LEEM'S RESPONSE TO THE PUBLIC CONSULTATION ON ARTICLE 52b) OF THE FALSIFIED MEDICINES DIRECTIVE (FMD)

LEEM is the French association representing the pharmaceutical industry, i.e. around 300 companies operating on the French territory.

Since many years, LEEM and its members are strongly committed to ensuring patient safety worldwide and in particular to protecting the public against falsified medicines. LEEM fully supports the objectives of the FMD and welcomes the possibility to comment on the concept paper released by the Commission in relation to this delegated act.

LEEM strongly believes that efforts to stop trafficking of falsified health products should be global and coordinated amongst countries and, critically, should involve *transit countries.*

Article 52b of the Falsified Medicines Directive (FMD) provides as follows:

"[…] Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are not intended to be placed on the market of the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified."

This Article also foresees the possibility for the European Commission to establish the necessary measures referred to above through the establishment of a delegated act, which is the subject matter of this consultation.

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 labelling, 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).

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?

LEEM's general comments:

Customs controls, including on products under transit or Customs warehouse regime, are mainly based on risk analysis, targeting and profiling methods developed by Customs authorities. This is because Customs capacities are limited and must, in practice, be mobilized in priority on the control of potentially illicit trade.

In order to reflect these practical considerations, LEEM would like to make the preliminary recommendations:

- Cooperation between Customs authorities and manufacturers of medicines, either originator or generic companies, should be core to the verification scheme. In case of doubt on the status of a trade flow or operator handling the medicinal products in transit at stake, Customs officials should make contact with the industry's experts. Verifications carried out by customs administration to find suspicious drugs should target trade of non Authorized Economic Operators (AEO) or operators which are not known or operators which are not authorized pursuant to a Community procedure but which have specific authorization to deliver or receive drugs. For that purpose, Customs officials can rely on manufacturer's knowledge of the legitimate distribution chain.
- In case of impossibility identify the legitimate manufacturer of the medicinal product in transit, Customs officials should solicitate their national Health Agency, who, in turn, will liaise with the Agency of the country of destination/consignment;
- Existing operational cooperation mechanisms between Customs authorities and industry (e.g. Customs notices) should form the basis of the control of falsified medicines in transit pursuant to Article 52b) of the FMD;
- Controls should be triggered on unusual trades (new traffics);
- Customs statistics for 2011 (DG TAXUD) showed that a majority of counterfeit medicines imported into the EU (but with a risk of diversion outside the EU) were retained through postal or express freight (internet orders and fragmentation of illicit trade). Controls by customs should therefore also focus on express delivery by express freight integrators (DHL, UPS, TNT, Fedex etc).

As regards, consultation items 15, 16 and 17 above, LEEM suggest that the chronologic verification sequence should be: 17, 16 and then 15. Chemical analysis of the suspected product at stake can be carried out, either by the manufacturer of the Health authority, i.e. in France, several public laboratories exist and have samples at their disposal for their testing activity.

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LEEM's comments:

In LEEM's view, the purpose of the delegated act provide for at Article 52 b) of the FMD, which is only intended to establish criteria to be considered and verifications to be made when assessing the potential falsified character of a medicinal product. The purpose of the checks and verifications is not to evidence the falsified character.

LEEM also understands that the criteria used to determine falsification of the identity of a medicine are not exhaustively listed at Article 13(a) of the FMD. Indeed, the term "*including*" is used in relation to the proposed criteria of checks and verifications:

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

As an example, many falsified medicines transit through the European Union territory in bulk. In addition, an increasing number of falsified medicines are sent to the patients following an order made via the internet (Title VIIA of the FMD specifically aims at addressing this issue) and may consequently transit through the EU territory by express or postal freight.

In order to increase efficiency of visual inspections carried out by Customs authorities, LEEM's members have established cooperation with such authorities, in particular through Customs notices procedure and further national operational agreement, in order to better define the risk analysis methods aimed at targeting these falsified medicines. We therefore suggest that all relevant data provided to Custom authorities (samples, original packaging etc.) by pharmaceutical companies are taken into account for the purpose of establishing checks and verifications criteria pursuant to Article 52b) of the FMD.

In practice, if the packaging of the product at stake does not bear the mandatory markings (compulsory mentions such as the INN, the name of the marketing authorization holder, the marketing authorization number, compulsory codification pursuant to Article 54 of Directive N° 2001/83/CE), this should suffice for the purpose of assessing the potential character of the product at stake. These measures can, if necessary, be complemented by a chemical analysis of the medicine at stake to assess its potentially falsified character.

