patients' rights in cross-border healthcare Directive 2011/24/EU¹² (9)

The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 concerns the application of patients' rights in cross-border healthcare (9).

The Directive supplements the legislation on the coordination of social security schemes (Regulation (EC) No 883/2004) and aims at facilitating access to safe and high-quality cross-border healthcare and cooperation on healthcare between the member states. At the same time the preserving of member states' rights to organize their own healthcare system stands unchanged. The Directive comes into force in national member states' legislation within October 25, 2013, and there are still several unsolved challenges.

¹² OJ L 088 , 04/04/2011 P. 0045 - 0065

When introducing the cross-border healthcare Directive one expects a uniform and coherent health legislation framework for all citizens in Europe. The Directive covers both public and private providers, and patients will have access to information on the quality and safety of the care they will receive. Within specific boundaries it is stated that:

- For hospital care a patient should be free to choose which healthcare provider to use.
- For non-hospital care the patient can seek healthcare abroad without prior authorization or formalities, and claim reimbursement when returning to the home country.
- Medical products prescriptions will be recognized throughout the EU provided that the product has a market authorization and is available in the country.

The Directive emphasizes the patients' rights to access safe and high quality treatment and to be reimbursed for it. Patients shall enjoy equal treatment with the citizens of the country in which they are treated and the treatment shall be based on quality and safety standards of healthcare (Memo/11/32 Brussels 19 Jan 2011 Press release).

Rules on information and assistance to patients, and guidelines on how national legislation will be affected, will be developed (EU Commission 2 July 2008).

4.7.1 Reimbursement of cross-border healthcare treatment

The cross-border healthcare Directive regulates patients' rights to reimbursement of treatment received in other member states of EU/EEA. It shall not influence on the rights according to regulation EC NO 883/2004 –27 (social security) of refund of cost of healthcare when temporarily staying in another member state.

Reimbursement will be given according to the following guidelines:

- The reimbursed amount will be equal to the cost in home state for the same type of healthcare.
- The member states must inform patients about the reimbursement tariffs.
- Treatment abroad can be reimbursed when not available in the home country.
- Reimbursement will correspond to the national "health benefits package".

Prior authorization from home state is necessary:

- For healthcare which involves overnight hospital stay of at least one night.
- For highly specialised and cost-intensive healthcare.
- In serious and specific cases where the quality or safety of the care provided abroad can be questioned.

Authorization can be refused

- If the treatment or healthcare provider could represent a risk for the patient.

- If the healthcare can be provided at home within reasonable time (This decision must be explained by the member state).

The cost of the chosen health care must be paid upfront by the patient. Member states can choose to confirm the amount they will reimburse in writing before the treatment is given.

***Of special interest** is how the cross-border healthcare legislation in the member states and in the EU will influence CAM practitioners and patients' rights in relation to CAM treatments. To clarify this, every issue pointed out by the Parliament and the Council of the European Union regarding this Directive could be described from a CAM perspective.*

5 EU Resolutions, Information and Questions of importance for CAM

In this chapter we list EU Resolutions, Information and Questions of interest for CAM. Thereafter we describe the content of the documents with a CAM perspective.

- **The status of “non-conventional medicine”. Resolution A4-0075/97¹³ (11)**
The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation.
- **Common values and principles in health systems, 2006/C 146/01 I (Information) Council 22.6.2006 C 146/1¹⁴(12).**
The Council of the European Union conclusions on Common values and principles in the European Health Systems.
- **Women’s health. 2006/C 146/02 I (Information) Council 22 June 2006 C 146/2¹⁵(13).**
The Council of the European Union conclusions on women’s health.
- **Question from The Greek Association of Homeopathic Medicine, 2001¹⁶(14).**
A question forwarded to the Commission about recognition of doctors practicing homeopathy.
- **Question about Naturopathy from Christina Muscardi, 17 June, 2002¹⁷(15).**
A question forwarded to the Commission regarding the recognition of naturopathy.

