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

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The European Parliament adopted by 569 votes to 12, with 7 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise reached between the European Parliament and the Council. They amend the Commission's position as follows:

Definitions: the amended text stipulates that a **definition of 'falsified medicinal product'** should be introduced in order to clearly distinguish falsified medicinal products from other illegal products, as well as from infringements of intellectual property rights. Furthermore, products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms 'active substance' and 'excipient' should also be defined.

Application of the legislation: persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. Given that the current distribution network for medicinal products is increasingly complex, the new legislation shall address **all actors in the supply chain**: this includes not only wholesale distributors, but also **brokers** who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.

Obligations of the holder of the manufacturing authorisation: the holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by verifying the appropriate **good manufacturing practice** on the basis of a formalised risk assessment. In this risk assessment, the holder of the manufacturing authorisation shall take into account the source and intended use of the **excipients** and previous incidents. The holder shall also, inter alia:

- inform the competent authority and the marketing authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those products were distributed in the legal supply chain or by illegal means, including sold illegally by way of information society services;
- verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established;
- verify the authenticity and quality of the active substances and the excipients.

Imports, third countries: Member States shall take appropriate measures to ensure that the **manufacture, import and distribution** on their territory of active substances, including active substances that are intended for export, comply with good manufacturing practice and good distribution practices for active substances.

Active substances shall only be imported if the active substances have been manufactured in accordance with standards of good manufacturing practice at least equivalent to those laid down by EU legislation. The active substances are accompanied by a written confirmation from the competent authority of the exporting third country of the following: (i) the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union; (ii) the plant concerned is subject to regular, strict and transparent controls and to the efficient enforcement of good manufacturing practice, including repeated and unannounced inspections, ensuring a protection of public health at least equivalent to that in the Union. In the event of findings relating to non-compliance, that information is supplied by the exporting third country to the Union without any delay.

It should be noted that the requirements on information shall apply to the supply of medicinal products to **persons in third countries** authorised or entitled to supply medicinal products to the public.

Safety features: safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering. The safety features shall **not be partly or fully removed or covered**, unless certain conditions are fulfilled. In particular, the safety features should be replaced in the case of **re-packaging** by equivalent safety features. To this end, the meaning of the term 'equivalent' should be clearly specified. Those strict conditions should provide adequate safeguards against falsified medicinal products entering the distribution chain, in order to protect patients, as well as the interests of marketing authorisation holders and manufacturers.

Medicinal products subject to prescription should as a general rule bear the safety feature. However, in view of the risk of medicinal products or categories of medicinal products there should be the possibility to exclude certain medicinal products or categories of medicinal products subject to prescription from the scope by way of a delegated act, following a risk assessment. Safety features should not be introduced for medicinal products or categories of medicinal products not subject to medical prescription unless, by way of exception, an assessment shows the risk of falsification, which leads to serious consequences. Those medicinal products should accordingly be listed in a delegated act.

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.

Sales at a distance to the public: the illegal sale of medicinal products to the public via the Internet is an important threat to public health as falsified medicinal products may reach the public through such sale. This Directive should address this threat. In doing so, account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty on the Functioning of the European Union (TFEU).

The natural or legal person or the body provided for by national law offering medicinal products for sale at a distance is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person or body is established. The authorised person or body shall communicate the following to the Member States: name or corporate name and permanent address of the place of activity from where the medicinal products are supplied; the starting date of the activity of offering medicinal products for sale at a distance by way of information society services; the address of the website used for that purpose and all relevant information necessary to identify that website.

Internet pharmacy sites will be required to display a **common logo**, which should be recognisable throughout the EU, so as to help the public to ascertain that they are linked to an authorised pharmacy. All

authorised internet pharmacies will be **linked to a central website** in each Member State and will be listed on that website. The various **national web sites will in turn be linked to an EU website**. Citizens will also have to been informed about the risks involved in buying medicines via the internet.

The Agency´s website shall explicitly mention that the Member States´ websites contain information on persons or bodies authorised or entitled to supply medicinal products to the public and entitled to offer them for sale at a distance by way of information society services in the respective Member State.

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. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally to the public via the Internet and the function of the common logo, the Member States´ websites and the Agency´s website

Preventing dangerous medicines from reaching the patient: Member States shall have a system in place which aims at preventing medicinal products that are suspected to be dangerous from reaching the patient. With this aim the system shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products and cover recalls by marketing authorisation holders or ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. 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.

International cooperation: the Commission and the Member States should cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol and the United Nations. In addition, the Commission, working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the commercialisation of falsified medicinal products at a global level.

Penalties: the new Directive lays down penalties applicable to infringements of the national provisions. Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.

Delegated acts: the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU which concern: (i) good manufacturing and distribution practices for active substances; (ii) detailed rules for medicinal products introduced into the Union without being imported and (iii) concerning safety features.

Implementing powers should be conferred on the Commission as regards the adoption of measures for the assessment of the regulatory framework applicable to the manufacturing of active substances exported from third countries to the Union and as regards a common logo that identifies websites which are legally offering medicinal products for sale at a distance to the public.