EU-Amendment Directive

ANTI-COUNTERFEITING OF MEDICINAL PRODUCTS

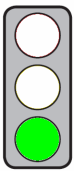
Status: 16.03.09

Centrum für Europäische Politik

MAIN ISSUES

Objective of the Directive: The Directive aims to improve protection against falsified medicinal products.

Parties Affected: Manufacturers, wholesalers, importers of medicinal products and ingredients.



Pros: (1) Affixing safety features on the packaging of medicinal products prevents falsified medicinal products from entering the legal supply chain – i.e. the distribution of medicinal products from manufacturers to customers via authorised manufacturers, wholesalers and pharmacists.
(2) The parallel import of medicinal products remains permitted.

Cons: –

CONTENT

Title

Proposal COM(2008) 668 of 10. December 2008 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 **falsified medicinal products**

Short Summary

References made relate to the "Community Code on medicinal products" (Directive 2001/83/EC) to be amended.

- **Object of the Directive and Parties Affected**
  - The Directive is to avert the dangers resulting from an "alarming increase" of falsified medicinal products entering the EU. Products are considered falsified if:
    - they contain "sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients" (Recital No. 2)
    - or if they "claim a falsified identity, history or source" (new Art. 52b).
  - The Directive mainly obliges holders of "authorisations to manufacture medicinal products" (Art. 40 (1)). This authorisation is required for "both total and partial manufacture, and for the various processes of dividing up, packaging or presentation" (Art. 40 (2)). The second part of the definition is often fulfilled by wholesalers and importers; pharmacists are excluded (Art. 3).
  - The Directive applies to the legal supply chain, i.e. the sale from manufacturers to pharmacists through authorised suppliers. The Directive does not affect the illegal sale of medicinal products through persons who are not authorised traders, as is common on the internet.
- **Safety Features on Medicinal Products Packaging**
  - Holders of manufacturing authorisations must affix "safety features" on each packaging of medicinal products being placed on the EU market (new Art. 51 (1) lit. c).
  - Safety features serve to ascertain the identity, authenticity and traceability of medicinal products and, in addition, they serve to verify whether the outer packaging has been tampered with (new Art. 54 lit. o; new Art. 54a (1)).
  - The Commission shall define requirements of the safety features and adopt requirements for their affixing, removal and replacement – provided that a committee consisting of national experts consents to it and neither the European Parliament, nor the Council contradict ("regulatory procedure with scrutiny"). (new Art. 54a (4))
  - Safety features may only be removed by holders of manufacturing authorisations. This applies particularly to wholesalers, who repack medicinal products bound for other EU Member States and then, adding a new instruction leaflet, re-import them into their country of origin ("parallel import"). The replacement of safety features is subject to the following conditions:
    - The holder of a manufacturing authorisation must first verify the authenticity of the medicinal product.
    - Having removed the safety feature, he must replace it with an "equivalent" feature.
    - Replacement is subject to the supervision of the competent authority (new Art. 54a (2)).
- **Manufacturing and Importing Active Pharmaceutical Ingredients of Medicinal Products**
  - Manufacturers and importers of active ingredients seated in the EU must notify competent authorities of their permanent business seat (new Art. 52a).

Contact: Klaus-Dieter Sohn | Phone +49 761 38693-231 | sohn@cep.eu
CEP | Kaiser-Joseph-Straße 266 | 79098 Freiburg | Germany | Phone +49 761 38693-0 | www.cep.eu

  - The manufacture and distribution of active ingredients in the EU must comply with "good manufacturing practices" and "good distribution practices" (new Art. 46b (1)). What this exactly means will be defined by the Commission under the "principles and guidelines" in the regulatory procedure with scrutiny (amended Art. 47 (3)).
  - Active ingredients may be imported from third countries only if:
    - they have been manufactured according to standards which are "at least equivalent" to the "principles and guidelines of good manufacturing practice" (new Art. 46b (2) lit. a)
    - and if the manufacturer submits a confirmation from his home country that the plant manufacturing the active ingredient concerned applies standards which are comparable to those applied in the EU and that the compliance is regularly checked and enforced (new Art. 46b (2) lit. b).
      Such a confirmation may be waived if the third country is listed by the Commission (new Art. 46b (3). A third country can be listed if it submits an according application and if it complies with the EU standards (new Art. 111b).
  - Medicinal products placed on the market outside the EU may not be imported into the EU if there is cause for the assumption that the information on identity, history or source of the medicinal product is falsified (new Art. 52b).