¹³ OJ C 182, 16/06/1997 P. 0067

¹⁴ 2006/C 146 01

¹⁵ OJ C 146 22.6.2006

¹⁶ E-2297/01

¹⁷ E-1734/02

5.1 Resolution on the status of non-conventional medicine. OJ C 182, 16/06/1997 P. 0067¹⁸ (11)

The European Parliament in this Resolution indirectly calls on the Commission to formulate European legislation in the area of **non-conventional forms of medicine**. They outlined specific areas that should be emphasized and linked to the legislation. Areas of importance were connections to conventional medicine, regulation and training of health professionals, medicinal products and European citizens' rights and consumer protection.

“Non-conventional medicine” was previously used as the EU term for “alternative medicine”, “natural medicine” and “complementary medicine”. In the EU FP7 R&D Framework programme 2007-2013 and the current EU Health Framework programme 2008-2013 the term used is “complementary and alternative medicine”. (*Remark: in the CAMbrella reports the notion is mostly “complementary and alternative Medicine (CAM)”*).

The Resolution underlined that the suggested activities on non-conventional medicine should focus on legislation and research on:

- Quality and safety of non-conventional medicinal products; including homeopathic medicinal products and food supplements.
- The effectiveness and regulation of other therapeutic methods than conventional therapies, **“in particular chiropractic, homeopathy, anthroposophic medicine, Chinese traditional medicine (including acupuncture), shiatsu, naturopathy, osteopathy, phytotherapy, etc.”**
- Making a clear distinction between alternative and complementary non-conventional medicine disciplines.
- Developing harmonized forms of legislation and recognition of non-conventional medicine at the European level and within the member states.

With regard to health professionals (doctors mentioned specifically) the Resolution emphasizes the right to provide the treatment that they think will be the best for their patients. The Resolution outlines that the Treaties' rights on free movement of persons and freedom of establishment in the member states should not be limited by heterogeneous regulation of non-conventional medicinal therapies and providers.

The Resolution underlined the patients' rights to choose treatment, to be protected against unqualified individuals, to be guaranteed maximum safety and have access to accurate information.

The development of the legislation in this field in the European Union is described below. See particularly the EU legislation on ***the right to move and reside freely - Directive***

¹⁸ OJ C 182, 16/06/1997 P. 0067

2004/38/EC¹⁹(8) and The Cross-border Healthcare Directive. /2011²⁰(“The Patient Rights Directive”) (9).

The Resolution established that non-conventional medicine disciplines should be clearly identified and defined. Consequently the legislation in the European bodies and in the member states’ **national legislation** should be developed so they would become **more homogeneous**. To outline the development on this issue the national regulation of some of the main treatments mentioned above is described in the CAMbrella WP2 report part I “Legal, regulatory, supervisory and reimbursement status for each member state and the associated states”.

The Resolution stated that **training criteria** for non-conventional medical providers should be **harmonized**, and training of conventional health professionals should include an introduction to non-conventional disciplines. **Mutual recognition of qualifications** of health personnel in Europe has been developed through **Directive 2005/36/EC²¹ Professional Qualifications (7)**, but does not make any specific reference to CAM disciplines.

The Resolution emphasises research on effectiveness and safety of non-conventional medicine therapies and medicinal products. Directives of importance are **Directive 2001/83/EC²²(16)** relating to medicinal products for human use, Directive 2004/24/EC²³(17) as regards traditional herbal medicinal products²⁴ and Directive 2002/46/EC on food supplements²⁵(18). Development of the European legislation on medicinal products and food supplements is described in the CAMbrella WP2 Report part II on CAM medicinal products.

Note that this Resolution is merely an indication of where the parliament would like the EU to move in the future. The Lisbon treaty still stands: “**Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care**”.

¹⁹ OJ L 158, 30.4.2004, p. 77–123

²⁰ 2008/0142 (COD)

²¹ OJ L 255, 30.9.2005, p.22

²² OJ L 311, 28.11.2001, p.67

²³ OJ L 136 30.4.2004, p.85

²⁴ Amended Directive 2001/83/EC

²⁵ OJ L 183, 12.7.2002, p. 51

5.2 Common values and principles in health systems, 2006/C 146/01 I (Information) Council 22.6.2006 C 146/1²⁶(12)

“The Council of the European Union conclusions on Common values and principles in European Health Systems” is an Information statement by the 25 Health Ministers of the European Union, built on discussions that have taken place in the European Council and with the Commission. The Council notes in this Information that the Commission has decided that healthcare services are exempt from the scope of the Directive on services in the internal market. There is a need to clarify the interaction between the EC Treaty provisions on the free movement of services and the health services provided by national health care systems.

