



European Alliance for Access to Safe Medicines

Directive 2011/62/EU

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.

Comments on Concept Paper

London, 15 January 2013

Background Information

EAASM is pleased to note the progress made to date with regard to the Falsified Medicines Directive, which it believes will be a highly significant instrument in increasing patient safety in Europe. As the FMD makes the physical supply chain more robust, it is essential that the online “virtual” supply chain is similarly secured. The EAASM welcomes the opportunity to comment on the Concept Paper.

Comment on Consultation item No 1

In our view, there are two critical elements to the successful implementation of the common logo. The first is that the system employed to link the logo to the national list(s) must be secure and future-proofed against forgery. The sites hosting the databases of legitimate pharmacies must use secure server connection, in order to avoid the possibility of “cloaking”. Similar national logos have, in the past, been forged. The second is that, in order to understand the meaning of the logo, EU citizens must be informed of its existence and the reason for that existence. From discussions with the Commission and Member State Drug Regulatory Authorities, we have concerns regarding the amount of funding that will be made available for this.

In our opinion, the technical aspects of the logo and the architecture to secure and link it, should be subject to discussion and proposals from a small group of experts in this area. We feel that this would greatly assist the Commission. The recently-formed Alliance for Safe Online Pharmacy in the EU (ASOP EU) has in membership many leading companies operating in the online space and would seem perfectly placed to convene such a group.

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In our view it is essential that the registration number of the pharmacy be directly associated with the logo and that the logo should be positioned directly alongside the name of the pharmacy. It would seem sensible to mandate the position and size of the logo, in order to give patients a consistent and easy way of verifying any website.

Whilst we accept that such proposals may or may not meet the requirements of every Member State, we do believe that they would help to prevent the unnecessary expense of devising and implementing up to 27 different generic versions that could be of varying quality and security, in essence pointing the way to a safe haven for online criminals.

Comment on Consultation Item No 2

We support the introduction of option 1, though we would have welcomed more than two choices from which to pick a favourite.

Comment on Consultation Item No 3

We believe that it is critical that the national flag and text elements are included. In particular the text will be the only clue to the potential customer that there is indeed a secure checker tool. We also feel that there is a potential missed opportunity if the common logo simply links to a national register. There is no indication in the suggested text of WHY the common logo is there. We suggest that the destination web page containing the register, also has a link to further information about the dangers of falsified medicines, the benefits of the system and broader elements of the Directive (such as security features). This would effectively communicate to the potential customer, the reason for the common logo in the first place, and increase vigilance once the medicines arrive. Public awareness of the scheme will be critical if it is to succeed in improving patient safety in the online environment. All steps should be taken to educate the public about the risks of falsified medicines and the scheme's purpose. If the common logo does not have this added feature, then we suggest that it would be a missed opportunity.

Comment on Consultation Item No 4

In our opinion, it is essential that a minimum size and prescribed location for the common logo, be specified in the Implementing Act. If a potential customer is to be expected to find and use the common logo, then the least that customer should expect is consistent size and placement across all legally-operating online pharmacies.

One option to maintain consistency might be to have the common logo open as a small pop-up window, prompting the potential customer click to check the website prior to entering the homepage of the pharmacy.

Other issues / comments

- 1) As previously mentioned, we are concerned about how the costs of the awareness-raising elements, will be covered. The concept paper is vague on this subject and our own discussions with interested parties have done little to inspire confidence in the likelihood of an effective, co-ordinated campaign of public awareness.
- 2) In the United States, the National Association of Boards of Pharmacy (NABP) has submitted an (unopposed) application for the right to control the domain name suffix “.pharmacy” We believe that this presents a tremendous opportunity to ensure that only legitimate legally operating online pharmacies can access that suffix. The NAPB will look to regional partners to distribute the right to use .pharmacy domains and we would urge the Commission to discuss with the EMA, whether the EMA could act in this capacity. Of course, nobody could compel all legally operating online pharmacies to adopt a .pharmacy domain, but we would at least know that any pharmacy using .pharmacy, was legitimate.
- 3) Similarly, there is an existing body of knowledge and expertise with regard to verifying websites. We suggest that the Commission take advantage of this. We have already suggested using ASOP EU to access its members and, in this particular context, we would suggest that the Commission talks to specialist providers, for example LegitScript, who have developed the pharmacy checker tool for US pharmacies. In these times of austerity it would seem sensible to take advantage of work already done.