- **Verification and Notification Requirements**
  - When purchasing ingredients from other manufacturers, holders of manufacturing authorisations must verify the compliance of the former with the "principles and guidelines of good manufacturing practice" (if seated in the EU) or with "equivalent" standards (if seated outside the EU); verification may be accomplished by the authorised manufacturer himself or through a body accredited for this purpose in his Member State (amended Art. 46 lit. f).
  - Holders of manufacturing authorisations must notify the competent authority should it come to their knowledge that a medicinal product might be falsified (new Art. 46 lit. g).

- **Liability for damages from falsified medicinal products**
  Holders of manufacturing authorisations are liable for each and any damage in accordance with the Product Liability Directive (85/374/EEC) "caused by medicinal products which are falsified in terms of their identity" if placed on the market by them (new Art. 54a (3)). This applies in particular to damages occurring due to wrong instructions regarding the characteristics and dosage of active substances, their scope of application and side effects.

- **Inspections through Member States**
  - Competent authorities must inspect importers and wholesalers to ensure that they too comply with the "principles and guidelines of good manufacturing/distribution practice" (amended Art. 111 (3)).
  - The Commission will set out the guidelines for such inspections (new Art. 111a; Art. 84).
  - Inspection results must be notified to the Commission and stored in a publicly accessible database ("EudraGMP") (amended Art. 111 (7).

Changes Compared to the Status Quo

- According to current EU law, medicinal products do not have to be provided with safety features.
- To date, the Commission has stipulated binding "principles and guidelines of good manufacturing practice" only for medicinal products (Directive 2003/94/EG). There are no binding "principles and guidelines for good distribution practice", nor for inspections at importers and wholesalers.

Statement on Subsidiarity

According to the Commission, the Directive 2001/83/EC contains exhaustive regulations for the trade with medicinal products. Member States are therefore not entitled to adopt additional rules. Furthermore, the overall aim to combat falsified medicinal products without impeding the functioning of the internal market for medicinal products could not be adequately achieved by single Member States and therefore should better be realised at Community level.

Political Context

The Proposal for a Directive is part of the "Pharmaceutical Package" submitted by the Commission on 10. December 2008. It further comprises a Proposal for a Regulation on the supervision of medicinal products for human use ("pharmacovigilance") [COM(2008) 664 amending Regulation (EC) No. 726/2004], a Communication on the renewed vision for the pharmaceutical sector [COM(2008) 666] as well as a Proposal for a Directive on information to the general public on prescription medicines [COM(2008) 663 amending Directive 2001/83/EC]. (cp. CEP-Policy Brief)
Several Members of the European Parliament have already demanded that medicinal products not subject to prescription also be provided with safety features.

Legislative Procedure

10.12.08 Adoption by the Commission
Open Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Leading Directorate General:	DG Enterprise and Industry
Committees of the European Parliament:	Environment, Public Health and Food Safety (in charge), rapporteur: Adamos Adamou (GUE/NGL-Group, ZY); Industry, Research and Energy; Internal Market and Consumer Protection
Committees of the German Bundestag:	Health (in charge); Economy and Technology
Decision Mode in the Council:	Qualified majority (approval by a majority of Member States and at least 255 out of 345 votes; Germany: 29 votes)

Formalities

Legislative competence:	Art. 95 TEC (Internal Market)
Form of legislative competence:	Concurrent legislative competence
Legislative procedure:	Art. 251 TEC (Co-Decision)

ASSESSMENT

Economic Impact Assessment

Ordoliberal Assessment

A free-market system erodes if actors cannot trust the authenticity of the goods traded. Hence, the avoidance of falsified products is indispensable for buyers and sellers alike. This is all the more true where falsifications might endanger life or health. From an ordoliberal standpoint, **public action to prevent falsifications is therefore appropriate** in principle.

In fact, there has been a significant increase in the number of falsified medicinal products in the EU. In 2007, 2045 medicinal product imports were confiscated as a result of patent and trademark right infringements, whereas in 2006 there were only 497 confiscations. Third countries are also registering a heavy increase in illegal medicinal products: The Swiss supervisory authority Swissmedic reported 669 infringements in 2008 and estimates that the total illegal medicinal product imports amount to 50,000 per year. Even if this figure includes pending patent litigation – both the EU and Switzerland accuse each other of causing 30-40% of such illegal imports – the problem as such is not being doubted. Reports by supervisory authorities further state that medicinal products which contain falsified or low dosed active ingredients have already caused in a number of cases – though still relatively low – damages to patients in the EU [SEC(2008) 2674, p. 12].

Since high profit margins are attractive yet regulatory controls rare, falsified medicinal products find their way into the legal distribution chain. Individual cases of medicinal product distributors seated in the EU having purchased falsified medicinal products have already emerged. **Safety features** as proposed by the Commission **could put paid to the entry of falsified medicinal products into the legal supply chain** and are therefore very welcome. Currently, the serial numbers printed on the original packaging of a medicinal product can only be assigned to a charge of 5,000 or 50,000 single packages only. Besides, original packages can be copied very easily. To remove this flaw from the legal supply chain, technically demanding safety features in the form of holograms or special codes ("2-D-barcodes") are considered. They would individualise each packaging and thus provide a high level of safety protection against falsification; **yet, at the same time, this might make the hitherto permitted parallel import of medicinal products** within the EU more difficult.

