Medicinal products for human use: information on products subject to medical prescription

2008/0256(COD) - 10/12/2008 - Legislative proposal

PURPOSE: to promote public health in the Community by establishing harmonised rules on the provision of information on medicinal products subject to medical prescription.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: Directive 2001/83/EC on the Community code relating to medicinal products for human use provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States. This legislation prohibits the advertising to the general public of medicines subject to prescription.

However, neither the Directive nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Therefore, Community legislation does not prevent Member States from establishing their own approaches regarding the provision of information on medicinal products as long as the above mentioned rules on advertising are respected. In addition, the boundaries between advertising and information, and therefore the field of application of the legislation's restrictions on advertising, are not interpreted consistently across the Community.

Pursuant to Directive 2001/83/EC, a Communication from the Commission to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" (see COD/1999/0134 under "*Follow-up documents*") was adopted and submitted to the European Parliament and the Council on 20 December 2007. According to the Report, rules and practices on what information can be made available vary significantly among Member States. Moreover, divergences in terms of rules and practices on what information can be made available have a negative impact on legal certainty for marketing authorisation holders with cross-border activity.

CONTENT: the Commission proposes to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 (see also COD/2008/0255) to address the gap in the current pharmaceutical legislation as regards the provision of information to the general public on prescription-only medicinal product for human use. 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 of the proposals can be summarised as follows:

- clarifying that **the provision of information** on prescription-only medicines directly to the public by marketing authorisation holders is allowed, without prejudice to the prohibition on advertising, provided that clearly defined conditions are fulfilled;
- establishing **harmonised conditions on the content of information** which marketing authorisation holders are allowed to disseminate (information approved by the competent authorities for granting marketing authorisation, whether used literally or presented in a different way, and other limited medicine-related information);
- establishing harmonised **quality standards** for such information, to ensure that it is of high-quality and non-promotional;
- determining the **authorised channels of information provision**, in order to exclude unsolicited means of dissemination;
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introducing the obligation for Member States to establish a **monitoring system** to ensure that the abovementioned provisions on content of information, quality standards and dissemination channels are complied with and ensure enforcement in case of non-compliance. The proposal leaves it up to the Member States to decide the most appropriate monitoring mechanisms, but lays down a general rule that monitoring should take place after dissemination of information, with certain exceptions (where prior approval would be necessary) in the case of certain modalities of information where the distinction between advertising and non-promotional information is more difficult to establish. For products authorised in accordance with Regulation (EC) No 726/2004, certain approval tasks are given to the European Medicines Agency;

- establishing specific monitoring rules for **information disseminated through websites**, to take account of the cross-border nature of information provided over the Internet and to allow Member State cooperation and avoid duplication of monitoring.