

Stockholm County Council
Regional Drug and Therapeutic Committee
Läkemedelssakkunniga (Läksak)

ANSWER TO PUBLIC
CONSULTATION
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Public consultation for Legal proposal on information to patients February 2008

Comments from Regional Drug and Therapeutic Committee, Stockholm Health Authority, Stockholm County Council

Background information on Regional Drug and Therapeutic Committee in Stockholm:

Regional Drug and Therapeutic Committee in Stockholm (Läksak) with a force of 22 ordinary members, 5 Local Committees, 23 Expert Groups on different medical specialties and an administrative unit of ca 50 persons, is commissioned by Stockholm County Council according to Swedish law (1997). Its main task is to promote rational drug use and Läksak and local committees carry out extensive information/communication activities mainly towards health care professionals but also for patients and public (www.janusinfo.se).

Comments on EC's legal proposal on information to patients

Läksak hereby would like to express support for key ideas of the forthcoming proposal presented but at the same time will emphasize a few issues of concern.

Main objective of the proposal, a framework for providing EU citizens with objective, high quality and relevant information on prescription drugs and harmonizing the work among member countries are supported by Läksak. Great potential of developments in information and communication technologies should further be used to increase availability of information for the patients and public with the purpose of improving rational use of prescription drugs.

However, Läksak wishes to express concerns about objectivity of the information to the patients and the difficult balance between advertising and non-promotional information. Especially in "pushed" information and information searched by citizens e.g. on the Internet that are commonly employed today, the distinction between advertisement and proper/objective information is getting more and more difficult. Commonly positive information mass on drugs and their effects sometimes leads to a misleading focus on drug treatment in proportion to other treatment alternatives for diseases including preventive measures. In addition, risk/benefit considerations, target patient populations for beneficial effects of drugs and patient safety issues are often neglected or disproportionately

underrepresented in such information sources. Our concern is that this type of information would not promote the desired patient empowerment towards better therapy outcomes.

Information content, realistic and objective risk/benefit analyses are especially important in introduction of new drugs and therapies. It is important that these drugs are used exactly for those patients in most need. All information to the public and patients must balance between benefits of new therapy and uncertainty associated with a new drug substance due to limited exposure and clinical experience at the time of introduction. This requires even more intense monitoring on the objectivity of information for new drugs.

On behalf of Läksak

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