efpia
European Federation of Pharmaceutical Industries and Associations

# Falsified Medicines Directive (FMD)

## Delegated act on the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced in the union but not intended to be placed on the market

## Concept Paper submitted for Public Consultation

## EFPIA Response

*7 December 2012*

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*The European Federation of Pharmaceutical Industries & Associations (EFPIA) welcomes the opportunity to comment on the Delegated Act which introduces considerations for strengthened measures to tackle the threat of falsified and counterfeit medicines through reinforced customs actions.*[1]

*EFPIA reiterates its strong commitment to enhancing patient safety across Europe and beyond. Counterfeit medicines represent a global threat to public health and must be tackled as such. Customs actions play a key role in this respect, in particular as regards medicinal products in transit, i.e. "medicinal products introduced into the Union but not intended to be placed on the market".*

*However we are concerned that unless there is a reversal of the current presumption, i.e. that import for export of products is acceptable and not illegal*[2]*, or a clear statement that the Delegated Act will supersede existing legislation as concerns medicinal products (representing a public health threat), the purpose of the Delegated Act will not prove effective.*

*EFPIA emphasises that it, in line with its public statement of 2009, has no interest in obstructing the legitimate trade in generic medicines from manufacturers for lawful sale to customers outside (or via) the EU.*

[1] Note: *The purpose of Article 52 ter and its Delegated Act is indeed to determine criteria for enabling Customs authorities to stop falsified medicines in transit (coming from a third country and going to a third country) on the grounds of the public health threat they represent. This would be irrespective of the Nokia and Philips decisions (ECJ case law) and of the amended 1383/2003 Customs Regulation.*

[2] See ECJ Philips and Nokia cases, C-446/09 and C-495/09, and EC Regulation 1383/2003, currently being revised

## CONSULTATION TOPICS

## 1. POSSIBLE CHECKS AND VERIFICATIONS

13. Article 1 (33) of Directive 2001/83/EC as modified by Directive 2001/62/EU defines a falsified medicinal product as:

"*Any medicinal product with a false representation of:*

*(a) its identity, including its packaging and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*

*(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or*

*(c) its history, including the records and documents relating to the distribution channels used.*

*This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.*"

14. The verifications of the potential falsified character of a medicinal product introduced into the EU but not intended to be released for free circulation should therefore relate to the identity, the source or the history of the medicinal product.

15. When checking the identity of the medicinal products, analytical testing of the composition as well as verifications of the packaging and of the labelling could be considered.

The medicinal products in question would not be intended for the EU market and therefore might not be authorised in the Union. Consequently from an analytical point of view such verifications could be particularly challenging (e.g. lack of reference samples, unknown original packaging…).

16. When checking the source of the medicinal products, information concerning the manufacturers could for example be requested to the importer or wholesaler of those products.

17. When checking the history of the medicinal products, documents concerning the distribution channels could be requested.

**Consultation item n°1: please comment on this abovementioned possibility for checks and verifications (paragraphs 15, 16, 17).**

EFPIA strongly believes that efforts to stop trafficking of counterfeit health products should be global and coordinated amongst countries and, critically, should involve transit countries. A harmonisation of the approach and measures to take by all stakeholders is imperative to maximise security of supply. We therefore welcome the above mentioned possibility for checks and verifications by EU customs, including for medicinal products which would not be intended for the EU market. Indeed, if there is a commitment to stopping counterfeit medicines at EU borders to protect the health of European patients, this should be extended to patients in the rest of the world (especially medicines that have passed through the EU). In the interest of patient safety, all medicinal products coming into the EU should be assessed in their entirety. Indeed, public health issues shall allow an intervention even if the goods are imported for re-export or in transit.

This is in line with the ECJ decision on the Philips and Nokia cases (cases C-446/09 and C-495/09)[3], stating that customs should retain their current powers to act against suspected counterfeit goods that pose a threat to public health in all situations in which the goods are under customs supervision (including in particular exportation, transit, transhipment, temporary deposit, customs warehousing procedures, placement in free zones or free warehouses), and not just in situations when the goods are declared for import.

When a medicinal product passes through the Union, the relevant information is provided with assignment (batch documentation - i.e. CoA, CoC, import license, invoice - delivered with the product gives the appropriate information).

The verifications to be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market should follow some of the methodology used by customs authorities to identify suspicious products and use the information given by the pharmaceutical companies in their customs request for intervention filed at EU level.

