



## European Public Health Alliance (EPHA)

### Position Paper on Counterfeit Medicines

Subject:	EPHA Position Paper on Counterfeit Medicines
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***EPHA is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. Our membership includes representatives at international, European, national, regional and local level.***

***EPHA's mission is to protect and promote public health in Europe.***

***EPHA brings together organisations across the public health community, to share learning and information and to bring a public health perspective to European decision-making. We help build capacity in civil society participation across Europe in the health field, and work to empower the public health community in ensuring that the health of European citizens is protected and promoted by decision-makers. Our aim is to ensure health is at the heart of European policy and legislation.***

***Please see [www.ephapro.org](http://www.ephapro.org) for more information.***

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#### **The Need for New Legislation**

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Patients safety and the access to high- quality medicinal products represent key issues in pharmaceutical policy. In this context, EPHA welcomes the Commission's legislative initiative aimed at combating counterfeit medicine, and more particularly for the following reasons:

- The risk of penetration of counterfeits into the legal supply chain is growing, even if the degree of such penetration has been modest and limited to certain countries up to now.
- Death and injury, untreated conditions, and a loss of confidence in the supply generally are examples of disastrous consequences of increased penetration of counterfeits in the supply chain. A precautionary approach is therefore necessary and action warranted before counterfeit penetration increases.



## European Public Health Alliance (EPHA)

### Position Paper on Counterfeit Medicines

- Many measures aimed at increasing security in the supply chain imply relatively low burdens and can easily be achieved. Furthermore, they can be implemented without compromising the high degree of efficiency of the European supply chain, in particular the easy availability of reasonably priced medicines at short order.

#### **EPHA Concerns**

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EPHA supports the majority of measures set out in the proposed Directive. We therefore limit our comments to those areas where we have concerns.

#### **Need for a clear definition of falsified medicines**

First and foremost, EPHA strongly calls for the insertion of a clear and internationally agreed definition for “*counterfeit medicines*”, which should replace the terminology currently used in the draft directive, i.e. “falsified medicinal products”, as it would better encompass the criminal relevance of such activities and the term is globally understood. Even though this legislative proposal only has bearing in European Union jurisdictions, the phenomenon of propagation of counterfeit medicines presents a global bearing.

In this context, we suggest to include reference to the World Health Organisation’s definition of counterfeit medicinal products: “*A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.*”

#### **Need to ensure that costs of improved safety measures are not solely born by patients and thus contribute to increasing health inequalities**

EPHA is particularly concerned by the lack of full measurement of the impact of the proposed actions from the draft legislation on the price of medicines. Increased costs for the safety of medicines should not have repercussions on patients’ access to medicines. The costs implied by the new safety measures need to be spread throughout the whole supply chain, in order to avoid creating new barriers to the affordability of medicines and therefore increasing already rising health inequalities in Europe.

#### **Need to ensure that the measures do not hinder competition or impose barriers to trade for third countries**

as has happened with the enforcement regulation that has led to the seizures of legitimate generic medicines in transit. Applying the proposed measures to medicines that will not be introduced into the EU market, thus in transit, as proposed in Article 52 and point 17 on page 9 could lead to problems.



## European Public Health Alliance (EPHA)

### Position Paper on Counterfeit Medicines

In general terms, any issues regarding false labeling as to identity or source (counterfeiting), should not be confused with compliance to Good Manufacturing Practice (GMP) or Good Distribution Practice (GDP). This would unduly widen the scope of counterfeit regulation to the extent it would hinder competition and impair access to medicines to consumers. This should be made clear in the proposal.<sup>1</sup> Furthermore, patent infringements should be explicitly excluded from the definition and the regulation.

#### **Authentication of medicines**

EPHA supports in principle the use of pharmacy level authentication of medicines.<sup>2</sup> The pharmacists represent an important line of defence against fake medicines getting into the hands of patients. The addition of a safety feature in the form of a bar code or RFID tag, together with the mass serialization of individual medicine packs, offers, in the view of EPHA, a strong line of attack against the counterfeiters.

However, EPHA would like to point out a number of issues arising from the approach set out in the proposed:

- The draft Directive does not indicate a particular form of authentication, as this would exceed Community competence. EPHA accepts and agrees with this approach. It is important also that existing approaches to authentication in some Member States are respected.

Mass serialisation will not in itself combat counterfeiting. At the national level, modalities of authentication will therefore need to be determined, including cost, scanning technology, the use and storage of dispensing data, and the choice of an 'end to end' system (manufacturer and pharmacist only) or full track and trace system ( all supply chain actors).

- In this context, if the Commission adopts the Comitology procedure to select the technology, it must consult with all relevant stakeholders about the range of technological options. The Comitology process must not be used to favour specific solutions behind closed doors.
- The risk based approach to the placing of the safety feature can be disputed. The following arguments should be duly considered in this regard:
  - a. In general, authentication systems imply a number of complex financial, technical and legal matters. The implementation of authentication

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<sup>1</sup> Under the IMPACT definition, "Quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate, authorised medical products should not be confused with counterfeiting".