The Council notes that the member states have different approaches regarding treatment reimbursement, payment and equity; terms of the rights of patients as well as obligations of healthcare providers. The document establishes that the member states should provide good quality care through training of healthcare staff based on clearly defined national standards to ensure best practice.

The Council underlines that an important part of the agenda relates to the principle of safety. There must be a systematic approach to ensure patient safety including monitoring risk factors, adequate training for health professionals and control with misleading advertising of health products and treatments. Emphasis must be given to evidence and ethics.

Finally the document confirms that the member states should work together through the Commissions High Level Group on Health Services and Medical Care or Open method of Coordination on healthcare and long-term care to standardise the health systems. The Council concludes in this Information that health systems are a fundamental part of Europe’s social infrastructure.

A question for CAM is whether or not the “Common values and principles for European Health Systems” apply to CAM services. These services are differently regulated in the European member states and many CAM services are not formally recognized or regulated as “healthcare services”. Consequently, if CAM treatment is not included in “healthcare services” the Common values will be very differently integrated in the European countries.

²⁶ 2006/C 146 01

5.3 Women's health. 2006/C 146/02 I (Information) Council 22.6.2006 C 146/2²⁷(13)

"The Council of the European Union conclusions on women's health" is an Information statement looking into the health status of women, gender specific data on health and the relationship between gender and health. The Council of the European Union invites the Commission to integrate gender aspects in health policy and research.

A number of research studies confirm a higher prevalence of CAM use among women and gender-related differences in health and the use of different CAM treatments.

Of interest for CAM is to further analyse the differences of CAM use between men and women, how this is taken into consideration and possibly influences CAM legislation, reimbursement, CAM practices and patient treatment choices in Europe.

5.4 Question from The Greek Association of Homeopathic Medicine, 2001²⁸(14)

The Greek Association of Homeopathic Medicine addressed in 2001²⁹(14) a question to the Commission about recognition of doctors practicing homeopathy. They asked how the Commission intended to ensure terms of equality throughout the European states for doctors practising homeopathy. The answer confirmed that the member states are free to organize the recognition of health professionals on its own territory. To initiate harmonization of professions on a European level three conditions have to be met:

- *"A high level of consensus among the representative professional associations*
- *Support from a large majority of member state authorities*
- *Certainty that such an initiative will significantly add value to the existing system of recognition.*
- *And unanimity within the Council would also be required before a text can come into force at European level".*

None of these conditions have been met, concluded the Commission in 2001.

²⁷ OJ C 146 22.6.2006

²⁸ E-2297/01

²⁹ E-2297/01

5.5 Question about Naturopathy from Christina Muscardi, 17 June, 2002³⁰(15)

Christina Muscardi forwarded a question to the Commission on 17 June, 2002³¹(15) regarding the recognition of naturopathy. The question described the increasing use of alternative medicine and numbers of practitioners that provide such treatment and asked:

“In which countries is the profession of naturopathy legally recognized? Is there a European form of recognition? If not, could it consider it useful and appropriate to take steps to promote the recognition...?”

The Commission answered in the same direction as in 2001(homeopathy question); “no widespread consensus exists of at least some of the activities concerned (acupuncture, homeopathy, phytotherapy, naturopathy) and no coordination exists of the conditions of education and training of CAM professionals at the Community level” The Commission mentions that **22 different titles of physiotherapist** are regulated in the European countries.

The Commission **defines a profession to be regulated** “when there is an **administrative, regulatory or other legal requirement to hold a diploma or other occupational qualifications** in order **to pursue the profession** in question”. Finally in the answer the Commission re-confirms that also the recognition of treatments lies with the member states.

