The ”Legal Proposal on Information to Patients”

-European Commission, DG Enterprise & Industry, Unit F2 Pharmaceuticals-

Comments
from
the Swedish Collegium of Chairmen of the Drug and Therapeutics Committees

Background information of the Swedish Collegium of Chairmen of the Drug and Therapeutics Committees.

Since 1997 each county council in Sweden is requested by law to have one ore more Drug and Therapeutics Committees (DTC). The members of the DTCs are experienced physicians and surgeons, general practitioners, dentists, clinical pharmacologists, nurses and pharmaceutical chemists.
The aim of the DTCs is to contribute to safe and cost-effective drug use within the county. DTCs face the challenge of providing prescribers with evidence-based, relevant and up-to-date information on the benefits, risks and costs of prescription drugs.
The Swedish Collegium of Chairmen of the Drug and Therapeutics Committees is the network for national cooperation and coordination of DTCs activities.

Comments from the Swedish Collegium of Chairmen of the Drug and Therapeutics Committees

1.
We agree with the intentions to decrease differences within the EC with respect to good-quality, objective, reliable and non-promotional information on medicinal products and other treatments.

2.
We would like to underline the fact that the use of drugs is only one of several potential strategies in the treatment of diseases and/or risk-factors for disease as e.g. advices and support to correct hazardous life-styles, surgery, physiotherapy, psychological consultations. The final decision concerning the optimal treatment has to be adapted on an individual basis. Extended possibilities for the pharmaceutical industry for marketing of over-the-counter as well as prescription-only drugs as proposed run an obvious risk of changing the focus from a holistic view on therapeutic strategies to a focus on drug treatment.

Thus, therapy with pharmaceutical drugs have to be initiated in its right context and need to be considered on an individual basis. This is counteracted by an extended producer-based information/marketing of prescription-only drugs to the public.

3.
In our opinion, each EC-country should have an organisation for providing its population with the possibility to search for good-quality, objective, reliable and non-promotional information on medicinal products and other treatments. Examples of such information can be found today in all countries as e.g. the information for the user in the packet leaflets. There are also good examples available in several EC countries as e.g. Sweden where information to the population is produced by different authorities, boards

and committees as e.g. Medical Products Agency, National Board of Health and Welfare, The Pharmaceutical Benefits Board and The Swedish Council on Technology Assessment in Health Care (SBU) and the Drug and Therapeutics Committees, respectively. There is also good quality information for public use produced by The Swedish Association of the Pharmaceutical Industry and available at www.fass.se. If a patient self cannot perform a relevant search for reliable information, it is more suitable that the health care provider give this assistance. The health care provider can also give an individually adapted information.

Thus, each country in EC has authorities and institutions which are experienced to critically evaluate the results of clinical trials as well as health economical aspects concerning medicinal products. These authorities and institutions should also be the base for information of medicinal products to the public.

4.
There are many examples in the past of trespassing by the pharmaceutical industry concerning the agreements of information and advertisement. We do not think that this phenomena will disappear in case of extended possibilities to inform and advertise prescription-only drugs in the media. On the contrary, the hazards will probably increase when wrong or biased information is distributed directly to the public. The balance between information and advertisement is often subtle and overstepping the agreements is difficult to discover even for experts, probably demands extended regulations but cannot be completely regulated.

Thus, extended possibilities to inform and advertise prescription-only drugs to the public in the media will (on the contrary to the proposals intentions) lead to increased bureaucracy.

5.
The pharmaceutical industries have to focus their resources for advertisements on new drugs for prompt establishment on the market. We think that important new drugs should be introduced in a structured and monitored order, until enough post-marketing experience of effects and adverse effects have been gathered.

Thus, it is questioned by us if it is on the whole a wise strategy to support a direction to extended possibilities for information and advertisement of new drugs in the media of prescription-only drugs directed to the public during the initial post-marketing period. Such steps could on the contrary lead to extended cost for the society without proven benefit.

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