



Fake medicines: Parliament approves new rules to protect patients better

Plenary sessions

A new law to prevent fake medicines from entering the legal supply chain was approved by Parliament on 16 February. Internet sales will be covered by the law, which also introduces new safety and traceability measures, as well as sanctions against counterfeiters. This law still needs to be formally approved by the Council of Ministers.

"Falsified medicines are silent killers, either because they are devoid of effect or because they contain toxic substances that may harm, or even kill, those who take them. The absence of a legal framework encourages counterfeiting, an organized crime. We have been witnessing a huge growth of this criminal activity, with an increase of 400% in seizures of fake drugs since 2005. Protecting patient safety is the core aim of this directive", said Marisa Matias (GUE/NGL, PT), who led discussions in Parliament. The resolution was adopted with 569 votes in favour, 12 against and 7 abstentions.

An estimated that 1% of medicinal products currently sold to the European public through the legal supply chain are falsified and the share is growing. In other parts of the world, up to 30% of the medicines on sale may be fake. In particular, more and more innovative and life-saving drugs are counterfeit.

Internet sales

MEPs deemed it necessary to regulate internet sales of medicines because this is a key route by which fake ones enter the EU market. The Commission's original proposal did not cover internet sales. Under the new law, in those EU Member States where internet pharmacies are allowed to operate, they will need to be authorised to supply pharmaceuticals to the public.

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

Safety features, traceability and product recalls from patients

The legislation updates current rules and provides for new safety features to be placed on individual packs in order to identify them, guarantee their authenticity, and enable pharmacists to check whether the outer packaging has been tampered with. These safety features - which still need to be developed by the European Commission - could for example include a serialization number which can be "read" by the pharmacy to ascertain that the pack is authentic.

Press release

As a general rule these features would apply to all prescription medicines, unless there is clearly no risk. They would apply to non-prescription medicines only in exceptional cases, where there is a risk of falsification. Where medicines are repackaged, these safety features must be replaced by equivalent ones.

Member States must also put in place a system to preventing dangerous medicinal products (falsified and with quality defects), from reaching the patient. This system must permit recalls, including recalls from patients.

If a medicinal product is suspected to present a serious risk to public health, all actors in the supply chain and in all other Member States must be rapidly alerted. If the falsified medicines reach patients, then the alert must be given within 24 hours, so that the medicines can be recalled.

Brokering, export to third countries and sanctions

Pharmaceutical distribution networks are becoming increasingly complex. They involve not only distributors, who are already covered by existing legislation, but also medicinal product brokers. MEPs stipulated that in future, brokers will have to register as such, and may be removed from the register if they fail to comply with the new rules.

MEPs wanted not only imports but exports of medicines to third countries to be better regulated. They therefore stipulated that the relevant rules on information must apply to the supply of medicines to authorized persons in third countries, too.

Finally the new directive states that sanctions imposed on those who infringe it must not be inferior to those applicable to infringements of national laws of similar nature and importance.

Next steps

The text approved by MEPs results from an agreement reached with Council, which must also give its formal approval. Once it is signed into law, Member States have 18 months to make any necessary changes to their national legislation.

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