

14 January 2013

Response of **the Netherlands** on the concept paper for public consultation regarding the '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'.

The Netherlands would like to thank the European Commission for the public consultation and we hereby send in our response. First we express our general opinion and in the second part we respond on the specific items of the consultation.

The main objective of health regulation and health control in general is to protect the population against health risks. Health authorities have the duty to establish rules and instruments to control the production, distribution and commercialization of medicinal products so as to ensure their quality, safety and efficacy. There are several irregular forms of production and commercialization of medicinal products, which circumvent the rules and health recommendations. Therefore, governments and Health Authorities must ensure that only medicinal products meeting the requirements of quality, safety and efficacy are produced, and used. Health Authorities should also find measures to ensure that medicinal products which do not comply with health requirements do not reach the population. Although the legal distribution chain in the Netherlands has proven to be solid, the Netherlands is of the opinion that there is an obligation to verify that the distribution chain remains solid in the future in order to ensure that the Dutch population can rely on the medicinal products they receive from their pharmacists and other points of sale.

On the other hand the quantity of falsified medicinal products which have been intercepted in the Netherlands has increased in the last few years. Internet is an important source for the purchase of falsified medicinal products. People are not aware of the risks involved in ordering medicinal products on the Internet or they are (for no good reason) convinced that they know where to order 'good' or 'genuine' medicinal products. We have not been able to offer the Dutch population a solid instrument to determine 'good' websites/suppliers from 'bad' websites/suppliers. The Netherlands are of the opinion that a common logo will also not be a solid instrument to determine right from wrong. The selling of falsified medicinal products is highly profitable. Falsifiers will sooner or later be able to copy the common logo. And we certainly don't want to refer people to illegal websites/suppliers and make them think that they are legitimate ones. On the other hand: offering them no tool at all is also not a favourable option.

Having stated our general position on this topic, we also would like to go into the details of the consultation paper.

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.

Response NL:

In order to keep up with the newest technological and electronic innovations it is wise to not draw up too specific or too detailed technical, electronic and cryptographic requirements but to create a system of requirements that can be easily adjusted according to the latest innovations. But it should at all times be clear which requirements are applicable. We will get back on that issue under item number 4.

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.

Response NL:

Buying online is increasing. In 2011 about seven in ten Dutch people aged 16 to 75 years shopped over the internet and about 13% of the Dutchmen over 18 bought medicinal products online. An awareness campaign should only aim at the part of the population that is buying medicinal products online or the ones that consider buying those products online (6% of the Dutchmen over 18). It would be useless to have a campaign set out for the general public and it would be too costly as well. Member States should be able to organize campaigns that fit their national system and is in line with their culture. A campaign should be effective and we have learned from previous campaigns that this is a tough issue.

Although it is possible to tell or advice people to click on the logo, there is still a chance that they will not do that. As long as people are convinced (for whatever reason) that a website is legitimate, they will not do that extra check. If you really want people to click on the logo before they order, another design is required. Clicking should then be part of the process of ordering.

Consultation item n°1: Please comment.

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.

Response NL

The presented logos are of use for people who are able to see clearly. But what about people who are for instance (colour)blind? It is difficult to predict whether people tend to recognise the logo or to remember the details of the logo once they browse on the internet. In general it takes a lot of time before people are familiar with logos. Companies usually spent lots of money creating such a bond with logos. These kinds of budgets are not available.

The two concept logos do not seem to be thoroughly examined. They look pretty standard. The use of colour does not catch the eye.

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.*
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"¹⁰.*

Response NL

A logo and the text around the logo should give customers faith that they are ordering their medicinal products at a genuine pharmacist or another legitimate supplier. A (Dutch or EU) flag or a national symbol could help but that is just a presupposition. There might be other symbols that will give consumers/patients confidence.

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.*

Response NL:

It should be very clear which requirements for the use of the logo are applicable. Not only the people who want to order online but also the competent authorities should be able to tell if the logo is rightfully used or not on a website. If the requirements are not clear, the logo will be meaningless. People might check it once but will soon see that there are too many variations of the logo and for the competent authorities it will not be feasible to perform their legal task. The proposed logos are not in balance, especially in combination with the proposed flags they are both a bit too large. And because of this largeness its use (on every page of a website) will certainly not be encouraging. There should not be an option for animation. This is discordant with the regulations on Web Guidelines (www.webrichtlijnen.nl). It seems advisable to agree on a fixed location for the logo; for instance top right. That will be helpful for everyone checking the logo (whether they are patients/consumers or the competent authorities).

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.*

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.

Response NL

When clear requirements of the use of the logo are set it should be possible for the competent authorities to check (when necessary) whether legitimate pharmacies and retailers use the logo as it is supposed to be used. But it will be impossible to check the internet on anyone who is illegally using the logo. We don't have the manpower to do so. And even if we did; internet is very fluid; websites come and go every minute.