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on the proposal for a regulation amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency - 2008/0255 (COD) - COM(2008) 662 final;
and
on the proposal for a directive amending, as regards information to the general public on medicinal products subject to medicinal prescriptions, Directive 2001/83/EC on the Community Code relating to medicinal products for human use - 2008/0256 (COD) - COM(2008) 663 final

Committee on the Internal Market and Consumer Protection

Rapporteur: Cristian Silviu Buşoi

Introduction

The European Commission has tabled two proposals relating to information to the general public on medicinal products. The first is a proposal[1] for a regulation amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. The second[2] is a proposal for a directive amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The existing Regulation and Directive prohibit the advertising to the general public of medicines subject to prescription. However, the existing legislation does not include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Hence, Community legislation does not prevent Member States from establishing their own approach regarding information. Moreover, the boundaries between advertising and information, and accordingly, the application of restrictions on advertising, are not interpreted consistently across the Community.

The current proposal seeks to address the gap in the current legislation. The aim is to enhance the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines. The main elements are:

- Clarifying that the provision of information on prescription-only medicines directly to the public by marketing authorisation holders is allowed;
- Establishing harmonised conditions on the content of information allowed to be disseminated;
- Establishing harmonised quality standards for such information;
- Determining the authorised channels of information provision;
- Introducing an obligation for Member States to establish a monitoring system on the abovementioned provisions, and;
- Establishing special monitoring rules for information disseminated through websites given the cross-border nature of the Internet and avoid duplication of monitoring.

The views of your rapporteur

Your rapporteur for these opinions supports the two proposals submitted by the Commission because he considers that the Commission has shown a balanced approach. He fully supports the idea that all European patients in all Member States should benefit from the same high quality information on medicinal products as this is an essential point for their health and safety. Hence, both the proposal for the Regulation and the proposal for the Directive are welcomed steps to this end. While your rapporteur reserves his right to raise other issues after further examining the proposals, the purpose of this working document is to highlight some

[1] 2008/0255 (COD) - COM(2008)0662 final
[2] 2008/0256 (COD) - COM(2008)0663 final

key issues to facilitate the discussion in the Committee.

The boundary between information and advertising

At this stage your rapporteur takes the view that the main political issue is to strike the right balance between ensuring objective information for patients, which is necessary and legitimate, and advertising. Your rapporteur is committed to maintaining the prohibition of direct-to-consumer advertising on medicinal products subject to medical prescription, as ensured by Directive 2001/83/EC. He insists on the fact that information to the general public should be presented in a "patient-friendly" way so that it reaches its goal, but, at the same time, calls for caution concerning the wording of this directive so that the separation between advertising and information is thoroughly respected.

Channels for dissemination of information

Your rapporteur agrees with the necessity of having multiple channels for the dissemination of legitimate information on medicinal products subject to medical prescription such as health professionals, websites, health publications etc. However, he would also like to put an emphasis on the necessity of assuring access to information on medicinal products for disabled persons who perhaps do not have access to information through the normal channels.

Concerning the proposed channels, your rapporteur is particularly concerned about dissemination of information online. It is reasonable to disseminate information on medicinal products through websites, since technology in society has evolved and the number of those seeking information on health matters online is increasing. Nevertheless, the control of the information published online is sometimes difficult, which is why your rapporteur calls for establishing strict rules regarding the monitoring process of these websites to ensure that the new provisions of Directive 2001/83/EC are fully complied with.

Your rapporteur fully supports the proposals of the Commission concerning the availability of product information in all official languages of the Member States where the product is authorized on the market. The competent authorities should also verify if this provision is respected.

Quality of information disseminated

In your rapporteur's view, the proposed criteria for ensuring that the information disseminated respects high quality standards are satisfactory.

Your rapporteur does not have any particular concern related to the fact that the pharmaceutical industry is a potential source of the information that is to be disseminated as long as the criteria regarding the quality of information are totally complied with. In order to ensure a high level of protection of European patients, the emphasis is to be put on the quality of information and less on the source, especially taking into account that the pharmaceutical industry as a producer would be a first hand source of information.