³⁰ E-1734/02

³¹ E-1734/02

6 The Council of Europe

The Council of Europe is not included in the European Union legislative system. However, they have passed one **CAM Resolution in 1999** as a follow-up of the European Parliament Resolution on the status of non-conventional medicine from 1997(11).

A European Approach to non-conventional medicines. Resolution 1206(1999) (19).

The Council of Europe is “an international organization in Strasbourg which comprises 47 countries of Europe. It was set up to promote democracy and protect human rights and the rule of law in Europe”(20). Except for Israel, all the countries included in the WP2 CAMbrella reports are members of the Council of Europe.

The Parliamentary Assembly outlines in the Resolution 1206(1999) 8 points on how non-conventional medicines should be met with a common approach in Europe. At the same time as they confirm the importance of preserving national legislation, they encourage the recognition of non-conventional medicines and the patients’ freedom of choice in European health care. The Resolution supports the European Parliament **Resolution A4-0075/97³² The status of “non-conventional medicine”(11)(see below)** which emphasizes the importance of research programmes especially on safety and effectiveness of CAM medicines.

The importance of professional training is discussed in the Resolution, both for doctors and for other practitioners of non-conventional medicines. University courses and official recognition are pointed out as important efforts to strengthen this field.

³² OJ C 182, 16/06/1997 P. 0067

7 Discussion on CAM aspects related to EU/EFTA/EEA legislation and regulations

In the report we have pointed out legislation, Regulations and Resolutions in the European Union and the Council of Europe that may influence the professional practise of CAM, whether practised by an authorized/licensed health care provider or by a provider without such authorization/licensing. This system of European-wide legislation, Regulations and Resolutions will of course also affect the conditions under which patients are receiving CAM treatment(s), of which patient safety is central.

7.1 Basic framework of European CAM treatment

Although the Regulations and Directives listed in this document all influence indirectly the practice of CAM in Europe, the intention of the European Parliament outlined in its 1997 Resolution(11), has not been achieved. The calls on the Commission given in the Resolution have only partly been implemented.

7.2 The Treaty of Lisbon – basic framework of EU health regulation

The basic framework of EU regulation reformulated in the 2007/2009 Treaty of Lisbon stands unchanged: ***“Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care”***. With CAM seen as a part of health policy and/or “health services and medical care” in each individual EU member state, the (lack of) EU regulation influences the **treatment choices** for patients seeking CAM.

7.2.1 Treatment offered

Due to the individual state’s responsibility for the organization of health care, European citizens experience a diverse situation with regard to how CAM treatments are offered.

In some countries (for example Germany, Hungary and France) only authorized/licensed personnel can legally treat patients. This means that patients can assume that the treatment providers are either conventional health care workers or are treatment providers with a separate CAM authorization/license. These approvals follow the fulfillment of requirements outlined by the countries’ health authorities. Providers operating outside of this system of

authorization/licensing are not allowed to treat individuals with health conditions, and sometimes operate as “health counsellors”.

At the other end of the spectrum we find Norway where, in principle, treatment providers can practise without any professional qualification at all. In Norway CAM can be offered by anyone ranging from an authorized/licensed conventional health care worker (with a few limitations), through a well-educated CAM provider, to a common citizen without any qualification.

Anyone will understand that this widely differing system of regulation raises serious challenges when patients are to be ensured “access to safe and high-quality cross-border healthcare and cooperation on healthcare between the member states” according to the Cross-border Healthcare Directive. Patients seeking CAM treatments will, in particular, find the systems so different that any expectation of patient autonomy is unrealistic.

7.2.2 Treatment sought

In conventional medicine there is a relatively high level of predictability with regard to which health professions a patient can gain access to across Europe. The Professional Qualifications Directive established an automatic recognition on the basis of harmonization of minimum training conditions for doctors, nurses, midwives, pharmacists and dentists within the health care system.

In the CAM sector there is some mutual recognition according to the “General System” in the Directive, but patients cannot expect to find the provider of their choice as an authorized/licensed treatment provider in all European countries. They might not even find that the treatment modality they are seeking exists at all in the country they are visiting or moving to.

Realizing that a substantial proportion of European citizens at any one time are seeking CAM treatment, it seems strange that a culturally homogeneous continent like Europe can accept this extremely unpredictable situation for its citizens.

