Medicinal products for human use: Community code. Codification

1999/0134(COD) - 20/12/2007 - Follow-up document

The Commission presented a report on the current practice with regard to the provision of information to patients on medicinal products, in accordance with Directive 2001/83/EC, as amended by Directive 2004 /27/EC on the Community code relating to medicinal products for human use.
This report reviews the activities carried out by Member States concerning the provision of information on medicinal products in order to respond to the needs of patients/consumers under the applicable legislative framework. Particularly, the report addresses the use of the Internet on the provision of information and its role in improving access to information.

The basic content of the report is based on information provided by Member States, as well as information published in various literature sources and contributions from patient groups, health professional organisations and other stakeholders. The report also takes into account discussions within the Pharmaceutical Forum on Information to Patients. Within this overall framework and based on a thorough analysis the report considers in particular: (i) existing information mechanisms and technologies on an EU and Member States level; (ii) the needs of patients; (iii) the role of different stakeholders.

The main findings of the report are as follows:

(a) based on a common basic principle that advertising to the public is prohibited for prescription-only medicines, evidence shows that the rules and practices on what information can be available still vary significantly among Member States. This results in **unequal access of patients, and the public at large, to information** on medicinal products;
(b) at the same time, **patients have become more empowered and proactive** regarding the treatment of their illnesses. Information needs of patients as regards medicinal products range from information on adverse effects to information about efficacy of the medicine to treat the disease concerned, including also information about the costs and duration of treatments;
(c) in general, the **Internet** plays a central role for those who are seeking information, even though non-electronic tools are still relevant for large parts of the population (like the elderly, or patients with special needs).
(d) the **quality of information** is currently very variable, in particular in view of the Internet where the providers have no or limited accountability toward EU citizens. Mechanisms such as educating consumers, encouraging self-regulation of healthcare providers, evaluation of information by third parties and the use of different enforcement procedures can be potential tools for quality management of information;
(e) currently, **public authorities** play a central role in providing information. However, the information that they provide varies widely, thus creating inequalities in access to information about medicines throughout the EU;
(f) **national authorities** may not be in a position to fully address patients' needs in terms of the substance of information and the access via different means. In turn, the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU.

The public consultation has provided an extensive set of contributions where views from the different sectors were expressed. Opinions expressed on the way forward converged as regards the need to: (i) improve information to patients, (ii) adopt common standards and quality criteria, (iii) distinguish between advertising and information, (iv) keep the ban on direct-to-consumer advertising on prescription-only

medicines, and (v) recognise the Internet as an important information channel. Different views were expressed on how to improve provision of information to patients, on the role of the pharmaceutical industry and on the mechanisms to regulate and enforce applicable rules.

On the basis of the outcome of this consultation, the Commission intends to propose, to the European Parliament and the Council, amendments to the current rules on the provision of information to patients by the end of 2008. This proposal will put the interests of patients first and, with this perspective, should aim to reduce differences in access to information and should ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products. The following main policy objectives will be pursued by this legal proposal:

- establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals;
- 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, in line with the principles of Better Regulation.

In accordance with Better Regulation practices, the proposal will be substantiated by an impact assessment of the different policy options.