Public consultation of the Commission concerning information to patients – HOPE comments

HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation, created in 1966. HOPE includes national associations of public and private hospitals and where those do not exist, national organisations of hospital owners. Today HOPE is made up of organisations coming from 26 Member States of the European Union and Switzerland as observer member.

The main mission of HOPE is "to promote improvements in the health of citizens throughout the countries of the European Union and a uniformly high standard of hospital care throughout the EU and to foster efficiency, effectiveness and humanity in the organization and operation of hospital services and of the health systems within which they function."

HOPE answers and comments to this consultation are then based on the diversity of perspectives it represents. For HOPE the consultation on information to patients directly concern the way healthcare systems are organised and financed. As such it cannot be viewed in isolation to the general healthcare context.

With Article 88a of the Directive 2001/83/EC, the European Community rejected direct-to-consumer advertising of prescription medicines by the pharmaceutical industry. At the same time, the European Commission was called upon to analyze the different processes in European countries and to draft proposals to define useful strategies to get good quality, reliable and non promotional information.

The diversity of approaches of Member States and the subsequent differences in the access to information by European citizens is a fact. This reflects the responsibility of Member states in organising and financing their health systems.

The present public consultation promoted by the Commission (Directorate-General Enterprise) is asking whether or not it would be necessary to amend Directive 2001/83/EC:

- establishing a framework which provides EU citizens with understandable, non-promotional, high quality drug information;
- maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information;
- avoiding unnecessary bureaucracy.

Establishing a framework which provides EU citizens with understandable, non-promotional, high quality drug information

The proposed system integrates the pharmaceutical industry in a co-regulatory process with the un-proven assumption that it would produce the expected results.

Co-authorship by stakeholders of different interests does not guarantee a more understandable, non–promotional and high quality information on prescriptive medicines.

There is no scientific evidence showing that the involvement of pharmaceutical companies in prescriptive medicines information allows patients to access to objective and un-biased, patient oriented, evidence based, up-to-date, accessible, transparent, relevant and consistent information on prescription medicines. On the contrary, there is evidence that direct-to-consumer advertising is directly correlated to an increase of prescriptive medicines consumption.

Direct-to-consumer pharmaceutical advertisements have been widely criticized for how they present data on drug benefit and side effects. In countries were direct-to-consumer information of prescription medicines is allowed, the misleading content of the advertisements and the commercial pressure on healthcare professionals have been noticed.

Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information

The proposed system looks like a way of by-passing the ban on direct-to-consumer advertising.

The key issue is to distinguish advertising from independent information. It seems more rational to maintain a clear distinction between promotional activities and non promotional drug information to patients.

Since it is difficult to separate evidence-based from promotional-based drug information, the system should accept to adopt procedures of vigilance distinguishing between the two activities. There is no other approach able to avoid the ambiguity of the information to patients. Priority setting and criteria to judge information on medicine able to contain non-promotional information looks a huge effort to pursue.

The proposed procedure creates ambiguity, making it more difficult than before to differentiate advertising from information.

Avoiding unnecessary bureaucracy

The proposed system looks like additional bureaucracy.

The proposal is not realist in assuming that it will be possible without huge bureaucracy: to say if a campaign promoted by a pharmaceutical industry is done according to objective and non-promotional criteria; to monitor systematically if the impact of any kind of prescription medicines information, including industry and direct-to-consumer information – but not direct–to-consumer advertising – influences prescription medicines use and consumption; to identify the responsibilities of the different stakeholders involved in prescription medicines information; to adopt a transparent and objective methodology at European and national level to evaluate prescription medicines information.

A European consultant committee implemented to define general guidelines on prescription medicines information directed to patients, national co-regulatory authorities with mixed working groups, etc, would increase bureaucracy.

Information on prescription medicines has to take into account local needs in terms of different accessibility to the sources, education, public health priorities and healthcare services. In this context, it would be important to share different experiences and not to aim for a unique model of prescription medicines information.