

Falsified Medicines Directive (FMD)

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

EFPIA Response

17 January 2013

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The European Federation of Pharmaceutical Industries & Associations (EFPIA) welcomes the opportunity to comment on the Implementing Act which introduces a common logo for legally-operating online pharmacies so as to increase patient safety in the EU digital environment.

EFPIA believes an EU logo constitutes a useful step in tackling the threat of illicit online pharmacies. However, only when coupled with additional measures (awareness raising, as pointed out in point 15 of the public consultation, regulatory and legislative action and enforcement, etc.) will it prove effective.

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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.

Consultation item n°1: Please comment.

EFPIA welcomes the introduction of a common logo across the EU in order to allow for verification of online pharmacies and thereby enhance patient safety. However we are concerned that if the system is not set up with care there is a strong likelihood that illegal operators will be able to copy the logo, place it on illegal pharmacy websites and link it to fake authentication pages. This could mislead patients into believing that they are purchasing from an authorised online pharmacy.

We are concerned with the wording in paragraphs 5 and 16 of the introduction, i.e. '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'.

EFPIA would recommend establishing a single website and a single list at EU level. While we recognize the provisions of Article 85c.4 of the Falsified Medicines Directive, requiring 27 national websites linked to that of the EMA, we believe that patient safety is best served by a single site to which patients can be directed. A requirement for national websites is likely to give greater scope for illegal operators to confuse patients with false national websites containing false lists of legitimate online pharmacies.

It is critical that the EMA and EU Member States conduct pan-European awareness raising campaigns 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.* Equally, clicking on the logo on a page will not provide a guarantee of authenticity as the page to which the logo links could also be fake. The campaigns should explain how patients can tell the authenticity of the websites by checking the URL. Customer information campaigns by banks for online banking provide a good example.

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.

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.

EFPIA prefers option 1 which clearly conveys the idea of verification or accreditation and thereby trust. We believe the logo should also include the EU flag or some other EU protected symbol, which would give EU authorities the right to prosecute unauthorised users.

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.

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".

Consultation item n°3: Please comment.

EFPIA agrees with the above provisions regarding national elements linked to the logo (as long as small, leaving the EU elements predominant).

The suggested text associated with the logo is not appropriate as it would not be obvious for the customer to notice whether he/she is directed to a fake site. It is crucial to point out, in the clearest and simplest way possible, that there is a single checking point for the whole EU.

The checking website address should be simple and end with e.g. the ".europa.eu" domain extension so as to make it more difficult for illegal pharmacies to set up fake checking sites. The ".pharmacy" domain extension (gTLD) – under the control of the US National Association of Boards of Pharmacy (NABP) - should equally be considered.

There should also be a warning against potential fake checking sites, even if it requires more space on the screen.

To prevent fraud, we suggest the text reads;

"Check legitimacy of this site using www.onlinepharmacy.europa.eu/.pharmacy only. Do not trust any web address that ends differently than europa.eu/.pharmacy."

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.

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.

EFPIA would like to add the following observations:

1. There should be clear sanctions in the event a website offering medicines uses the logo without authorisation. In addition, those websites should be blocked from appearing in search results in any of the EU Member States.
2. The website listing those authorised to sell medicines online should also provide information regarding the legality of purchasing medicines online by residents of each member state. For example, if a country prohibits buying medicines online, there would be no list of authorised sites, only that information.
3. To further support Article 85c.6 the single EU level site should include a way for the public to report suspicious websites selling medicines in the EU that are not on the approved lists. Those websites could be blocked from appearing in search results if they use the logo. If they do not use the logo, they should be referred to national authorities for takedown or a notice could be sent to the domain name registrar, or other action taken.

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EFPIA stands ready to work with public authorities and relevant stakeholders at EU and national levels in order to secure the digital environment for medicinal products and protect patient safety.

We are proactively engaged in a recently launched multi-stakeholder alliance – Alliance for Safe Online Pharmacy EU (ASOP) – aiming at making the internet a safer place through voluntary and collaborative actions. For further information on ASOP EU, please see www.asop.eu

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About EFPIA

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 37 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

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