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

2008/0261(COD) - 01/06/2011 - Final act

PURPOSE: to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products.

LEGISLATIVE ACT: 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.

CONTENT: following an agreement in first reading with the European Parliament, the Council adopted a directive aimed at preventing falsified medicines from entering the legal supply chain. The Directive acts against the increase of falsified medicines detected in the EU and the public health risk which that poses. The main provisions of the new Directive are as follows:

Safety features: 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.

Good manufacturing practice: 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. In the case of manufacture in third countries of active substances which are intended for export to the European Union, the competent authority of the exporting third country must certify that the manufacturing plant concerned is subject to regular, strict and transparent controls so as to ensure a protection of public health at least equivalent to that in the Union.

Obligations of importers, manufacturers and distributors: 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 well as must 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.

Obligation to inform competent authorities about suspect products: 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.

Inspections : the competent authority of the Member State concerned shall, in cooperation with the Agency, ensure that the legal requirements governing medicinal products are complied with, by means of

inspections, if necessary unannounced. Manufacturers, located in the Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections.

Recall of dangerous products: Member States shall have a system in place which aims at preventing medicinal products that are suspected to be dangerous from reaching the patient. The system shall also allow recalls from patients, who received them, where necessary with the assistance of health professionals. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which the product was first identified, shall without any delay transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients.

Distance selling to the public: 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 web pages 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.

Public awareness: the Commission shall, in cooperation with the Agency and the competent authorities of the Member State, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products.

Sanctions: Member States must impose effective penalties inter alia for the manufacturing, distribution, import and export of falsified medicinal products.

ENTRY INTO FORCE: 21/07/2011.

TRANSPOSITION: 02/01/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts in accordance with Article 290 TFEU which concern good manufacturing and distribution practices for active substances, detailed rules for medicinal products introduced into the Union without being imported and safety features.