Opinions on the legal proposal on information to citizens

The opinions presented below represent opinions from two parties highly involved in the work for rational drug use, i.e. the Executive committee of the Swedish Association of Clinical Pharmacology and the Department of Clinical Pharmacology in Sahlgrenska University Hospital. The parties are described below:

The Swedish Association of Clinical Pharmacology is an association for doctors working in the specialty clinical pharmacology with approximately 140 members. The aim of the association is to promote the medical service concerning medical treatment, i.e. to work for rational drug use.

The Department of Clinical Pharmacology is a department within Sahlgrenska University Hospital with the overall aim to work for rational drug use, taking risks, benefits and costs into account. Employees in the department are six specialists in clinical pharmacology, five doctors during residency, six pharmacists, three nurses and one secretary.

The main outlines of our opinions
We fear that rational drug use and consequently the patients are at risk if the proposal is approved. Information from the pharmaceutical industry to citizens can never be considered as objective, reliable and non-promotional. Taken into account the risks and benefit mentioned below, the risks of the present proposal by far exceed the benefits. We suggest that independent parties, i.e. health care professionals and national regulatory bodies, manage information on prescription medicinal products to citizens.

Background
The European Commission is preparing a legal proposal on information from the pharmaceutical industry to citizens. The European Commission is now consulting stakeholders and interested parties for feedback on the proposal. Deadline for this consultation is 7 April 2008.

Proposal
The aim of the proposal is to allow the pharmaceutical industry to inform citizens on prescription-only medicinal products. A harmonization of the situation in the Member States is considered desirable. Direct-to-consumer advertising of prescription medicines will be banned as previously. The following paragraphs (1-4) are assumed to create a proper framework for the industry to provide information on medicinal products to the public, e.g. through TV and radio, through material actively distributed and through information in printed media.

1. Distinction between advertising and information
According to the proposal, a clear distinction between advertising and information is required. No comments on how to make this distinction are made. No difficulties regarding this matter are mentioned.

2. Quality criteria
According to the proposal, the information should be of good quality, objective, reliable and non-promotional. No difficulties regarding these matters are mentioned.

3. Content of information provided

The information should be compatible with approved summaries of product characteristics and patient information leaflets. Information about scientific studies, prevention of diseases, accompanying measures to medical treatment and prices can be given as well. Comparisons between medicinal products should not be allowed.

4. Means of information provided and structure for quality monitoring
A distinction between "pushed" and "pulled" information is made. "Pushed" information includes information actively distributed by the pharmaceutical industry through e.g. TV and radio, postal items and printed media, whereas "pulled" information is distributed when specifically requested by the citizens. The monitoring of these methods differs. Before "pushed" information action is taken, quality monitoring by national co-regulatory bodies should be made. No further information on this topic is given. "Pulled" information should be monitored based on complaints. No consequences or reprimands for information not harmonizing with the regulations are discussed.

Risks

- *Distinction between advertising and information and Quality criteria*
    - Good-quality information should be objective and reliable, as indicated in the proposal. However, the objectiveness and reliability of information from the pharmaceutical industry can be questioned, since their existence depends on the sales of the medicines they inform about. Independent information on medicines from parties without conflicting interests is preferable.
    - Good-quality information should be non-promotional. However, distinction between information and marketing is subtle. Even though criteria could be set up to distinguish allowed information from not allowed information, it will still be difficult to differentiate information delivered by the pharmaceutical industry from advertising, since the information will originate from a source which existence depends on the sales of the medicines they inform about.

- *Content and means of information provided*
    - Information from the pharmaceutical industry will probably be focused on new medicinal products since stronger economic interests exist in these. Knowledge on new medicinal products (effects and adverse effects) is limited and the expected unbalanced information between new and old products can lead to increased use of new products. In addition to increased costs for the health care, this could be directly unfavourable for the patients, since safety aspects are not fully known for new products. An illustrative example of this is rofecoxib (Vioxx®), which was intensively given information on/marketed, and later taken off the market for safety reasons, when adequate knowledge was gained (increased risk for myocardial infarction).
    - Not allowing comparisons between products is ambiguous. Leaving out the possibility to compare products may be a way of diminishing the usefulness of the information to the recipients, i.e. the patients. In the current proposal this limitation may be necessary since the pharmaceutical industry is the source of information. The question remains whether information without comparisons will increase the knowledge and improve the ability to take rational decisions concerning drug treatment for the citizens.

- *Structure for quality monitoring*
    - According to the proposal, the authority to control the quality of the information will fall back on national co-regulatory bodies. This arrangement is clearly not in line with the aim of harmonizing the situation in the Member States. Swedish experience concerning information from the pharmaceutical industry to health care personnel indicates that the costs for the industry for non-adherence are far less than the benefits. This raises the question of how the monitoring system should be arranged to work properly and if it is at all possible to find a system that will work properly.

- *Rational drug use*
    - Medicinal products are mutually financed in many Member States. Experience from information on medicines from pharmaceutical industry to health care personnel points towards increased drug costs for the society. The increment in drug costs is an increasing economic problem in many Member States. To the best of our knowledge, no evidence of correlated increase in quality of prescribing exists.
    - The present proposal will probably make rational drug use more difficult. Doctors should be expected to have more competence and training than citizens in general to critically evaluate information regarding effects, safety and costs of medicines. Patients "informed" by the pharmaceutical industry may demand prescription of irrational drug treatment, which can affect doctors' choice of prescription medicines.

Benefits

- *Relevance of the issue*
    - Information on medicinal products to patients is essential. Thus, the present proposal deals with an important issue.
    - Ensuring good-quality, objective, reliable and non-promotional information on prescription-only medicinal products is essential for rational use of medicines.
    - Maintaining the ban on direct-to-consumer advertising of prescription medicines is essential.
    - A discussion concerning the origin of information to citizens on medicinal products is needed.

- *Harmonization*
    - A harmonization of the existing situation in Member States could be desirable.
    - Regulatory units to ensure adherence to rules and regulations of information on medicinal products are important.