Also, inspection of the trademarks as well as other distinctive signs, should be performed as a means to identify the potentially falsified character (relating to the identity, the source or the history) of a medicine in transit by customs authorities and market authorisation holders in the context of the EU Falsified Medicines Directive. As stated on several occasions by the ECJ, trademarks constitute an indication and guarantee of origin from a specific manufacturer and a guarantee of quality for all products bearing such trademarks.

Should there be any reason for suspicion, the marketing authorisation holder should be contacted immediately to ensure clarification and avoid any mistakes that can

[3] As the CJEU points out in the recent Nokia/Philips case in §76 "*As regards, secondly, the risks to consumers' health and safety which goods that are imitations or copies sometimes pose, […] precautionary considerations may militate in favour of an immediate seizure of goods identified as posing such risks, irrespective of the customs procedure under which they are placed. In such a context, the question whether the operators responsible for the manufacture and distribution of those goods direct them to consumers in the European Union or in non-member States is irrelevant*"

lead to unjustified disruptions of trade flows. Visual inspection, should of course, be required, specifications (i.e. signs of tampering, packaging aspect, variable data printed, codification, serialisation, content of the unit) shall be provided. ID checks should only be mandatory if the source and history of the product cannot clearly be clarified.

The local health authority and the manufacturer should collaborate to ensure optimal verification of the packaging and of the labeling. If necessary, this should include analytical testing of the composition. To this point, it should be noted that in ensuring effective action by EU customs it is important to rely on existing information and tools, thereby optimising resources and avoiding duplications.

Initiatives such as those stemming from Interpol (e.g. Pangea missions) or the World Customs Organisation with its *Interface Public-Members* (IPM)[4], as well as from private stakeholders (individual companies), should also be taken into account. For background, IPM consists of an online database enabling market authorisation holders to provide customs field officers with real-time data on their products as well as information making it possible to distinguish between "genuine" and "fake" goods. Customs field officers can access this information and training tool, free of charge, anywhere in the world via simple and secure user interfaces in their own language.[5]

EFPIA would like to highlight that only national databases are currently available to customs when checking whether or not a medicinal product is intended for the EU market. This makes it difficult to carry out conclusive verifications. Customs might liaise with national health agencies, but it is uncertain whether these have the necessary information regarding products intended / not intended for the EU market. To implement the Falsified Medicines Directive in an optimal way it might therefore be recommendable to ensure that the EudraVigilance Medicinal Product Dictionary (with precise information on dosage, form, etc. for all products registered in the EU, either via the centralised procedure or nationally) is made available to customs.

EFPIA encourages the European Commission and EU Member States to ensure alignment on existing tools and best practices.

*More specifically;*

16) Please clarify what the role of the wholesaler is?

17) Shipping documentation shows the history of the consignment. The activities should be done at the warehouse/distribution hub.

For clarity, it would be meaningful to introduce a definition of 'medicinal product in transit'. EFPIA suggests the following: *"a medicinal product coming from a non-EU country and passing by the EU on its way to another non-EU country".*

[4] IPM, launched by the WCO after signing the Cotonou Declaration in June 2010 as a symbolic gesture of the Customs community's commitment to stopping the trade in fake medicines as part of a united front.
[5] Information from WCO website - http://www.wcoomd.org/press/?v=1&lid=1&cid=8&id=247

**Consultation item n°2: do you consider that all the verifications mentioned in paragraphs 15, 16 and 17 should be carried out? If not, in which cases it would not be necessary to check all these verifications?**

The July 2012 European Commission annual report on customs actions to enforce IPRs[6] provides statistics showing that medicines were among the top categories of articles stopped by customs (24%) in 2011. The report also highlights that the increase in the number of detained postal packages continued in 2011, with 36% of the detentions concerning medicines. These figures are alarming and clearly stress the need for strengthened customs action. As previously mentioned, counterfeit medicines pose a serious threat to public health and therefore any verification allowing customs to prevent medicinal products - towards which there are sufficient grounds to suspect that they are falsified - from reaching the patient should be welcomed.

It is, however, recognised that the actions taken should be proportional to the risk.