7.2.3 Reimbursement

In Europe insured persons are covered by Article 2 of Regulation (EC) No 883/2004 on the coordination of social security systems⁽⁵⁾ (nationals of a third country are covered by Regulation (EC) No 859/2003). Limitation of treatment under the Cross-border Directive should be without prejudice to the member states’ obligations under **Regulation (EC) No**

883/2004 of The European Parliament and of the Council of 29 April 2004³³(5) on the coordination of social security systems.

If the patient is in a country temporarily and gets sick the reimbursement of treatment costs follows the regulations in the social security systems. If the patient has travelled to another country with the aim to receive treatment following the Cross-border Healthcare Directive(9) the reimbursement will follow the home states' regulations, but this reimbursement will normally only happen after the patient has paid up front.

This system is, however, not directly transferable to CAM. The reimbursement systems of CAM treatments differ widely between the states. Cross-border CAM treatments are currently mostly for patients that can afford the cost of travelling and paying the costs themselves with only partial or no reimbursement in the home state. This means that patients must know how CAM is regulated in the relevant countries according to the Cross-border healthcare or Social Security Directives. However, these two insurance and reimbursement systems are not coherent. The member states can limit reimbursement relating to the quality and safety of the healthcare provided. CAM treatment is generally less documented than conventional medicine and CAM is in many countries not included in the national health supervision system. This means that reimbursement of CAM treatment can be refused because regulation of CAM in the country of affiliation differs from the country of treatment.

The current system, as we see it, is not designed to accommodate CAM treatments. European citizens must assume that CAM treatment received beyond their home legislation has to be covered out-of-pocket.

7.2.4 Safety

The member states have not harmonized their regulatory systems for responding to harm and protection of patients. This includes protection of personal data. CAM treatment is in some countries regulated and supervised as part of the conventional health care system, in other countries not. Consequently how a patient is handled when safety issues arise in connection with CAM treatment is, not surprisingly, also very different between the European member states.

³³ OJ L 166, 30.4.2004, p.1

7.3 Consequences of (lack of) EU regulation on clinical practice of CAM

It is difficult to see how the regulations influence CAM treatments. Is a consequence of this that harmonization of CAM regulations in Europe is a necessary pre-condition for improvement of the patients and CAM providers' access to correct information and safe treatment?

7.3.1 Authorized/licensed health care providers

Directive **2005/36/EC 7 September 2006³⁴(8)** on the recognition of professional qualifications influences the provision of CAM treatment in Europe. Providers of healthcare can work in all the European states under the **DIRECTIVE 2004/38/EC³⁵ (4)** (Rights of Union citizens to move and reside freely). The free movement of persons and services within conventional medicine has been achieved by a mutual recognition of medical qualifications. EU-wide approval of education and certificates are regulated in the **Directive 2005/36/EC(8)** (Amended up to March 2011) for selected health professionals. Included are medical doctors, nurses, midwives, dentists, veterinarians, pharmacists and physiotherapists (for some countries).

For medical doctors the Directive 2005/36/EC(8) facilitates the mutual recognition of conventional medical qualifications (basic training, additional training as general practitioners or medical specialists, if applicable). The system does, however, not recognize their possible additional qualifications in specific CAM therapies. A European-wide recognized medical CAM specialty is not viable at the moment because the length of the existing specialised training courses is less than 3 years of full-time training, and, as stipulated by article 26 of this Directive, new medical specialties can only be included if they are common to at least two fifths of the member states.

The authorized/licensed health care providers with or without a local specialty can practise CAM in another state according to legislation in that specific country. However, such practice is sometimes impossible due to the heterogeneous regulation in Europe.

Obstacles can be:

- Authorizations and licences allowing the practice of CAM differ between states.
- There are differences from state to state with regard to which CAM treatments that can be provided by the authorized/licensed health care providers included in the **Directive 2005/36/EC(8)**.

