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Document :	**AEMH 10-007**
Title:	**Info: MEPs amend draft directive on counterfeit medicines**
Author :	**EUROPOLITICS**
Purpose :	**Manon Malhère**
Distribution :	**AEMH Member Delegations**
Date :	**27 January 2010**

EUROPOLITICS
The European affairs daily

Falsified medicines

MEPs to amend draft directive

By Manon Malhère | Tuesday 26 January 2010

The European Commission's proposal for amending the directive on the prevention of the entry into the legal supply chain of falsified medicinal products obviously contains measures to combat the general problem of falsification. For the ENVI committee, however, which discussed its draft report on 25 January, the executive's proposals are not up to the mark. The draft report (1), published on 7 January, proposes around 50 amendments, a number that could continue to rise before the cut-off date of 9 February. The committee is set to vote on 7 March and the report will be brought before the plenary in May.

The protection of public health against falsified medicinal products must be the directive's top priority. The first amendment therefore establishes a dual legal basis, Article 95 (internal market) plus Article 152 (public health).

The report also notes that clearer definitions are needed. The respective roles of all actors in the distribution chain should be clarified, including brokers and traders but also transporters and operators involved in parallel trade. The directive must prevent confusion and rule out all grey areas.

Safety features

Some MEPs have misgivings over the issue of re-packaging of medicinal products - practiced mainly on parallel markets – but the draft report does not intend to ban the practice. However, an amendment states that actors who make changes to labelling or packaging must be holders of a manufacturing authorisation. The Commission's proposal mentions only actors in the supply chain who package medicinal products.

On the safety features of subscription drugs, the draft report provides for the Commission to report to the EP and Council on the application of such safety features and their contribution to reducing the problem of falsified medicines, within five years of the directive's entry into force. The report also recommends the organisation of risk assessment to rank safety features in terms of the risk of falsification of the different categories of medicines. It should also be possible to exempt certain generic drugs from the performance criteria applying to safety features. Another amendment provides for submitting the manufacture of excipients to good manufacturing practices. The Commission's proposal mentions only active pharmaceutical ingredients.

Lastly, MEPs find that the Commission's proposed sanctions are not severe enough. The draft report recommends sanctions at least equivalent to those typically applied for illegal acts related to narcotics.

Internet sales

Given the Commission's silence on the adoption of measures to address the problem of excessive sales of falsified medicines via the internet, the draft report proposes measures to raise public awareness of this problem and to give patients ways of recognising sites that respect legislation. According to the report, the Commission, which dodges the issue of internet sales because it considers them "part of the illegal chain of supply," disregards the fact that some member states have legalised internet sales of medicines. For the Commission, if member states have legalised the practice, there is nothing more EU law can do (see *Europolitics*3872).

(1) The report is available at www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/800/800835/800835en.pdf