In addition, even if a medicine is not authorized in the EU (where it is in transit) but is authorized in the country of destination, LEEM believes that cooperation mechanisms between pharmaceutical companies, Health and Customs authorities in the EU and in third countries as well as competent investigation services, can contribute to achieve the purpose of Article 52b) of the FMD.

This can be achieved for example by regular and systematic exchange of intelligence gathered by competent authorities through a coordinated system on new trends, networks or illicit activities. As an example, in the UK, MHRA coordinates the checks, investigations and enforcement against traffic of medicines at national level in cooperation with all competent public authorities and the private sector. This model could be replicated for the purpose of better targeting trade of falsified medicines in transit through the EU.

To illustrate the above mentioned cooperation mechanisms suggested, LEEM would like to point out the fact that a list of names (INN + trade names) of products identified by the manufacturers as the most likely to be falsified was compiled and sent to the following competent authorities : Customs, including French "Cyberdouane" and OCLAESP (National Police dedicated to Health and Environmental offences). Furthermore, an operational cooperation agreement was entered into between LEEM, several of its members and French Customs Administration, back in 2010, in order to increase exchanges of intelligence and information.

Furthermore, all registration of products should be available through internet (with specific access to customs) and in EC working language. If this exceeds the EC capacity, at least name, address and contact of manufacturers and their product should be provided by secure Internet media.

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.

LEEM's comments:

If the manufacturer of the medicine cannot be identified by the competent Customs authorities performing the checks and verifications, the national Health Agency should be contacted. This Agency will, in turn, contact the relevant authority in the country of destination/consignment of the medicinal product.

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

LEEM's comments:

Documents concerning the distribution channels constitute, in LEEM's view, the main ground for suspecting a falsification. EU Customs authorities are used to analyzing such documents to detect illicit trade flows.

The following documents appear to be of particular relevance:

- Certificates, authorizations from relevant health authorities regarding the manufacture/distribution of the product
- Customs documents
- Invoices
- Licences

These documents will be requested to the importer/carrier of the products by Customs authorities.

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 organizational 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.

LEEM's general comments on consultation item n° 3:

Checks and verifications mentioned at paragraphs 15, 16 and 17 should be carried out, in the first place by EU Customs authorities. Customs authorities are already entrusted with powers to control all products introduced in the EU but not intended to be placed on the EU market pursuant to the Community Customs Code.

This is particularly true with respect to restrictions imposed on the ground of public health (Article 58 of the Customs Community Code) and for all kind of Customs regimes, including for procedure regarding non-Community goods (Article 84 of the Customs Community Code).

In addition, the ECJ, in its decision on the Philips and Nokia cases (cases C-446/09 and C-495/09) , has clearly stated 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, transshipment, temporary deposit, customs warehousing procedures, placement in free zones or free warehouses), and not just in situations when the goods are declared for import.

However, LEEM believes that current EU Customs regulation should be amended through the delegated act so as to reflect the necessity for EU Custom authorities not only to control potentially falsified medicines in transit **but also to detain them before they reach third countries market**. In addition, the delegated act should determine the modalities of cooperation between EU Customs authorities, manufacturers of the authentic medicines (affected by third parties falsification) and competent health authorities. Indeed, in some cases, the medicine can be falsified without misrepresenting itself as originating from a specific manufacturer. In that case, the competent health authority will need to cooperate with the EU Customs authorities in order to determine the potentially falsified character of the product.

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

LEEM's comments:

In order for the provisions of the Directive to be effective, it is crucial that the different organizational frameworks at national and EU level are clearly coordinated.

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.

LEEM's comments:

LEEM takes the view that a minimum harmonization should be provided through the delegated act in order to lay down clear cooperation procedures. We do not see anything in the TFEU that would prevent European Commission's intervention to set up harmonized cooperation rules and modalities among the competent authorities within the EU.

At EU level, the EMA should be seen as playing a central role with respect to coordination of relevant information and action, allowing competent authorities (Customs in particular) and Member States to efficiently comply with provisions of Article 52b) of the FMD. In particular, EMA could ensure the maintenance and availability to Customs officials of a secured internet platform of all products registered in the EU and third countries.

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.

LEEM was consulted by the French Health Directorate at the end of October 2012 and requested to comment on the draft FMD transposition bills into French law. LEEM drew the attention of the French Health Directorate to the fact that provisions of Article 52b of the FMD were not reflected into the French legal scheme (in particular French Customs Code) and that such provisions should be included in the national transposition law (which was not the case in the draft bill received).