³⁴ 2005L0036 — EN — 24.03.2011 — 006.001 — 1

³⁵ OJ L 158, 30.4.2004, p.77-123

- Education and training programmes both for health professionals included in the **Directive 2005/36/EC(8)** and for other CAM providers differ from state to state. Consequently a medical doctor in one state could have some training in the CAM field included in the curriculum, while CAM training is not included in the curriculum in another state. Both curriculums are, however, accepted according to the professionals Directive.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practice performed by authorized/licensed health care providers. This ranges from providers with no training in CAM practicing in a state where no, or only a select few, CAM modalities are permitted used by these providers, to, at the other extreme, providers practicing in states where there is considerable CAM training within the current curriculum, post-graduate accredited CME training courses in several CAM modalities, and authorization/licensing of CAM specialists in the respective professions.

This situation raises concerns with regard to the predictability, quality and safety of health care delivery to European citizens by licensed health care providers practicing CAM.

7.3.2 CAM provider without an authorization/license as a health care provider

Directive 2005/36/EC (8) on the recognition of professional qualifications influences the provision of CAM treatment in Europe also for those CAM providers who are not authorized/licensed as health care personnel. A few countries have established separate authorization/licensing for some categories of CAM providers (for example acupuncturists and chiropractors), and these are included in the professional groups regulated by Directive 2005/36/EC. These CAM providers can seek professional recognition within the countries that regulate them. Also CAM providers have a basic right to work in all European states under the **Directive 2004/38/EC³⁶ (4)** (Rights of Union citizens to move and reside freely). However the individualised nature of member states' recognition of CAM professions means they cannot exercise this right across all member states. They can thus possibly be legally recognized in their own country, but not recognized in other EU or EFTA countries(21). With regard to what treatment they are allowed to give, and the provider and insurance regulations within private or public health systems, they are required to follow national legislation/regulations in each state. This severely hampers the free movement of both providers and patients even if the Cross-border Healthcare Directive and Social Security Regulation are in place.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practice performed by providers who are not authorized/licensed health care

³⁶ OJ L 158, 30.4.2004, p.77-123

providers. This ranges from an extreme of being refused to practise at all, because all treatment of people with health conditions is reserved for authorized/licensed health care providers only, to another extreme in some European countries where anyone can practise CAM without any CAM education or training. In a few countries fully trained providers are allowed to practise CAM with an authorization/license on equal terms to an authorized/licensed health care provider.

This extremely diverse situation raises, as in the case of authorized/licensed health care providers, concerns with regard to the predictability, quality and safety of CAM health care delivery to European citizens.

7.4 Obstacles

We have identified three obstacles that hinder the European Parliament Resolution call for “a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees”.

The most important obstacle for this process is the Treaties of Rome and Lisbon clearly stating that the individual state has the responsibility for “the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them”. This legitimizes and sustains the wide variations in CAM regulation across Europe.

The second obstacle is the unwillingness of individual European countries to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a larger degree both patients and providers would be able to benefit from both “The right to move and reside freely” Directive, “The Professional Qualifications” Directive “The Cross-Border Healthcare Directive”, as well as the Service and the Social security Directives.

The third obstacle identified is the unwillingness of some CAM organizations themselves to harmonize their self-regulation across Europe. A number of CAM disciplines have organized themselves at European level and established common professional platforms that have set standards and procedures for voluntary self-regulation across Europe. But the lack of any legal backing at EU level and the lack of a requirement for CAM professionals to register with a professional association in many countries make it hard to firmly exert any common regulatory process across Europe.

Within the current European legal framework we think the second identified obstacle is the one where there is the largest window of opportunity. Sadly, this is also the obstacle with, in our view, the largest discrepancies.

8 Conclusions

The European Parliament Resolution on non-conventional medicine from 1997(11) stated that non-conventional medicine disciplines should be clearly identified and defined. The Resolution also calls on the Commission “to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees”.

In contrast to this, the EU treaties have repeatedly established that health policies are a national responsibility for the member states even if several EU Directives, Regulations and Resolutions influence how member states organize their national health policy and services.

The Cross-border healthcare Directive, in particular, respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedom that enable patients to choose to seek treatment across borders. This could potentially also include CAM treatment in countries where CAM treatment is included in the public health services. Regional collaboration between providers, purchasers and regulators from the different member states can ensure safe, high quality and efficient cross-border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to have the best chance to facilitate cross-border opportunities in the CAM area more than EU-wide Directives, Regulations and Decisions.

