



European Commission
Enterprise and Industry

Sent via e-mail: Entr-pharmaceuticals-counterfeit@ec.europa.eu

Date 2008-05-08

Our ref IMAN

Your ref -

Position from H. Lundbeck A/S on preparation of Legal Proposal to combat Counterfeit Medicines for Human Use

Dear Colleagues,

H. Lundbeck A/S welcomes this preparation of legal proposal to combat counterfeit medicines for human use. Furthermore we welcome the opportunity to comment.

Overall the proposal is very positive and it is supported that the Commission has taken up the problem of counterfeit.

H. Lundbeck A/S fully agrees with sections 1-3 in the proposed document and has no comments to add to these sections.

As to the three areas of medicinal products legislation that are covered in sections 4.1-4.2 of the report we have the following comments:

Section 4.1.1:

The suggestion in 4.1.1 that all actors of the distribution chain should be subject to pharmaceutical legislation would certainly make it more difficult for the counterfeiters to spread their goods, and would enhance the awareness of all parts of the distribution chain to ensure that they do not distribute counterfeit goods as they would then lose their permission to distribute pharmaceuticals. Had this provision been in place H.

Lundbeck A/S would have been able to stop the counterfeiting of products from Bulgaria via UAE to Lebanon that is currently ongoing.

Section 4.1.3:

The suggestion in 4.1.3 regarding a unique seal on each package combined with a ban against repackaging would certainly increase the product security. As it is now the counterfeiters often copy the packages of parallel imported original products which packages are often more anonymous than the branded packages and which are not as well known as the branded packages. The suggestion is controversial, as it would without doubt make life more difficult for the legal parallel trade. However, we believe it should be supported by the suggestion as the interest in product and thereby patient safety should weigh more than the interest in the free movement of goods.

Section 4.1.5:

Especially with respect to 4.1.5 regarding mass serialisation it should be considered that mass serialisation should make it possible to check authenticity of each pack without having access to a special device that can read e.g. two-dimensional bar codes. In such a system the end user can verify the authenticity of a package by submitting the mass serialisation number to the manufacturer via a web site, by sending email or via the phone. It is essential in this respect that it is allowed for the manufacturers of medicines to put a statement on the packages that verification of authenticity is possible and referring to an email address, a phone number and preferably even a web site (the latter would require a change of the current regulation regarding labelling).

Section 4.1.6:

With respect to 4.1.6 please see the comments to 4.1.1, which cover 4.1.6 as well.

Section 4.2:

The suggestion in 4.2 that also transit through EU should be covered by the EU legislation is extremely positive, and will close a wide gap in the current legislation that prevents the customs from stopping illegally diverted products when they are only in transit in Europe. A recent example was when a H. Lundbeck A/S product was stopped by the Italian customs. The product was produced for the Indian market, but was in the process of being shipped to the Bahamas, which would without any doubt not be its final destination. The Italian customs had to release the goods when it was ascertained that the goods were not counterfeit, even though the transit through EU infringed Lundbeck's intellectual property rights. Furthermore, recent English case law states that even in the cases where it is established that goods in transit through the EU are fake, the customs cannot stop them, as they are not destined for the European market.

Kind regards,

A handwritten signature in black ink that reads "Iman Barilero". The signature is written in a cursive style and is positioned above a solid horizontal line.

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