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### **Parallel trade “considerable risk” to patient safety, says EC**

*By Lynne Taylor*

The European Commission is to prioritise and speed up moves to deal with the issue of counterfeit drugs in parallel trade and will launch a legislative initiative on the issue after the summer break, Commission Vice President Guenter Verheugen has announced in the European Parliament.

At the end of December 2006, the Commission began a two-part study into pharmaceutical distribution channels. The first part of the study, dealing with safe medicines in parallel trade, was completed at the end of 2007 and the second, covering counterfeit medicines, was due to present this year.

However, Commissioner Verheugen told Parliament last week: “Unfortunately, the first results of the study show that parallel trade brings a considerable risk for the safety of the patients. The reasons for that are numerous - there are problems with the packaging and labelling of the products as well as with product recalls, the complexity of distribution channels and the supply. And finally it is difficult to effectively enforce the law.”

The Commission is now analysing these findings “in order to develop a coherent strategy to avoid these risks,” he told Parliament. Different political options are being examined in terms of their social, economical and ecological effects, but the issue is a priority for the Commission, given its importance for public health policies, and a decision on further procedure will be made in the near future, he said.

This initiative will require a change to the work program of DG Enterprise and Industry, which is headed by Commissioner Verheugen and has responsibility for the pharmaceutical industry, he added.

The Commission Vice President was responding to questions from Mairead McGuinness, Member of the European Parliament (MEP) for Ireland East. She asked him how the Commission planned to respond to last November’s report from the European Alliance for Access to Safe Medicines (EAASM), which warned that counterfeit and sub-standard medicines are now finding their way into the European Union (EU) supply chain.

In particular, she asked, does the Commission plan to tackle this problem by reviewing parallel trade and promoting a genuine single market in pharmaceutical products which, she said, “is in the interests of consumers and appears essential to ensure that the benefits of the internal market, including affordable medicines, extend to all parts of Europe’s economy?”

#### **High priority**

Commissioner Verheugen replied by outlining the plans to prioritise the issue of counterfeits, and continued that additional ways to address parallel trade are currently being explored, in particular with respect to pricing initiatives.

Revision of the transparency directive to include specific information on pricing would also be a possible way forward, he said, but added that the first thing to do is to clarify the situation, know exactly what is happening, and then examine whether EU legislation is able to change it.

"The whole issue of pricing and reimbursement of medicines in the EU is under the full responsibility of the member states; we have no powers whatsoever, but it is obvious that we need to cooperate," which is why pricing and reimbursement is a priority for the Commission, he said.

"I am well aware that, for citizens, the fact that the same medicine has completely different prices in different European member states is difficult to understand. It is also difficult for me to understand. The fact that these prices are regulated is only one factor. Another factor, of course, is that the pharmaceutical industry is part of the market economy. They are free to set their prices, but we are intensely studying the situation and I think that we will be able to present solutions," Commissioner Verheugen told Ms McGuinness.

In its response to the Commission's call for evidence for its probe into safe medicines in parallel trade, the European Federation of Pharmaceutical Industries and Associations (EFPIA) had claimed that EU regulatory authorities "apply two sets of regulatory standards, ie, one set for strict rules applied to the Marketing Authorization holder (or manufacturer) and a set of 'substandard' rules applied to parallel traders. This leads to the belief that the 'free movements of goods' principle appears to be the Commission's overriding objective, superseding objectives such as patient safety or continued appropriate and balanced supplies of medicinal product to all the member states' markets."

The response to the Commission submitted by the European Association of Euro-Pharmaceutical Companies (EAEPIC), which represents parallel traders, stated that: "parallel distribution, the only form of intrabrand price competition which exists in the pharmaceutical market, makes expensive, innovative medicines more affordable for patients and governments." And last November, EAEPIC attacked the EAASM report as "black propaganda" which was about "discrediting the legitimate and safe practice of EU-internal distribution of medicines which introduces price competition for manufacturers."

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