We think it is important to encourage individual states within culturally similar regions to voluntarily harmonize their CAM legislation and regulation. If this does not happen, and the EU sees such harmonization as valuable, it might need to reconsider its general respect for member states’ health care organizational diversity.

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Attachment 1: The history of The European Economic Area (EEA)

- EFTA was established in 1960.
- EEC and EFTA - individual countries signed free trade agreements.
- **Original EFTA member states:** Austria, Finland, Iceland, Liechtenstein, Norway, Sweden, Switzerland.
- 6 December, 1992: Switzerland decided by a referendum not to join EEA – since then bilateral agreements have been established in certain areas.
- 1 January, 1994: The Treaty on a European Economic Area entered into force.
- 1 January, 1995: Austria, Finland and Sweden were included in EEA as EU member states.
- 1 May, 1995: Liechtenstein became a full participant in the EEA.
- 2004 and 2007: EEA expanded to include the twelve new member states joining the EU respectively in 2004 and 2007
- Free trade agreements are signed between EFTA/EEA and Turkey, Israel, Macedonia, Croatia, Albania and Serbia (among others).

European CAM associations:

ANME (Association of Natural Medicine in Europe)

CAMDOC Alliance (alliance of the four major European medical CAM umbrella organizations ECH, ECPM, ICMART and IVAA)

ECCH (European Central Council of Homeopaths)

ECH (European Committee for Homeopathy)

ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products (E.E.I.G.))

ECPM (European Council of Doctors for Plurality in Medicine)

EFCAM (European Forum for Complementary and Alternative Medicine)

EHTPA (European Herbal and Traditional Medicine Practitioners' Association)

EICCAM (European Information Centre for Complementary and Alternative Medicine)

ELIANT (European Alliance for Applied Anthroposophy)

EPHA (European Public Health Association)

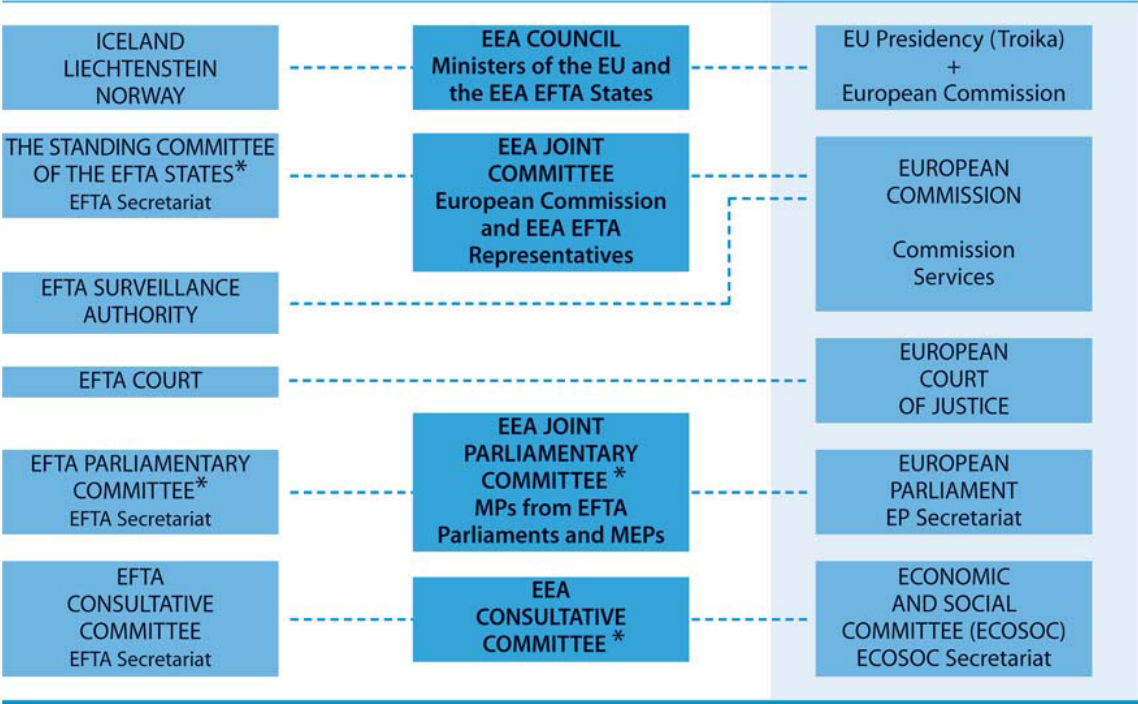
ICMART (International Council of Medical Acupuncture and Related Techniques)

