

# EU Insight

EU REGULATORY AND POLITICAL  
DEVELOPMENTS ON ADVERTISING-RELATED ISSUES



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## Pharmaceuticals

The European Commission is working on a legal proposal on information to patients to ensure good-quality, objective, reliable and non-promotional information on prescription-only medication and to harmonise the situation in EU member states.

### What you should know

Patients are becoming more involved and search for information on diseases and possibilities for therapies. They feel the need for information especially in the case of chronic diseases and therefore the Internet provides to be an easily accessible source. However, this type of information can be found only on non-EU sites, mostly US or Canadian and sometimes having some promotional intent.

Direct-to-consumer (DTC) information from the pharmaceutical industry is legal in the US and several other countries. As legislation differs between Europe and the US, patients might receive information that is not valid for them and European companies suffer from a competitive disadvantage. In addition, untrustworthy organisations, promoting and selling uncontrolled and ineffective or even dangerous substances use primarily the Internet to reach potential customers.

It is therefore crucial that current European bans on information to patients via pushed media (i.e. classical method of transmitting information to interested parties) and the Internet are adapted. This corresponds to the proposal of the European Commission. The European advertising industry welcomes and supports this approach.

Advertising of over-the-counter products (OTC) is legal in most EU member states but advertising of prescription-only medicines is prohibited. These regulations should be changed in a way that DTC information is permitted. It is therefore necessary to distinguish clearly between advertising and non-promotional information.

US studies have shown that DTC information obligatorily included in US advertising, increases awareness amongst patients, enables them to recognise symptoms and seek a doctor early enough, thereby increasing chances to be fully cured (or as far as possible with the diagnosed disease). Furthermore, well-informed patients can take more thought-through decisions and are more likely to comply with advice regarding their medication (e.g. take it regularly and on time). Future regulations should assure that information is valid, clear, reliable, objective, easy-to-understand and non-promotional.

Access to information is a fundamental human right and in the case of health information a key element to ensure equal access to quality healthcare throughout Europe.

### The context

In the EU, all advertising as well as DTC information to the general public of prescription-only medicinal products is prohibited on all media. Prescription medicines can only be promoted to medical practitioners and pharmacists (under precise legal conditions).

Prescription-only products are those medicinal products a patient gets after he/ she had visited a doctor. The costs of the prescription product are partially or entirely repaid.

Only vaccination campaigns are excluded from this ban if carried out by industry and approved by the responsible authority of the member state.

In other markets, such as the US market for example, DTC advertising and information are allowed under precise legal conditions. The European advertising industry does not wish to practice similar campaigns in Europe but believes that objective educational or information campaigns can be valuable to European patients. We therefore support the Commission's plan to define DTC information and to allow it under precise conditions in Europe. The advertising industry expects the European Commission to propose a draft directive on information to patients in the autumn of 2008.

## The Commission position

The Commission published a "Report on current practices with regard to the provision of information to patients on medicinal products" on its website in 2007. This report revealed the need to harmonise the way in which information on medicinal products is made available in the EU, in order to ensure that all patients have equal access to information on medicinal products.

A public consultation was held between 5 February and 7 April 2008 on the key ideas of a legal proposal aiming at ensuring that all EU citizens have access to information on prescription-only medicinal products. A summary of the outcome of the public consultation is available on the Commission website<sup>1</sup>.

The Commission believes that advertising should remain prohibited but strictly regulated information to patients should be possible. The aim is to guarantee the distribution of good-quality, objective, reliable and non-promotional information. Furthermore a harmonisation of the regulation in all member states is to be achieved.

All information provided would be under the control of a national co-regulatory body composed of public authorities and stakeholders. This body would be responsible for the adoption of a code of conduct on information to patients and the monitoring and following-up of all information activities by industry. At EU level, an Advisory Committee chaired by the Commission would oversee the different co-regulatory bodies. Its role would be the approval of national codes and it would deal with information to patient questions with an EU dimension.

During the meeting with the Parliament Committee in April 2008, EU Commissioner Günter Verheugen presented his plans regarding information to patients. The following issues were addressed:

### Advertising:

A clear distinction between information and advertising needs to be drawn. The Commission is not going to soften the advertising ban on prescription medicines.

