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Council acts against falsified medicines

The Council today adopted[1] a directive aimed at preventing falsified medicines from entering into the legal supply chain (*3/11* + *10313/11 ADD 1 REV 1*).[2] It herewith acts against the alarming increase of falsified medicines detected in the EU and the public health risk which that poses. The directive amends directive 2001/83 and reflects a first-reading agreement with the European Parliament reached during the Belgian presidency[3].

Falsified medicines usually contain sub-standard or false ingredients, or no active ingredients or ingredients in the wrong dosage. Their infiltration in the legal supply chain poses a particular threat to human health, on the one hand directly since such medicines might deprive patients of effective and necessary treatment, and on the other indirectly as their infiltration might lead patients to lose trust in the legal distribution chain.

The new directive includes inter alia the following provisions to address falsified medicines:

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1 The directive was adopted, without debate, at a session of the Transport, Telecommunications and Energy Council in Brussels.

2 The Latvian delegation abstained.

3 The European Parliament confirmed this agreement in its plenary vote on 16 February 2011.

P R E S S

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- Medicinal products subject to prescription must bear **safety features** which should allow verification of the authenticity and identification of individual packs throughout the supply chain, and provide evidence of tampering. Non-prescription medicines are normally exempt from this obligation. In the light of a risk assessment, it will, however, be possible to extend the scope of safety features to non-prescription medicines for which this turns out to be necessary and to exclude certain prescription medicinal products from the obligation to bear safety features. Re-packaging of medicinal products remains possible, but the safety features must be replaced by equivalent safety features.[1]

- The **manufacture of active substances** intended for use in medicinal products must follow **good manufacturing practice** regardless of whether these ingredients are manufactured in the EU or imported. The manufacture in third countries of active substances which are intended for export to the European Union must provide for a level of protection of public health equivalent to that provided by EU law.

- In order to strengthen the protection of the legal supply chain, importers, manufacturers and distributors of active substances must be registered with the competent authority as brokers of medicinal products. Furthermore, the **manufacturers of medicinal products must verify** that the manufacturer and the distributor of the respective active substances comply with good manufacturing practice and good distribution practices. They must also ensure that the excipients used are suitable for use in medicinal products. Wholesale distributors must verify that their supplying wholesale distributors are authorised.

- **Manufacturers** will be **obliged to inform competent authorities** about medicinal products they suspect of being falsified. A legal basis is created for customs authorities in co-operation with competent authorities to take measures aiming to prevent that medicinal products suspected of being falsified enter into circulation.

- Member states will be obliged to have systems in place that make it possible to **recall falsified or otherwise dangerous medicinal products**.

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[1] Re-packaging of medicines is usually necessary to sell medicines destined for one member state in another member state.

- The new directive also contains provisions aimed at protection patients from receiving falsified medicines through the **sale of medicines via the internet**. Websites offering medicines must be linked to the website of the respective competent authority on which a list of all persons or bodies in that member state that are authorised to offer medicinal products for sale via internet must be available. Furthermore, such webpages must, in order to facilitate identification, display a common logo. These new provisions are without prejudice to member states' right to regulate retail sales of medicinal products.

- Member states must impose **effective penalties** inter alia for the manufacturing, distribution, import and export of falsified medicinal products.

- Member states have **18 months in which to transpose** the new rules into national law.