IVAA (International Federation of Anthroposophic Medical Association)

KB (Kneipp-Bund eV)

Attachment 2: The EEA structure

The Two-Pillar EEA Structure



* Switzerland is an observer

This figure illustrates the management of the EEA Agreement. The left pillar shows the EFTA States and their institutions, while the right pillar shows the EU side. The joint EEA bodies are in the middle.

Source: EFTA Fact sheet of the European free trade association - November 2007.

Attachment 3: Historical development of the right to move and reside freely

The states included in the CAMbrella project have developed their national legislation within this field according to their agreements with EU/EEA/EFTA. That means that every state's national legislation for health professionals and patients has to be investigated and compared to the EU legislation.

Below are some of the main documents showing the development in Europe:

Commission Regulation (EEC) NO 1251/70 of 29 June 1970³⁷(22)

on the right of workers to remain in the territory of a member state after having being employed in that state (no longer in force).

Family members who are not nationals of a member state exempt to the requirement to obtain an entry visa (**Council Regulation (EC) No 539/2001** of 15 March, 2001)³⁸(23).

Directive 2004/38/EC(8)³⁹ of the European Parliament and the Council of **29 April 2004** on the right of citizens of the Union and their family members to move and reside freely within the territory of the member states **amending Regulation (EEC) No 1612/EC** and repealing Directives 64/221/EEC, 68/360/EEC 72/194/EEC 75/35/EEC 90/364/EEC and 93/96//EEC (text with EEA relevance).

The European Parliament Resolution of 15 November 2007 on application of Directive 2004/38/EC- P6_TA(2007)0534⁴⁰(24).

Decision of the EEA Joint Committee No 158/2007 of 7 December 2007⁴¹(25) – amending Annex V (Free movement of workers) and Annex VIII (Right of establishment) to the EEA Agreement - Incorporation of the Directive 2004/38/EC.

Report from the EU commission. Brussels 10.12.2008⁴²(26)

from the Commission to the European Parliament and the Council on the application of **Directive 2004/38/EC** on the right of the Union and their family members to move and reside freely within the territory of the member states.

MEMO/09/311- Guidelines⁴³(27) on how to get the best out of Directive 2004/38/EC
Brussels, 2 July 2009.

³⁷ OJ L 142, 30.6.1970, p. 24–26

³⁸ OJ L 81 21.3.2001, p.1

³⁹ OJ L 158, 30.4.2004, p. 77–123

⁴⁰ OJ L P6_TA(2007)0534 B6-0462 and 0464/2007

⁴¹ OJ L 14, 20.1.1975, p. 14–14

⁴² COM(2008) 725 final 10.12.2008

⁴³ MEMO/09/311 02/07/2009

Commission Report 10 December 2008 on the implementation of Directive 2004/38/EC(4).

Citizens from the member states that joined EU recently (see p.2.2.) enjoy unrestricted right of free movement. Transitional arrangements apply only to access to labour markets.

Directive should come into force by 30 April 2006. All the member states had in 2008 implemented the Directive text.

The Directive is incorporated in the EEA Agreement (EEA Joint Committee No 158/2007 of 7 December 2007), but the report writes that in 2008 the Directive 2004/38/EC was not adapted in the non-EU EEA countries Iceland, Liechtenstein, Norway.

The report mentions that the transposition of the Directive is incorrect. Cyprus, Greece, Finland Luxembourg Malta Portugal and Spain had in 2008 small problems of compliance. In other member states crucial provisions of the Directive had been incorrectly transposed.