

Stockholm County Council
Koncernledningen
Miljödirektören

ANSWER TO PUBLIC
CONSULTATION
April 07, 2008

For information:
Dr. Åke Wennmalm
Stockholm County Council
PO Box 22550
S-104 22 Stockholm
ake.wennmalm@sll.se
phone +46 70 7373805

European Commission
DG Enterprise & Industry, Unit F2 "Pharmaceuticals"
Dr. Ulla Nähri
45, Avenue d'Auderghem
B-1049 Brussels
Belgium

**Comments from
Stockholm County Council and Apoteket AB
on the public consultation of the European Commission
concerning**

“LEGAL PROPOSAL ON INFORMATION TO PATIENTS”

In its web document of February 5, 2008, the Commission invites interested parties and stakeholders to comment on the document “Legal proposal on information to patients”. Stockholm County Council (SCC), provider of all public health care in the Stockholm region, and Apoteket AB (AAB), sole owner of all pharmacy shops in Sweden hereby submit the following viewpoints.

SCC and AAB have read the document with great interest, and fully agree on the concept to establish a framework concerning how to provide high-quality and non-promotional information to the EU citizens on the benefits and risks connected to use of human medicinal products. The information needs to be scientifically based but presentation should primarily be based on intelligibility by patients without medical or other scientific competence.

SCC and AAB strongly propose that the information should also include information on the environmental impact of the medicinal product. Such information is currently available. It is included by the pharmaceutical producer in the application portfolio submitted before marketing of a new product. The information is, however, not open to the public.

There is an emerging interest in the public opinion and in media for environmental issues in general. REACH, the new EU legislation on chemicals, did explicitly exclude pharmaceutical products, obviously with the assumption that these products would be regulated elsewhere. The new EU directive (2004/27/EC) on pharmaceuticals also states, in recital 18

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“The environmental impact should be assessed and, on a case-by-case basis, specific arrangements to limit it should be envisaged.”

The patient information system under consideration by the Commission appears as one ideal arena to present the environmental information, which is already available in the producer files, to the general public. By doing so the information system would offer a possibility for patients to contribute to environmental protection. One example of such protection is by correct disposal of unused or expired medicines (cf. article 127b in the new directive). It also opens up for the Commission to provide the requested environmental information on human medicines to the general public.

In Sweden a national system for environmental information on human medicines has been developed, giving information to patients as well as to doctors. The system is open to the public, and presented on the web. The system has been developed in collaboration between producers, governmental authorities and public health care stakeholders. Its web address is www.fass.se.

SCC and ABA suggest that harmonisation of the medicinal information to patients in all member states might be developed by considering the favourable experiences of the Swedish information system. SCC and AB, together with the other parties behind its development, would also be prepared to offer further information on the system.

Åke Wennmalm
Environmental Director
Stockholm County Council

Stefan Carlsson
Chief Executive Officer
Apoteket AB