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

2008/0261(COD) - 27/04/2010 - ${summary.subTitle}

The Committee on environment, public health and food safety adopted the report by Marisa MATIAS (GUE/NGL, PT) on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

It recommended that the European Parliament?s position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Definitions and responsibilities: Members want to establish precise and clear definitions on not only the scope but also on the different actions in the supply chain and their responsibilities. With this in mind, they introduced definitions for ?falsified medicinal products?, ?active substance used as starting material? and ?excipient?.

The amended text also introduces a distinction, in the definitions, between traders and brokers. For the system to be able to effectively protect public health, it is essential for the responsibilities of the various stakeholders to be clearly identified and for all stakeholders to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.

Excipients: falsified excipients can also present a serious risk for health and must also be included within the scope of the directive under examination. Both excipients and active pharmaceutical ingredients should be subject torelevant good manufacturing practices developed at the European level taking into accounttheir own specificities.

Obligations of the holder of the manufacturing authorisation: Members consider that it is necessary to require the holder of the manufacturing authorisation to i) inform the competent authorities of products he gets knowledge of which are or which are reliably suspected to be falsified in relation to the identity, history or source of products manufactured by him in the legal or illegal supply chain, including on the internet; ii) verify the authenticity and quality of the active substances and the excipients.'

The Commission shall submit every year to the European Parliament and to the Council a report with reliable and accurate data on the current situation and trends in the falsification of medicinal products. The report shall, as a minimum, include where, how and by whom the falsified products were detected, their origin, and an exact description of the nature of the falsification. That report shall clearly distinguish falsified medicinal products from patent infringements.

Third countries: Members consider that the protection offered in third countries should be at least equivalent to that in the Community. In the event of non-compliance, this information should be immediately supplied by the exporting third country to the Community.

Other means of preventing counterfeiting: the Commission shall study the possibilities for the authentication of individual dosage forms, as a method of detecting falsified medicinal products.

Safety features: the safety features should guarantee the identification, authenticity and uninterruptedtraceability of the medicinal product from the factory to the consumer. The identification, authenticity and traceability of medicinal products must be guaranteed in all circumstances. Furthermore, the additional costs should be as low as possible.

Where original safety features have been removed and replaced, Members consider that patients and other actors in the supply chain must be explicitly informed via a label on the pack.

Safety features shall be considered equivalent where they comply with the harmonised measures provided for in the Directive, which shall ensure that they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal products, and that they are equally technically difficult to duplicate.

According to Members, the performance criteria for the safety features can be waived for certain generic medicinal products or product categories

The decision the advisability of extending the safety features to other categories of medicinal productsnot subject to medical prescription will depend on an assessment carried out by the Commission no later than four years following the entry into force of this Directive.

Data protection: the measures contained in this Directive shall comply with the relevant provisions of Union law with regard to the protection of personal data.

Member States shall ensure that no collection or commercial processing of data takes place that would enable a link to be made between the medicinal products provided and the corresponding patients and shall ensure that the confidentiality of data generated by the use of safety features to authenticate medicinal products is safeguarded.

Internet sales: given that the internet is one of the main routes by which falsified medicinal products enter the European market, Members suggest that a distinction should be made between legitimate mail order or internet pharmacies and the illegal supply chain through non-controlled internet purchasing.

Internet pharmacies should, in Member States in which they are allowed to operate, require a special authorisation by the competent authority. The Commission shall adopt an EU logo for the front page of internet pharmacy sites, helping the public to identify whether a website offering to sell medicinal products is connected to an authorised pharmacy. The logo shall be linked to a central website at Member State level, to be established by the Member State, that allows the visitor to check the authenticity of the logo and that provides background information on the risks related to buying medicinal products on the internet.

Member States shall take the appropriate measures to ensure that all authorised pharmacy internet sites linked to pharmacies within their

territory display the EU logo.

Member States shall also ensure that i) the internet is continuously monitored with regard to the selling of medicinal products; ii) all legitimate mail-order pharmacies operating in the internal market adhere to professional standards and guidance for internet pharmacy services, including a specific code of ethics.

Public awareness: Members call on the Commission, in cooperation with the European Medicines Agency (the ?Agency?) and Member State authorities, to launch campaigns informing and raising awareness among consumers of the risk involved in purchasing falsified medicinal products.

Inspections: in order to guarantee the safety of medicinal products, Members consider it vital to strengthen and extend the system of inspections. In this regard, it will be necessary to take into account all the actors throughout the supply chain and not simply the wholesale distributors.

Exports: the Directive should also seek to reduce the wholesale distribution of falsified medicines towards third countries. Members consider that applying less stringent rules to exports or products in transit to third countries would damage the Community?s credibility in its insistence on strengthening international cooperation in the combat against falsified medicines. This is why the report calls on the Member States to take all necessary measures to ensure that no falsified medicines are distributed or exported from their territory to third countries.

Sanctions: Members propose further strengthening the measures proposed by the Commission. They stress that the falsification of medicines is a serious criminal activity, which places human lives in danger and that appropriate sanctions are required. The threat that falsified or counterfeit medicines represent to human health needs to be taken into account when drawing up rules on the sanctions to be applied. These sanctions need to be equivalent to those typically applied for illegal acts related to narcotics.

Exchange of information and reports: Members call on the Commission to create a network between it, the Agency and the Member States? competent authorities and involve patients' and consumers' organisations to ensure the exchange of information on the measures taken to combat the falsification of medicinal products, including on the penalties systems in place. This network shall aim at defining best practices and shall contribute to increased cooperation in the area of prevention and enforcement. The Commission, the Agency and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

International cooperation: the European Union should support the drafting of an international agreement increasing the penalties for falsifying medicinal products, and of an additional protocol to the United Nations Convention against Transnational Organised Crime (Palermo convention). In addition, the Commission and the Member States should cooperate closely with the Council of Europeon the establishment of a European Convention on the suppression of the falsification of medicinal products and trafficking in falsified medicinal products.

Lastly, many amendments adopted by Members seek to replace the ?old comitology procedure? by the new procedure foreseen in Article 290 of the Treaty on the Functioning of the European Union (delegated acts).