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Protecting the legal supply chain against counterfeited medicines

There is an alarming increase of medicinal products detected in the EU which are falsifications in relation to their identity, history or source. These products usually contain sub-standard or false ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients, thus, posing an important threat to public health. Past experience shows that such medicinal products are not only marketed through illegal supply chains, but also infiltrated into the legal supply chains e.g. via manufacturers, wholesalers, traders and pharmacies. This poses a particular threat to human health and may lead to a lack of patient trust in the legal supply chain. Faced with this situation the Commission has proposed today to protect the legal distribution chain from the infiltration of fake medicines. This will help to ensure confidence of distributors, health care professionals and patients in the medicinal products they trade, prescribe and purchase in the legal supply chain.

Falsified medicines are usually unsafe, inefficient, or low-quality products as they usually do not include the correct or any active ingredient or are not manufactured in the declared sites. These products pose a threat to human health. Often they are referred to as "counterfeit medicines".

The number of detected false medicinal products is on a steady rise. In addition the risk profile has changed. Whilst previous figures indicated that the risk related more to so-called "lifestyle" drugs, there are strong indications that the number of false representations of innovative and life-saving medicines is increasing. Moreover, in order to increase the volume of fake medicines, these products are channelled through the legal supply chain towards patients.

What are the key measures proposed?

The European Commission is proposing a number of legislative actions to address this problem. These actions build on an initiative launched by the World Health Organisation in its International Medical Products Anti Counterfeiting Task Force (IMPACT). Today's package proposes amendments to Directive 2001/83/EC by laying down a general frame for future legislation in the form of implementing legislation to be approved in 2009/2010.

Measures in relation to the product itself: As regards the rules relating to medicines sold in the EU, it is proposed that certain categories of products bear a "safety-feature", which would help to identify falsified products. To achieve this, it is proposed to establish a legal basis for rendering those safety features mandatory. Details regarding the design of those safety features would have to be set out in implementing legislation. Safety features should help to ascertain identification,

authenticity and traceability for specific medicinal products. Examples of such features could be:

- **individual product codes** (so-called “product serialisation”) on the packaging, which can be read by legal actors in the distribution chain, including pharmacies, or
- **seals** which reveal any opening of the pack.

For these safety features to be effective, it is crucial that only certified manufacturing authorisation holder can affix them, and that they can be replaced only under strict conditions and control. The proposal sets out the requirements in this regard. In particular, the proposal ensures that re-packaging of medicines remains possible. Re-packaging of pharmaceuticals is usually necessary to sell medicines which are destined for one Member State in another Member State.

Strengthening supervision of actors in the distribution chain: Already today, the various actors in the distribution chain are subject to numerous obligations in pharmaceutical law. These obligations are clarified and their enforcement will be facilitated. For example, it is proposed that wholesale distributors:

- who have undergone inspections are **listed in a database** managed by the European Medicines Agency.
- will be subject to **mandatory audits by purchasers** to ensure reliability of actors.

Finally, products which are introduced into the EU with the intention of **transit** through the EU or which are **imported for being exported** are going to be subject to **stronger supervision**.

Measures with respect to active pharmaceutical ingredients ("API"): The API is the “backbone” of a medicine. It is therefore crucial to ensure quality and safe manufacturing standards. This holds particularly true for APIs manufactured outside the EU. Therefore in the future:

- Manufacturers of medicinal products will be obliged to **audit all companies** who manufacture the API they use.
- Various measures shall ensure that **imported APIs** have been manufactured in **accordance with rules setting safety standards equivalent to those in the EU**.
- Member States will be obliged to **enhance inspections** in particular in those countries where the level of public health protection with respect to the regulatory framework, control and supervision is not equivalent to the EU.

Why no specific action is taken with respect to illegal medicines sold over the Internet?

The Internet clearly offers possibilities for criminals to sell illegal medicines. The World Health Organisation estimates that 50% of medicines purchased from Internet sites concealing their address (in particular those which are not connected with a licensed pharmacy) are fake.

Presently, it is **up to Member States** to decide whether they want to ban or permit the sale of prescription-medicines via the Internet and to fix the conditions thereof. For a variety of reasons, Member States have taken very different approaches and regulations. The Commission does not, for the time being, propose harmonised specific rules for Internet sales of prescription medicines.

Member States have to ensure that the Internet-supply of medicines – if permitted at all - takes place within the legal limits. The main challenge in this respect is the **enforcement of domestic laws vis-à-vis illegal Internet-pharmacies**, which are usually established in third countries. To address this, Member States as well as several stakeholder groups have launched awareness raising campaigns for patients and healthcare professionals.

When will the proposal become law?

The proposal will now be transmitted to the European Parliament and the Council where it will be discussed and voted in the so-called “co-decision procedure”.

[More information on counterfeit medicines](#)

[More information on the complete pharmaceutical package](#)

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