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Q&A: Directive on falsified medicines

What are falsified medicines and why are they a problem in the EU?

Falsified Medicines are fake medicines that pass themselves off as real, authorised medicines.

Falsified medicines may contain ingredients, including active ingredients, which are of low quality or in the wrong dosage – either too high or too low. Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by the EU authorisation procedure, they can be a major health threat .

The production and trade of falsified medicines has become a growing worldwide illegal business. For example, according to the statistics of EU Customs[1], the number of medicines seized at the outer border of the EU (not counting patent issues) has tripled between 2006 and 2009 to reach approx. 7.5m items.

In addition, whereas this problem used to be related mainly to 'life-style' medicines, now innovative and life-saving medicines, e.g. medicines against cardiovascular diseases are being increasingly falsified. Worryingly, past experience[2] shows that these products can find their way into the legal supply chain in the EU. This means that the sale of falsified medicines is not limited to illegal trading channels, such as illegal online sales.

What is the difference between falsified and counterfeit medicines?

Falsified medicines are not to be confused with **counterfeit medicines.** The latter term refers to medicines that do not comply with EU law on intellectual and industrial property rights, such as registered trademarks or patent rights. The Directive on 'falsified medicines' does not deal with this aspect.

What is the aim of this Directive?

The Directive aims to prevent falsified medicines from reaching the patients by introducing harmonised, pan-European safety and control measures. These measures will ensure easier identification of falsified medicines, and improved verifications and controls at EU borders and within the EU.

New measures include:

- An obligatory authenticity feature on the outer packaging of the medicines : this feature will be decided at a later stage (see question "What remains to be done ?") via a delegated act;
- Strengthened requirements for control and inspections of plants manufacturing active pharmaceutical ingredients;

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[1] http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm

[2] http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/counterfeit-ia_en.pdf

- Strengthened record-keeping requirements for wholesale distributors;
- Strengthened rules on inspections;
- The obligation for manufacturers and distributors to report any suspicion of falsified medicines.

What is an 'authenticity feature' and how does it work?

The authenticity feature is a unique identifier on the outer packaging which allows verification of the authenticity of the medicinal product.

Up to now, the regulation of authenticity features on medicines was conducted at Member State level. This Directive addresses this aspect at EU level. It provides a legal basis for establishing details for these safety features and the level of their control in the distribution chain.

This obligation applies to all prescription medicines – with the possibility of exceptions if a risk assessment has shown that these products are not at risk. It normally excludes over the counter (OTC) medicines, as these products are usually not the target of falsifiers. However, based on a risk evaluation, OTC medicines can be included in exceptional cases.

How will the Directive ensure that the active ingredients in medicines are authentic and safe?

Active pharmaceutical ingredients (API) are the 'backbone' of a medicine and the Directive introduces measures to ensure their authenticity and quality.

Today, most APIs are produced outside the EU. This legislation builds on a strengthened international collaboration between the European Commission, the European network of national competent authorities in charge of medicines, including the European Medicines Agency, and authorities in third countries to ensure inspections of API manufacturing plants both inside and outside the EU.

Does the Directive address the sale of falsified medicines over the internet?

Yes, the Directive provides for an obligatory 'trust mark' on the websites of legally-operating online pharmacies. A click on the 'trust mark' links the user to an official national register with a list of all legally-operating pharmacies. If the user clicks again on the register, he is linked back to the website of the legally-operation pharmacy.

However, the Directive does not harmonise the rules and regulations for online pharmacies in the EU. The question of whether and how medicines can be sold over the internet remains a decision for each Member State to take within the limits of the EU Treaty.

What remains to be done ?

The EU legislation has to be transposed by each Member States into the national law. In parallel, the Commission works on various measures to implement and supplement the legislation in order to ensure that its objectives are met. These Commission measures relate in particular to the characteristics and verification of the 'safety feature'.

When will this law come into effect?

The Directive must be transposed by the Member States within 18 months and is going to apply as of then. However, some measures, such as those related to the safety feature, have a longer implementation time – up to approx. 5-6 years - in order to allow for the necessary technical adaptations.

For further information:

http://ec.europa.eu/health/human-use/quality/fake-medicines/index_en.htm