Parallel importers take advantage of the differing prices offered by pharmaceutical manufacturers in the EU internal market. By buying medicinal products destined for "low-price countries", repacking them and then placing them on the markets of "high-price countries", they can offer the products more cheaply. Thus parallel imports reduce the turnover of manufacturers and extend the period they need to amortise investments in research and development. On the other hand, parallel imports lead to cost savings in the health system of "high-price countries", though at 100 to 600 million Euros the Commission does not consider these savings as being very high [SEC(2008) 2675, p. 4]. The concrete implementation of the obligation to affix equal safety features when repacking will prove whether parallel imports will become too expensive to be still profitable.

Currently, most falsified medicinal products are distributed through unauthorised traders, in particular via the internet. Patients buying medicinal products through internet pharmacies often cannot find out whether these are authorised pharmacies or unauthorised traders merely pretending to operate an authorised pharmacy. The proposed Directive does not contain any proposals as to how to protect patients from erroneously purchasing medicinal products from unauthorised traders, i.e. from outside the legal supply chain. **Worth considering** therefore **is the restricting of internet trade with prescription medicines to a state-controlled platform** for accredited traders.

Impact on Efficiency and Individual Freedom of Choice

The new safety features increase the costs for medicinal products, but also their safety. Provided the implementation of safety features does not push parallel importers to withdraw from the market, traders, pharmacists and patients can continue to choose whether to purchase medicinal products directly or through parallel imports.

Impact on Growth and Employment

The direct costs of the new safety features in terms of growth and employment are negligible. However, if parallel import was de facto disrupted, on the one hand the costs in the health sector would increase and have a slightly negative impact on the overall economic growth, but on the other hand investments into research and development would be made more attractive.

Impact on Europe as a Business Location

The proposed Directive is neutral in terms of business locations since its safety requirements apply irrespective of the place of manufacture of medicinal products.

Legal Assessment

Legislative Competence

The proposed measures are to prevent impediments of the functioning of the internal market resulting from deviating measures of the Member State measures. Consequently, Art. 95 TEC is applicable as the relevant legislative competence. According to the case law of the European Court of Justice, this also applies if health protection is a "decisive factor" for the proposed measures, as long as the requirements pursuant to Art. 95 TEC are complied with (ECJ Case C-380/03, Germany ./. Parliament and Council – tobacco advertising No. 39).

Subsidiarity

Unproblematic.

Proportionality

The additional obligations proposed impose new burdens on manufacturers and wholesalers. Nevertheless, such burdens are justified since an improved protection of the legal supply chain against falsified medicinal products is appropriate and necessary in order to protect the life and health of citizens. Although until now it has been rare for falsified medicinal products to enter the legal supply chain and there have been few cases of ensuing damage to patients, the growing number of falsifications stands for an increasingly serious problem. Besides, more safety in the legal supply chain reduces the liability risk for manufacturers.

Compatibility with EU Law

Maintaining the parallel import of medicinal products is in line with settled case-law of the European Court of Justice (leading case: ECJ Case C-104/75, de Peijper). According to the ECJ, the admissibility of parallel imports follows from the free movement of goods (Art. 28 TEC). The proposed obligation to use equivalent safety features when repacking could – depending on how such obligation is implemented – make it unavoidable for wholesalers to infringe the manufacturer's trademark rights. When regulating details regarding safety features, the Commission should ensure that such a case is excluded.

Compatibility with German Law

The German Pharmaceutical Law – in particular the Pharmaceutical Act (AMG) and the Regulations Governing Pharmaceutical Wholesalers (AMGrHdlBetrV) – will have to be adjusted. Product liability law would not have to be amended due to the liability provisions under the Pharmaceutical Law (§ 84 AMG).

Alternative Policy Options

Although the proposed measures improve the safety of the legal supply chain, they do not reduce the risks resulting from medicinal products sold by unauthorised traders. As falsified medicinal products are mainly distributed via the internet, the restricting of internet trade in prescription medicines to joint platforms operated exclusively by accredited traders should be considered.

Possible Future EU Action

Not foreseeable.

Conclusion

The proposed Directive meets its aim to improve the prevention of falsified medicinal products entering the legal supply chain. In addition, it is to be welcomed that the parallel import of medicinal products remains permitted. Nevertheless, it will depend on the concrete characteristics of the safety features to be defined whether the costs of repacking medicinal products will rise to an extent that parallel imports could be impaired or even eliminated.