

## **Counterfeit medicines**

**European Commission**

***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  
- COM(2008) 668 -***

## **Joint Position Paper of the European Social Insurance Platform (ESIP)**

**Submitted 2 June 2009**

### **About the *European Social Insurance Platform (ESIP)***

The *European Social Insurance Platform (ESIP)* represents Europe's social insurers in 16 EU Members States and Switzerland, active in the field of health insurance, pensions, family benefits, occupational safety and accident insurance and unemployment insurance. The aims of ESIP and its members are to preserve high-profile social security for Europe; to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European decision-making process and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

**Position statement:** ESIP members support this position in so far as the subject matter lies within their field of competence.

For more information please visit the ESIP website at: [www.esip.org](http://www.esip.org)

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This position paper was drafted in consultation with the Medicine Evaluation (MEDEV) Committee.

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### **Summary**

- **ESIP supports the initiative to combat counterfeit medicines for human use. It is reported that counterfeit medicines are an increasing threat to public health. Nevertheless, ESIP would encourage the European Commission to launch studies to confirm the real situation as regards counterfeiting so that proposed measures are effective and proportionate.**
- **Call a spade a spade: "Counterfeits" instead of "falsified medicines"**
- **The Internet as the main distribution channel of counterfeits is not sufficiently considered in the proposal. ESIP suggests a register of legitimate internet pharmacies, which should be publicly available.**
- **Data generated by verification of the authenticity of the product needs to be protected against misuse by industry to optimize their distribution profiles and marketing measures.**
- **Parallel trade should not be compromised: it does not cause significant risks with regard to counterfeit medicines and plays a crucial part in ensuring free trade, competition and the cost-effectiveness of health care systems.**

## **ESIP supports this initiative to combat counterfeit medicines**

Counterfeiting of medicinal products is to be condemned because it compromises the health and lives of people. In addition, **confidence and trust in pharmacotherapy are undermined.**

Counterfeiting of medicinal products is a **criminal offence** that needs to be combated by national and European authorities for criminal prosecution. Therefore, it is essential to strengthen and enforce their powers through stronger cooperation between the responsible authorities within the EU and within individual Member States and also by establishing an international convention on effective prosecution. In particular, intensive monitoring and prosecution of illegal internet trade is essential. Furthermore, it is the duty of the manufacturers, traders, wholesalers and pharmacies to guarantee the supply of safe and effective medicines. Nevertheless, **ESIP would encourage the European Commission to launch its own studies to confirm the true extent and principle sources of risk as regards counterfeiting to ensure that any proposed measures are effective and proportionate.**

### **"Counterfeits" instead of "falsified medicines"**

Like many other parties, for example the European Economic and Social Committee rapporteur for this proposal, Mr Peter Morgan (Group I), ESIP suggests that the Commission proposal should **better speak of "counterfeit" medicines rather than "falsified" products**: "counterfeit" better encompasses the criminal relevance of this topic and is a term globally understood. The WHO has suggested the following definition, which should be supported by the Commission:

*"The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products.*

*Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.*

*Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting."*<sup>1</sup>

### **The Internet as the main distribution channel for counterfeits is not sufficiently considered in the proposal**

The vast majority of counterfeit medical products enter the market via the Internet and not through the normal legalised distribution channels. This is a fact which the Commission's proposal chooses to ignore. The proposal addresses only the traditional legal supply chain and presents no strategy to combat the trade of counterfeit medicines via the web; no

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<sup>1</sup> See Summary report of the 3rd IMPACT (International Medical Products Anti-Counterfeiting Taskforce) General Meeting on 3-5 December 2008 in Hammamet, Tunisia; p.6; available under: [http://www.who.int/impact/resources/IMPACTthirdgeneralmeeting\\_%20report.pdf](http://www.who.int/impact/resources/IMPACTthirdgeneralmeeting_%20report.pdf)

reference is even made to the “internet” or “world wide web” in the proposal. ESIP consider it essential that actions against illegal internet sales are taken up in this proposal.

**A study by the German Federal Criminal Police Office shows that a large percentage (80%) of counterfeit medicines is entering the legal supply chain via the Internet.**<sup>2</sup> This finding has been the basis for an oral question put by two MEPs to the European Commission in March this year.<sup>3</sup> The MEPs ask if the European Commission is "doing enough to protect the consumer from that source of danger" in the context of the current proposal. They suggest that listing Internet pharmacies and certifying Internet websites will hinder illegal Internet trade and serve as an efficient tool for combating the main source of counterfeit medicines. The recommendations of the European Economic and Social Committee follow similar lines.<sup>4</sup>