EFPIA does not consider that as a standard procedure all verifications mentioned in paragraphs 15, 16 and 17 should be carried out. Verifications that are easy to perform should be given priority. Therefore, the normal sequence should be 17, 16 and then 15. Within the tests mentioned in paragraph 15, those which can be done by the authorities themselves, e.g. using the IPM database, should be carried out first. If a suspicion of falsification remains, the manufacturer may be asked for further checks, such as visual inspection of packaging and labeling, using electronic transmission of detailed photographs of the product in question. The manufacturer may also be requested to perform analytical testing of the composition, bearing in mind, however, that such testing requires considerable efforts; that laboratory capacities may not be available immediately, and that, for technical reasons, results may not be expected immediately, i.e. within a few days.

Finally, it might be easier to verify suspicions of falsification if it were possible to verify the involved parties too. The control would then not be triggered by the products only but equally by the entities handling them.
This would translate into the introduction of a new concept of recognised/safe stakeholders Vs unregulated/unsafe stakeholders. This distinction is already made through the security program of Authorised Economic Operators (AEO), in the EU Community Customs Code.

[6] EC Customs Report - http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2012_ipr_statistics_en.pdf

## 2. WHO PERFORMS THE VERIFICATIONS?

20. Checks and verifications are currently performed by different authorities in the different Member States. It would be important to maintain this organisational flexibility in the delegated act.

21. It will be the responsibility of the competent authorities in the Member States (such as, for instance, customs and public health authorities) to lay down clear procedures for cooperation between themselves.

**Consultation item n°3: please comment on this consultation topic.**

EFPIA agrees with the statements made in consultation item 3. For optimal operations and efficiency it is important to leave flexibility and leeway with national stakeholders who are best placed to decide upon national organisation.

This being said, in order for the provisions of the Directive to be effective, it is crucial that the different organisational frameworks at national level are communicated in a clear manner (and that the information can be easily accessed) so as to ensure smooth coordination and cooperation among relevant actors (knowing whom to contact and liaise with within each Member State) across the EU for greater patient safety.

Also, it should be stressed that customs or authorities engaged in customs related activities occupy a key role when it comes to verifications. Customs grant the ability to issue and discharge customs regimes, e.g. transit (without interfacing any information to health authorities) and they are, by organisation and power of control, the only authority that has the right to open parcels. If different authorities beyond customs are involved in the process of verifying falsified medicinal products, their verification activities should be triggered by customs control.

When it comes to the actual verification measures and checks, beyond organisational considerations, specific guidelines should be established for customs outlining proportionality and checking regimes.

The verification methods should indeed be harmonised across the EU. It is important to have a common high standard to protect patients and ensure trust from the public. The importance also lies in each Member State to secure that there is no loopholes for counterfeiters in one Member State due to non-harmonised procedures.
Checks and verifications (analytical testing) carried out by the customs authorities should be made jointly with the manufacturer.

Also, and as mentioned under item 1 of the consultation, it is likely to be difficult for customs to transfer information and goods to national health agencies, particularly because market authorisations granted nationally are not known from one Member State to the other (and resources for checks have been and/or are being reduced due to budget cuts). The recently launched EudraVigilance Medicinal Product Dictionary is likely to address this issue.

As already pointed out, counterfeit medicines constitute a global threat requiring global action in a coordinated manner.

## 3. Other issues

### 3.1 Date of application

22. Member States will have to apply the provisions of article 52b from 2 January 2013.

23. Concerning the delegated act the time limit for transposition would be at the latest 6 months after its publication on the Official Journal.

24. The date of application of the delegated act and of the corresponding transposing national law would be set at 12 months after the publication of the delegated act on the Official Journal.

**Consultation item n°4: please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.**

EFPIA would like to take this opportunity to underline our commitment to patient safety, within as well as beyond EU borders. We believe the finalised Delegated Act should go further than the established EU case law so as to avoid double standards in protecting patient safety. We call for action to:

- Stop ALL falsified medicines – there is no reason for stopping only those intended to be sold on the EU market; everyone is at risk;
- Address the loopholes in the current legislative framework allowing counterfeiters to take advantage of the single market by importing fake medicines into Member State 1 for onward transit to Member State 2.

We reiterate that controlling falsified medicinal products is of utmost importance to protect patient safety. We therefore call for timely yet realistic measures to be introduced at the national level taking operational aspects and practicalities into account. We acknowledge that the time frame for implementation is rather short and, while we welcome this expression of willingness to take action, we recall that the introduction of new regulatory measures without enforcement will not serve much purpose.

EFPIA stands ready to assist and work with customs authorities and other relevant actors across the EU in order to increase coordination and best practice sharing in the interest of patient safety.

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***About EFPIA***

*EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.*