### Changes in habits/ Digital divide:

People are increasingly using the Internet to gather information; the issue is that people who have access to information on the Internet are not able to properly evaluate whether this information is "hidden advertising" or not. There is also a second group of older people who do not use the Internet and who need to be reached by other means.

### Possible way out:

The information intended for patients are in first place the instructions contained in medicines' boxes & packages. This information is the product of an authorisation process and could be used elsewhere if it was easier to understand.

### Public Opinion / Lobbying:

Contrary to common assumptions, the pharmaceutical industry is not 'interested' in this issue. Mr. Verheugen said that there had been heavy lobbying in the European Parliament by the publishers and by "many organisations that pursue all sorts of different goals".

### Commission's future proposal:

Commissioner Verheugen called upon all MEPS to help build the consensus.

## The Parliament position

In 2001, the EU Commissioners for Public Health David Byrne and for DG Enterprise Erkki Liikanen believed that the existing regulations were inadequate. Due to the increasing influence of the Internet, patients could easily access US and other medical websites. They found it anticompetitive that there were no European equivalents to the broad communication activities of US companies.

The European Parliament blocked this proposal made by the European Commission, to update the Directive for a Codex on Pharmaceutical Products for Human Use. In this update the member states had been asked to allow information to consumers on prescription medicines for the treatment of aids, asthma, chronic pulmonary diseases and diabetes. The Parliament's argument for the rejection was that the Commission project did not foresee an independent body to oversee and ensure the objectivity and reliability of the information that would have been posted on these test-websites.

In April 2008, EU commissioner Günter Verheugen and the European Parliament Committee on environmental and health issues exchanged views on the legislative proposal. The comments made by the parliament were the following:

### Timing:

The timing was described as being very bad since it would be difficult to fit this item on the Parliament agenda before the next elections in 2009.

### Information versus Advertising:

In particular, concerns were raised over the lack of distinction between advertising and information and between objective and independent information.



## Industry's interests:

Some MEPs questioned the fact that the pharmaceutical industry did not have any interest in this debate and said that the documents circulated by the Commission did not reflect patients' point of view.

Several MEPs, including Jorgo Chatzimarkakis (German, Liberal), expressed their support for the future proposal.

## Points of view

It is a fact that patients seek information themselves, often on the Internet. The current legislation prohibits the pharmaceutical industry to advertise their products or give information regarding the active pharmaceutical ingredients in the case of prescription-only medicinal products.

Neither the European Commission, nor the European Parliament nor the advertising industry wants to abolish the ban on advertising of prescription-only medicinal products. But to ensure that patients are well informed and receive reliable information, it is necessary to change the regulations regarding non-promotional information.

Direct-to-consumer information from the pharmaceutical industry would not harm the work of independent reliable sources such as patient associations but might hinder some of the dubious organizations using the Internet to give misleading or false information to patients.

The majority of the European advertising industry therefore welcomes and supports the Commission proposal to allow giving information to the public via pushed media as well as on Internet websites.

To make the future legislation a success it is crucial to distinguish between advertising (to remain banned) and Direct-to-consumer information (possibly allowed in the future).

The European Association of Communications Agencies (EACA)<sup>2</sup> proposes the following definitions:

**Advertising** of prescription medicines is any representation made to the public via media with the clear intention of selling a specific medicinal product sold on prescription.

**Information to patients** about prescription medicines is any information given to the public via media with the clear intention of improving the understanding of the conditions for use, dosage and eventual side-effects of a specific medicinal product sold on prescription within the context of a particular disease.

The objectives of this review of current legislations are:

- Maximisation of patient information
- To increase risk awareness and knowledge of symptoms,
- To motivate diagnosis by a competent health practitioner and
- To involve the patient in the decision making process.

A proposal for such a new directive is to be expected in autumn 2008. The European Commission will present it to the European Parliament and the Council of Ministers. The legislative process will be slowed down by the Parliament election and the change of Commissioners in June 2009.

We suggest that the chapters of the IAA communicate proactively with the involved decision-makers, i.e. members of Parliament and delegates to the council. The arguments presented here might act as a basis for this communication.

<sup>1</sup>[http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary\\_publ\\_cons\\_220508.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary_publ_cons_220508.pdf)

<sup>2</sup>[www.eaca.be](http://www.eaca.be)