DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

(Text with EEA relevance)

Article 52b

1. Notwithstanding Article 2(1), and without prejudice to Title VII, 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.

2. In order to establish what the necessary measures referred to in paragraph 1 of this Article are, the Commission may adopt, by means of delegated acts in accordance with Article 121a, and subject to the conditions laid down in Articles 121b and 121c, measures supplementing paragraph 1 of this Article as regards the criteria to be considered and 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.

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health systems and products
Medicinal products – quality, safety and efficacy

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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

INTRODUCTION

1. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products was published[1] on 1 July 2011. This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.[2]

2. Medicinal products may be introduced into the Union while not being intended to be imported, i.e. not intended to be released for free circulation in the EU.

3. Those products, if falsified, may constitute a risk for patients in the Union. In addition they may also present a danger for patients in third countries.

4. For this reason Directive 2011/62/EU has provided for the obligation for Member States to 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[3].

5. The Directive also foresees that the Commission may set up in a delegated act the criteria to be considered and the verifications to be made when assessing the potential falsified character of those products[4].

6. It is important to underline that the delegation of powers provided to the Commission by the co-legislators is limited. Therefore, the delegated act will be limited only to the criteria to be considered and the verifications that may be carried out to establish the potential falsified character of those medicinal products (verifications in the text of the consultation).

7. As regards the attribution of control tasks to national authorities, the principle of subsidiarity applies. It is the competence of Member States to attribute verification tasks to specific national authorities (e.g. customs, health authorities,…).

8. Verifications may be carried out by different authorities in different Member States. Different authorities may be competent of different verification procedures in the same Member States. Taking into account the principle of distribution of powers between the Union and the Member States, the delegated act will not interfere with this.

9. The verifications that will be foreseen in the delegated act will have to be compatible with international trade laws and customs legislation.

10. The verifications that will be proposed in the delegated act will have to be properly enforced to be effective. As the delegated act will be applicable to all Member States, the availability of sufficient resources to implement it will also be crucial.

11. This concept paper is being rolled out for public consultation with a view to prepare the abovementioned delegated act.

12. The adoption of the delegated act is tentatively scheduled for 2013.

CONSULTATION TOPICS

1. POSSIBLE CHECKS AND VERIFICATIONS

13. Article 1 (33) of Directive 2001/83/EC as modified by Directive 2011/62/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).

18. The level and range of controls and verifications should be governed by the principle of proportionality to avoid unjustified disruptions of trade flows.

19. Particular care will have to be taken to ensure, in view of the human resources available in Member States, that the verifications that will be proposed in the delegated act are properly enforced.

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?

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.

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.

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Concept paper submitted for public consultation. Answers formulated by a private individual. (*)

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

"..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…"

The above mentioned situation where medicinal products are introduced into the union (introduced in the European customs territory) together with the intention not to place them on the market (through bringing them into free circulation) means that these products are kept under special customs regime. Commonly we call such a situation "transit". In fact ***COUNCIL REGULATION (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights*** *gives customs, jurisdiction to apply Intellectual Property Rights in transit and sets out the conditions for action when e.g counterfeit medicines are entered for release for free circulation,export or re-export. Moreover customs have jurisdiction when goods suspected infringing IPR and entering the community customs territory, placed under a suspensive procedure, in the process of being re-exported or placed in a free zone or free warehouse. In most Memberstates customs do not have jurisdiction on medicines legislations and are through absence of expertise not familiar with medicines regulations. Advice and field support from health inspectors are urgently needed as to avoid further seizures of lifesaving generic medicines in transit which happened in december 2008 by dutch customs. From this point of view it is high time that health inspectors get suitable jurisdiction as to conduct inspections and enforcement in transit. They should be assigned jurisdiction on* ***medical products*** *not only on falsified medicines.To day*