<sup>2</sup> The EPHA view of the issues involved in establishing such authentication systems is available in a separate position paper.



## European Public Health Alliance (EPHA)

### Position Paper on Counterfeit Medicines

systems will involve considerable costs for the supply chain actors involved. However, the fixed costs of an authentication system will remain broadly the same for a few products or for all. A restricted list of products therefore greatly reduces the proportionality of the costs.

- b. Member States have the right to determine their own level of healthcare protection. When the Commission chooses to reserve for itself the decision regarding the included medicines, it takes an inconsistent approach with the above mentioned principle.
- c. The risk based approach is inconsistent with the idea of pre-emptive action on the basis of precaution. For example, a particular medicine may be currently counterfeited and present risks because it represents the least opportunity cost for the counterfeiters. Removing that medicine from the possibility of counterfeiting does not imply that the potential profits offered by other medicines are not sufficiently attractive to make counterfeiting worthwhile. The counterfeiters will effectively be invited to divert their attention to these medicines. In this context, the fact that other medicines will have been deemed to be low risk by definition might make it easier for such medicines to enter the supply chain.

In many cases, it may therefore be counterproductive to divide medicines into high and low risk. As long as opportunity costs remain sufficiently low for any medicine, including over the counter medicines, that medicine is at risk of being counterfeited.

Similarly, the counterfeiting of medical devices must not be ignored.

#### **The risks in addressing internet pharmacy<sup>3</sup>**

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#### **The proposed solutions to the problem of counterfeit medicines however rely on an inadequate analysis of the problem.**

The data the European Commission relies on is not clear and the problem of counterfeits is being overstated. The WHO estimates 1% of sold originator brand meds are counterfeits while there almost no counterfeits of generic medicines<sup>4</sup>. Furthermore, the Commission's proposal concentrates on the legal pharmaceutical supply chain, without even mentioning the internet, and ignoring that the world wide

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<sup>3</sup> By 'internet pharmacy' we mean the long distance purchase of medicines from internet sources outside of the network of actual pharmacies. This is distinct from so-called 'clicks and mortar' or other e-trade solutions, where internet ordering is part of the service provided by ordinary pharmacies, and subject to the same regulation. Nonetheless, it may be difficult for patients to recognise what category an internet website belongs to. In any case, the topic of internet sale of medicines should be treated with the greatest possible sensitivity, respecting the Member States' regulatory competences.

<sup>4</sup> WHO Fact Sheet N275



## European Public Health Alliance (EPHA)

### Position Paper on Counterfeit Medicines

web is the main distribution channel for counterfeit medical products. Many commenters have already expressed concern at the failure of the proposed Directive to deal with internet pharmacy, by far the major source of counterfeit medicines in Europe.

In this context, the proposed initiatives are insufficient to protect consumers and patients from this source of danger, and we urge the European Union institutions to foster European and international cooperation on this matter and to recognise illegal Internet sales as the main illegal supply chain of counterfeits.

However, given that in most Member States internet provision of prescription only medicines is already illegal and that even where internet pharmacy for prescription medicines is legal, the counterfeit medicines tend to come from unlicensed sources, the options for the EU Institutions are limited.

#### **Measures to address illegal internet sales could however include:**

- Stronger cooperation between the EU and individual Member States, involving the stakeholders acting in this field, including the public health community;
- A ban on sponsored advertising of illegal pharmacies on line;
- The creation of certification systems for authorised on-line pharmacies in those countries where online sales are legal;
- Special initiatives to make consumers aware of the risks they run when purchasing on line medicines from unknown sources on the internet;
- Educating consumers and patients about the dangers of counterfeit medicines and the hazards of buying prescription only medicines from unregulated sources.

Many of these counterfeit medicines are bought from fake online pharmacies offering for sale prescription medicines helping “lifestyle” conditions, such as erectile dysfunctions and obesity, thus allowing patients bypassing difficult and embarrassing interviews with doctors. However, treatments against life threatening diseases are increasingly falling into this illegal trade, including lifesaving medicines for conditions such as cancer and heart problems. Through the web, fake products, which are designed to look indistinguishable from the genuine one, can easily reach unaware patients. “Illegal Internet pharmacies conceal their real identity, are operated internationally, sell medications without prescriptions, and deliver products with unknown and unpredictable origins and history”<sup>5</sup>.

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<sup>5</sup>See IMPACT (International Medical Products Anti-Counterfeiting Taskforce) Report of WHO updated May 2008: <http://www.who.int/impact/FinalBrochureWHA2008a.pdf>



## **European Public Health Alliance (EPHA)**

### **Position Paper on Counterfeit Medicines**

In this context, even if current restrictions in Member States were lifted (something we strongly oppose), and internet pharmacies were made subject to a licensing regime, it is a strong possibility that there would be a significant rise in counterfeit penetration, as patients would not be able to reliably distinguish between licensed and unlicensed sites. A culture of internet purchase of medicines will inevitably lead to a rise in counterfeits.

It is essential therefore that the existing restrictions in most Member States stay in place. Member States should remain free to restrict internet sales at national level and the law should be enforced as effectively as possible, in a framework of increased cooperation between Member States.