EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

Sanco.ddg1.d.6(2012)1117276

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

---

1 OJ L 174, 1.7.2011, p. 74

2 OJ L311, 28.11.2001, p. 67. A consolidated version of Directive 2001/83/EC including the amendments by Directive 2011/62/EU is here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF

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 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

[3] Article 52b (1) of Directive 2001/83/EC

[4] Article 52b (2) of Directive 2001/83/EC

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.

Stakeholders are invited to comment on this consultation paper, and especially on the boxed text, by 10 December at the latest. Responses should be sent preferably by e-mail to:

SANCO-INTRODUCTION-FALSIFIED@ec.europa.eu

or by post to:

European Commission, DG SANCO, Unit SANCO/D/6, DM24 02/36, BE-1049 Brussels.

When sending your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association this is (patient, pharmacy, retailer, manufacturer, etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

All comments and responses will be made publicly available on the 'Europa website' on pharmaceuticals once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the documentation you send us (i.e. not just in the covering letter or e-mail). In this case, only the name of the contributor will be disclosed.

Professional organisations are invited to register in the Union's Register for Interest Representatives (http://ec.europa.eu/transparency/regrin/) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.