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001on the Community code relating to medicinal products for human use does not provide in such a jurisdiction nor does penal law. And very little national medicines acts allows inspections in transit and still use the words "import" in their lawtexts meaning entering their national territory.
Internationally organized criminals know very well all aspects of keeping goods in transit which is the ultimate solution of transfering counterfeit and illicit goods from one country to another to finally enter the distribution chain where they planned market infiltration. Numerous investigation cases have proven the dangers of transit situations where customs control are weak or unexistant. On the other hand Europe has a moral duty not to be ***accessory*** *when medicines passing in transit on the European territory are compromised intentionally or unintentionally (e.g substandard). We all know that a lot of medicines are passing through Europe destined for developement countries who lack all basic control possibilities to check quality. Since customs do not have expertise nor analytical possibility to analyse medicines, health authorities are the only one who may conduct effective surveillance.*
Europe may at least require that importers and wholesalers present due documentation (analysis certificates, manufacturing authorizations, GMP-GDP certificates…). Warehouses (bonded) storing these medicines should apply the new GDP guidelines (SANCO/C8/AM/an D(2010) 380358).

Checking history of the products may be a good indicator if analytical testing is needed. Other risk analysis (customs) may result in targeted checks and verifications. Close collaboration with the destinee country health authorities may be conclusive in taking action. A list of "no pasarán" criteria may be established and communicated to the health authorities of the sender countries. A complete sensibilisation program may be set up by the EU towards countries like India and China. Since systematic chemical analysis is too much a financial burden only when suspicion of compromised quality is obvious, products could be analysed and results transmitted to destinee countries. Organoleptic and physical characteristics of the product are easy to check. Analytical testing without references may also produces conclusive results. Through e-mail, pictures of the packaging may be send to the original manufacturers for checking. In the case of adulterated products (foodsupplements with unlabeled API – which all are medicines through the medicines definition and subsequently falsified medicines in relation with identity) most European MS have build up expertise and databases as to recognize easily those products. So between medicines inspectors having no jurisdiction and not able to check and verify and the freedom given by adapted legislation there is a big difference where Europe may contribute to basic health in development countries. The falsified medicines directive relies heavily on data from third countries. International collaboration and information exchange should be the rule and not the exception. These basic values are also clearly stipulated and promoted in the Medicrime Convention.

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?

Risk analysis is necessary to be able to make correct judgement. A risk analysis model may be outlined and criteria for all MS set forward. Information exchange may play an important role. Verifying every batch passing through Europe is not the objective. Random check may be the bottom line and risk analysis criteria adjusted along. After a period certain importers, manufacturers and wholesalers may be classified as part of "a green line" were checks and

verifications may be limited to administrative surveillance and monitoring. Customs may play an important role through compliance verification and the WHO may be of help through their prequalifation program. As it comes to proportionality the basic line should be to get dangerous compromised products out of the distribution, not punishment.

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

If flexibility means that customs still want to keep all exclusivity of border and transit control for themselves then discussion is finished. The basic principles of multidisciplinary and multisectoral management of these kind of problems should be long time achieved in the 21st century. If this kind of unilateral approach is understood by organizational flexibility then there is no flexibility at all.
Using the subsidiarity principle for hiding a transnational and transborder health problem is not acceptable. Instead of harmonizing the EU divides. Nothing withholds MS to establish collaboration procedures but knowing that all MS do have the same approach is basic line for multidisciplinary and multisectoral SPOCs networking (See Medicrime Convention on Single Points of Contact Network)

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.

It seems that the Commission has a very conservative idea about falsified medicines. This gives the impression that not health but IPR is at stake. The actual babel-like confusion about definitions in the Memberstate Mechanism of the World Health Organisation will not make discussion univocal and easier. The merging of counterfeit medical products and similar crimes in the Medicrime Convention is to my idea the largest platform for combating pharmaceutical crime. Not only counterfeit medicines are passing "in transit" but also adulterated foodsupplements, diverted authentic medicines (originating from access programs for development countries), illicit unauthorized medicines, medical devices and so on…Question is to give jurisdiction to health inspectors in the largest sense possible as to be able to face all kind of problems if compromised products are found under suspensive measures, in free zones, in bonded warehouses etc..

(*)The answers on this consultation document represents the personal conviction of the author as to preserve an upright opinion also in the interest of development countries.

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