**LEO Pharma** **research based, people driven**

LEO PHARMA
1908-2008

9 May 2008

European Commission
Enterprise and Industry

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

**RESPONSE TO THE PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE**

Dear Sirs

LEO Pharma A/S welcomes the preparation of a legal proposal to combat counterfeit medicines for human use and welcomes the opportunity to take an active part in the consultation process in respect to assessing the need for action by the European Commission.

In general, LEO Pharma supports the Commission's approach and supports that the Commission has taken up the problem of counterfeit medicines and the serious consequences that counterfeit medicines can cause.

We totally agree that only a concert of various measures designed to change and improve the current regulatory framework can help minimize the risk of counterfeit medicines entering the supply chain, from leaving the original manufacturer to receipt by the end user! We understand the key ideas as a whole and not as individual ideas or as a "buffet". As far as we are aware, no features are capable of hindering counterfeit products.

In connection with the three defined areas we have the following few comments:

LEO Pharmaceutical Products Ltd. A/S
(LEO Pharma A/S)

Industriparken 55
DK-2750 Ballerup – Denmark

CVR. NO. 56 75 95 14

Phone +45 44 94 58 88
Direct + 45 72 26 30 32
Fax + 45 72 26 33 50

Internet www.leo-pharma.com
E-mail Isabell.Jensen@LEO-pharma.com

1) Tightening requirements for manufacture, placing on the market of medicinal products and inspections.

We support the idea of working on a short supply chain but have to stress that a "door-to-door" supply chain is not workable. It is our opinion that in order to guarantee a safe supply chain, harmonization of the coding rules across Europe is essential.

In order to combat counterfeit medicines we support the ideas proposed including the suggestions concerning tamper-evident packaging at end user level. However, the requirements for tamper-evident packaging must be reasonable and all ambulatory patients, e.g. patients with arthritic fingers, must be able to open the tamper-evident packaging.

2) Tightening requirements for the import/export/transit (transshipment) of medicinal products.

We fully support the suggestion that transit through the EU also should be covered by the EU legislation as this will close a wide gap in the current legislation and prevents the customs from stopping illegally diverted products in EU transit only.

3) Tightening requirements for manufacture, placing on the market of active substances and inspections.

We fully support the proposed key ideas that the competent authority may carry out announced or unannounced inspections of active substance manufacturers in order to verify compliance with the principles of good manufacturing practice for active substances placed under the Community market.

In connection with all measures suggested by the Commission it is important that the requirements set out will cover all member states equally and are implemented at the same time. If not, the counterfeiters will find an alternative route right away.

Also, it is our opinion that further measures, in addition to the three areas of regulation of medicinal products mentioned above are important. The proper enforcement of legislation and the introduction of severe penalties will act as a significant deterrent, and besides

criminal sanctions it is also very important to look into the huge problem of how to combat sales of counterfeits over the Internet.

Public awareness and mutual information between all stakeholders is also very important elements in the fight against counterfeit medicines.

Finally, we support the idea of harmonization of how to address the problem of counterfeit medicines. As mentioned, it is important that the rules against counterfeit medicines are harmonized and that the levels of protecting the public health and safety are identical thoughout Europe.

Kind regards

Isabell Jensen
Head of Trademarks, Designs & Domain Names
Corporate Legal Affairs