Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

2008/0261(COD) - 10/12/2008 - Legislative proposal

PURPOSE: to prevent the entry into the legal supply chain of medicinal products which are falsified.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: there is an alarming increase in the EU of medicinal products which are falsified in relation to their identity, history or source. These products are, from the point of view of EU pharmaceutical legislation, illegal insofar as they do not comply with the Community rules for medicinal products. Moreover, the number of falsifications of innovative and life-saving medicines is increasing. In this way, in 2007, many thousand packs of falsified life-saving drugs reached patients in the EU.

The underlying causes for falsified medicinal products remaining undetected in the legal supply chain are manifold, but can be reduced to four aspects: (i) falsified medicinal products can not always be easily distinguished from originals; (ii) the distribution chain has become very complex and is only as strong as its weakest link; (iii) there are legal uncertainties as to the regime applicable to products introduced into the EU while allegedly not being placed on the market; (iv) lastly, already the active pharmaceutical ingredients (API) entering the manufacturing process may be a falsification of the original API.

The existing provisions of Directive 2001/83/EC are in some respects insufficient to address these concrete causes. In view of the time span between the proposal for amendments to Directive 2001/83/EC and their effective implementation, there is a clear need for the Commission to act now.

CONTENT: in order to address the risk of falsified medicinal products entering the legal supply chain, the Commission proposes a number of amendments to Directive 2001/83/EC. These include:

- certain obligations for stakeholders other than wholesale distributors, who are involved in the distribution chain. These stakeholders are typically involved in the transactions without actually handling the products (for example, by auctioning or brokering products);
- a legal basis for the Commission to render obligatory specific safety-features (such as a serial number or a seal) on the packaging of prescription-medicines;
- a prohibition in principle of manipulating (i.e. removing, tampering with, or over-labelling) safety features on the packaging by stakeholders situated “in-between” the original manufacturer and the last stakeholder in the distribution chain (typically the pharmacist) or end user (doctor/patient);
- compulsory audits of wholesale distributors of medicinal products in order to ensure reliability of business partners;
- strengthened requirements for imports of API from third countries if it could not be established that the regulatory framework in the respective third country ensures a sufficient level of protection of human health for products exported to the EU;
- audits of manufacturers of API;
- stricter rules for inspections including increased transparency of inspection results through publication in the EudraGMP database managed by the EMEA.