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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

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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 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

[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).

The received contributions together with the identity of contributors will be made publicly available on the 'Europa website' on pharmaceuticals once the consultation period is over, unless the contributor objects to publication of his or her personal data on the grounds that such publication would harm his or her legitimate interests. In this case the contribution may be published in anonymous form. Otherwise the contribution will not be published nor will, in principle, its content be taken into account. For more information on the processing of your personal data in the context of this consultation, read the specific **Privacy Statement** available on pages 7 and 8.

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.

PRIVACY STATEMENT

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OBJECTIVE

The objective of this consultation is to receive the views of stakeholders and potentially to publish the received contributions on the Internet, under the responsibility of the Head of Unit "Medicinal Products, Quality, Safety and Efficacy", Directorate-General for Health and Consumers, European Commission.

As this online service collects and further processes personal data, it is subject to data protection rules as established by Regulation (EC) 45/2001[5].

1. WHAT PERSONAL INFORMATION DO WE COLLECT AND THROUGH WHICH TECHNICAL MEANS?

1.1. Identification Data

Personal data collected and further processed are only those data which are necessary for the management of contributions (such as name, surname, profession, postal and e-mail addresses, phone number/fax number, etc.), as well as the views of contributors on the topics concerned.

The processing operations on personal data linked to the management of this consultation are necessary for the functioning of the Commission as mandated by the Treaties, and more specifically by Articles 5 and 13 TEU and Articles 244 - 250 TFEU.

1.2. Technical information

Your contribution will be collected, together with your personal data, through e-mail. The e-mail system of the European Commission abides by the Commission's security decisions and provisions established by the Directorate of Security.

[5] Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

2. WHO HAS ACCESS TO YOUR INFORMATION AND TO WHOM IS IT DISCLOSED?

Received contributions, together with the identity of the contributor, will be published on the Internet, unless the contributor objects to publication of his/her personal data on the grounds that such publication would harm his or her legitimate interests. In this case, the contribution may be published in an anonymous form. Otherwise, in the absence of a legitimate interest to oppose publication of personal data, the contribution will not be published nor will, in principle, its content be taken into account. Any objections concerning publication of personal data should be sent to the service responsible for the consultation (see Contact information below).

3. HOW DO WE PROTECT AND SAFEGUARD YOUR INFORMATION?

Received contributions will be recorded in a secured and protected database hosted by the Data Centre of the European Commission, the operations of which abide by the Commission's security decisions and provisions established by the Directorate of Security for this kind of servers and services. The database is not accessible from outside the Commission. Inside the Commission, the database can be accessed using a UserID/Password.

4. HOW CAN YOU VERIFY, MODIFY OR DELETE YOUR INFORMATION?

In case you want to verify which personal data is stored, have it modified, corrected or deleted, please contact us using the Contact Information below and explicitly specifying your request.

5. HOW LONG DO WE KEEP YOUR DATA?

Your personal data will be part of a list of contact details shared internally amongst Commission staff for the purposes of contacting you in the future in the context of subsequent Commission's initiatives. If you do not agree with this, please contact us using the Contact Information below and explicitly specifying your request.

6. CONTACT INFORMATION

In case you wish to verify which personal data is stored, have it modified, corrected, or deleted, or if you have questions regarding the information processed in the context of the consultation, or on your rights, feel free to contact the support team at:

European Commission, DG SANCO, Unit D6, "Medicinal Products, Quality, Safety and Efficacy", DM 24 02/36 B- 1049 Brussels.
SANCO-INTRODUCTION-FALSIFIED@ec.europa.eu

7. RECOURSE

Complaints, in case of conflict, can be addressed to the European Data Protection Supervisor.