ESIP also supports the idea of **registering legitimate internet pharmacies** in each Member State and making this registry easily accessible via a **public database**. In this context, international cooperation could bring a real added value. For example, in Germany a registry of Mail Order Pharmacies was introduced in April 2009. The register and the related safety logo DIMDI (German Institute of Medical Documentation and Information), administered on behalf of the Federal Ministry of Health, lists pharmacies that possess an official permit issued in accordance with the German Drug Law. The competent bodies responsible for the content of the mail order pharmacy register are those also responsible for monitoring pharmacies according to federal state law. The corresponding entry in the register can be viewed by clicking on the safety logo on the website of the mail order pharmacy. If the pharmacy is registered, a window opens containing the relevant data for this pharmacy, e.g. address and contact data. The internet address given then links (back) to the pharmacy website(s). If the pharmacy is not listed in the register, a message appears indicating that no statement can be made as regards the pharmacy's authorisation to trade by mail order. The register is available under the following link: <http://www.dimdi.de/dynamic/de/amg/var/index.htm>

Sensitising patients, physicians and pharmacists to the problem of counterfeiting is essential if this problem is to be tackled effectively and efficiently. An additional **added value** could therefore be found in investing at European level in a diversified **awareness campaign** within the population, because it seems that the broader public is not yet sufficiently aware of the serious danger of purchasing falsified medicines via the internet. Educational programmes to increase consumer awareness about the existence of counterfeit products and the risk of buying drugs through unauthorised channels should be put in place.

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<sup>2</sup> Heike Sürmann (2007): Arzneimittelkriminalität – ein Wachstumsmarkt? Eine explorative Untersuchung aus polizeilicher Sicht; Polizei + Forschung Bd. 36 herausgegeben vom Bundeskriminalamt (BKA) Kriminalistisches Institut, Luchterhand Köln.

<sup>3</sup> Counterfeit medicines on the Internet: ORAL QUESTION WITH DEBATE pursuant to Rule 108 of the Rules of Procedure by Jorgo Chatzimarkakis and Karin Riis-Jørgensen, on behalf of the ALDE Group to the Commission from the 12 March 2009 (Doc.No.: O-0058/09); available under: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+OQ+O-2009-0058+0+DOC+XML+V0//EN>

<sup>4</sup> EESC: INT/472: Prevention of falsified medicinal products – Working document of the Section for the Single Market, Production and Consumption 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 COM(2008) 668 final - 2008/0261 (COD) - Rapporteur: Mr Morgan from 3 April 2009.

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### **Data generated by verification of the authenticity of the product needs to be protected against misuse**

New track and trace technologies and product **authentication technologies** (e.g. RFID-technology or 2D-barcode) will help to identify counterfeit medicines on the market. However, ESIP has serious concerns about the tracing mechanisms allowing identification of the authenticity of the product foreseen in Article 54a para. 2 lit.a: this clause indicates that the pharmacist will read the safety feature with a special scanner and the registered data will be instantly checked against the manufacturer's file in an electronic database.

Unless suitable provisions are made such a mechanism could be open to abuse by the manufacturer since it reveals important data about the dispensing activities of individual pharmacies. **Such data would be of enormous value to the pharmaceutical industry in building up a detailed distribution profile for the pharmacy** and linked to this the identification of prescribing practices (esp. medical specialists) in the surrounding area. This information would allow the industry to initiate concerted, individual/practice related sales strategies for their products targeting doctors, pharmacists, and other professional distributors.

Therefore it is indispensable that the industry should not be able to read and analyse the data registered by the pharmacists when scanning the safety feature on the product. One possible solution would be that the electronic database is hosted by an independent third party such as the health ministry or public health authority, to which the industry submits the data needed for the authentication process and against which the pharmacies check the authenticity of the product.

Finally, the **cost-effectiveness** of the process should be taken into account when decisions are made as to which technology is the best. Further increases in the prices of pharmaceutical products would be a significant financial burden for the health insurer, especially in the current climate of economic crisis.

### **Parallel trade should not be compromised**

In the context of the current proposal, ESIP welcomes the Commission's decision to reconsider its position on a repackaging ban and to introduce a clause into the proposal which allows all marketing authorisation holders, including parallel traders, to repackage a medicinal product. This is important because arguments surrounding the serious issue of counterfeit medicines have often wrongly implicated the legal practice of parallel trade and led to a general mistrust of generic medicinal products.

We briefly recall here that cases of counterfeits entering the market as a result of parallel trade are rare. The restriction of parallel trade by banning repackaging of medicines is not a measure which is likely to be effective in combating counterfeit medicines nor is it in line with the principle of proportionality codified in the Treaty. Parallel trade (worth 4 billion Euros a year) is legal according to the European Treaty (ruling of the ECJ<sup>5</sup>) and currently provides tough competition for many of the players in this market. The "de facto"-hindrance of parallel trade of pharmaceuticals would for many Member States result in a further increase in healthcare expenditures (up to 600 million euros per year) and would add to the enormous cost pressures which already face healthcare systems across the EU.

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<sup>5</sup> Cases C-468/06 to C-478/06 *Sot. Lélos kai Sia and others versus GlaxoSmithKline*