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

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**IMPLEMENTING ACT ON A COMMON LOGO FOR LEGALLY-OPERATING ONLINE  
PHARMACIES/RETAILERS OFFERING MEDICINAL PRODUCTS FOR HUMAN USE FOR SALE  
AT A DISTANCE TO THE PUBLIC**

**CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION**

## INTRODUCTION

1. On 1 July 2011, 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.<sup>1</sup> This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.<sup>2</sup>
2. Directive 2011/62/EU introduces EU-wide rules in relation to '*the offer of medicinal products for human use for sale at a distance to the public by means of information society services*' as defined in EU legislation.<sup>3</sup> For simplicity and clarity reasons, the term 'online pharmacy/retailer' shall be used for the purpose of this concept paper.
3. Directive 2011/62/EU introduces a "common logo" for websites of legally-operating online pharmacies/retailers.<sup>4</sup> This logo has to be clearly displayed on every page of the website offering the medicinal products.
4. The common logo shall be recognisable throughout the Union, while enabling the identification of the Member State where the online pharmacy/retailer is established.<sup>5</sup>
5. In addition, Member States are under an obligation to set up a dedicated website providing, *inter alia*, the national list of all legally-operating online pharmacies/retailers.<sup>6</sup>
6. Each entry of this list shall contain a hyperlink to the website of the respective online pharmacy/retailer.
7. In parallel, the common logo shall contain a hyperlink to the entry of the online pharmacy/retailer in the national list (reciprocal link)<sup>7</sup>.

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<sup>1</sup> OJ L 174, 1.7.2011, p. 74

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

<sup>3</sup> Title VIIA of Directive 2001/83/EC.

<sup>4</sup> Article 85c(1)(d)(iii) of Directive 2001/83/EC.

<sup>5</sup> Article 85c(3) of Directive 2001/83/EC.

<sup>6</sup> Article 85c(4) of Directive 2001/83/EC.

<sup>7</sup> Article 85c(1)(d)(iii) of Directive 2001/83/EC.

8. This reciprocal link is aimed to allow customers to verify the authenticity of the logo displayed on the webpage of the online pharmacy/retailer.
9. The Commission is under an obligation to adopt implementing acts<sup>8</sup> regarding:
  - the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;
  - the design of the common logo.
10. This concept paper is being rolled out for public consultation with a view to preparing the implementing act.
11. The adoption of the implementing act is scheduled for 2013.

#### **CONSULTATION TOPICS**

1. **The technical, electronic and cryptographic requirements for verification of the authenticity of the common logo**
12. The verification of the common logo is done via a reciprocal link (see above). In order for the reciprocal link to work reliably it might be necessary to ensure a secure information transit between the common logo and the national list of legally-operating online pharmacies/retailers.
13. In view of fast technical progress, and in order to ensure the efficacy of the system, it might be preferable not to draw up details for the technical, electronic and cryptographic requirements.
14. Rather, it might be preferable to provide for a generic obligation to ensure by means of encryption a secure transit of information between the common logo on the website of an online pharmacy/retailer and the national list of legally-operating online pharmacies/retailers.
15. Communication campaigns will be organised in cooperation with the European Medicines Agency and with Member States in order to inform the general public that the simple presence of the logo on a webpage will not be sufficient to ensure that the online pharmacy/retailer is authorised, as the logo may have been copied.
16. Customers will have to verify the national list of legally-operating online pharmacies/retailers by clicking on the logo itself.

<b>Consultation item n°1: Please comment.</b>
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2. **Design of the common logo**

17. According to Directive 2011/62/EC, the design of the common logo would be set out in the implementing act.

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<sup>8</sup> Article 85c(3) of Directive 2001/83/EC.

18. For the purpose of this public consultation, two options for a common logo are put forward:

19. Option 1:



20. Option 2:



21. The logos displayed in paragraph 19 and 20 are registered in the Benelux Office for Intellectual Property and cannot be used or reproduced without the explicit authorisation of the European Commission.

**Consultation item n°2: Please comment on these options. If you plan to submit another, alternative, design for the common logo as part of your submission, please be aware that the Commission does not intend to engage in any financial commitments for the use of the design of the common logo, or reference thereto, in the implementing act.**

**3. National element and text associated with the common logo**

22. The common logo shall be recognisable throughout the Union, while enabling the identification of the Member State where the online pharmacy/retailer is established.<sup>9</sup>
23. Therefore the logo that will be chosen will have to be associated to a national element, for example the flag of the concerned Member State.
24. A text could be associated with the logo to make clear to potential customers that the presence of the logo in itself is not sufficient to ensure that the online pharmacy/retailer is authorised, as the logo may have been copied.
25. Such text could be: "click to check this website"<sup>10</sup>.

**4. Size and position of the logo**

26. The logo should be clearly displayed on every page of the online pharmacy/retailer. A minimum size of the logo may have to be established.
27. In principle the logo will be static, however the possibility to introduce some animation may be considered. Such animation should not create confusion in the public and difficulties in the recognition of the logo.
28. In order to enhance the visibility of the logo a negative format of the selected logo could also be authorised.

**Consultation item n°4: Please comment.**

**4. Other issues**

**4.1. Date of application**

29. The national laws transposing the rules on online pharmacies/retailers set out in Directive 2001/83/EC shall apply at the latest 1 year after the date of publication of the implementing act mentioned in paragraph 9.<sup>11</sup>

**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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<sup>9</sup> Article 85c(3) of Directive 2001/83/EC.

<sup>10</sup> Examples of how the logo with the proposed text and the national element could look like can be found in the Annex to this document.

<sup>11</sup> Article 2(2)(c) of Directive 2011/62/EU.

## Annex

### Examples of possible logos with a national element and a possible text

In these examples the national flag of the Member State in which the online pharmacy/retailer is authorised/entitled to supply medicinal products to the public, is replaced by the EU flag.

#### Option 1



#### Option 2



Stakeholders are invited to comment on this consultation paper, and especially on the boxed text, by 17 January 2013 at the latest. Responses should be sent preferably by e-mail to:

[sanco-logo-falsified@ec.europa.eu](mailto:sanco-logo-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 8 - 10.

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**

### **IMPLEMENTING ACT ON A COMMON LOGO FOR LEGALLY-OPERATING ONLINE PHARMACIES/RETAILERS OFFERING MEDICINAL PRODUCTS FOR HUMAN USE FOR SALE AT A DISTANCE TO THE PUBLIC CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION**

#### **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<sup>12</sup>.

#### **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.

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<sup>12</sup> 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-logo-falsified@ec.europa.eu](mailto:sanco-logo-falsified@ec.europa.eu)

## **7. RECOURSE**

Complaints, in case of conflict, can be addressed to the [European Data Protection Supervisor](#).