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

2008/0255(COD) - 11/10/2011 - Modified legislative proposal

The Commission presents an amended proposal for a Regulation of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. Incorporated within the amended proposal are amendments proposed by the European Parliament at its first reading which are acceptable to the Commission.

12 amendments on the proposal were adopted by Parliament at first reading. The Commission considers that a **majority of Parliament's amendments are acceptable in full, in principle, or in part,** as they maintain the aims and overall scheme of the proposal.

The Commission therefore incorporates in full or in part, the following amendments of the European Parliament in the amended proposal:

- it underlines that in the Commission Communication transmitted on 20 December 2007 concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" the need for a more precise distinction between advertising and information was highlighted;
- it is specified that the new Title introduced in Directive 2001/83/EC is intended to place emphasis on the rights and interests of patients. It also states that although the pre-control of information is performed by the Agency for centrally approved medicinal products, the monitoring of the information rests with Member States. It is appropriate to ensure consistently that the Agency is also responsible for the control of the information made available through Internet websites registered in the Member States. Specific provisions are introduced to clarify the operation of this control mechanism in such case of information made available through Internet websites registered with the Member States. The Commission acknowledges that a number of Member States have expressed concerns regarding conformity with their national constitutions. The Commission is prepared to enter into a dialogue with those concerned to find suitable solutions while fully respecting the objectives of this Regulation;
- it provides for the procedure regarding cases when the Agency requests changes within the information submitted for control and for the fees applicable which should be proportionate to the additional work. Considering that the normal delay is 60 days, the subsequent delay should be of 30 days;
- the text provides that the EudraPharm database it should be available in all EU languages. Such a change has been introduced as regards the lay-out of the database. However, the information contained in the database will be available in the languages of Member States where the medicinal product is authorised. In another respect, it is not necessary to further specify that the information provided is designed for non-experts, as it is already provided that it should be worded in an appropriate and comprehensible manner. EudraPharm should be actively promoted to European citizens. This should be done through the development of the European medicines web-portal established by Regulation (EU) No 1235/2010 as the central point of access to information about medicinal products. However, it is not appropriate that information available on marketing authorisation holder websites is reproduced on EudraPharm, which is a public database.

Pharmacovigilance: in addition to the changes introduced on the basis of the European Parliament resolutions regarding the Commission proposals on information to patients, the Commission considers that limited changes to Regulation (EC) No 726/2004 in the area of pharmacovigilance should be

introduced. Regulation (EC) No 726/2004 has been recently amended by Regulation (EU) No 1235/2010 to revise the EU pharmacovigilance system. Since Regulation (EU) No 1235/2010 has as legal basis Article 168(4)(c) of TFUE, **the amended proposal should also be based on Article 168(4)(c) of TFUE**.

Regulation (EU) No 1235/2010 substantially strengthens the legal framework for the surveillance of medicinal products in the EU. However, in view of recent pharmacovigilance events in the EU, the Commission has detected certain areas where the legislation could be further strengthened.

Therefore:

- the new public list of medicinal products subject to additional monitoring introduced by Regulation (EU) No 1235/2010 will not necessarily include all medicinal products subject to post-authorisation safety conditions. Competent authorities will have to decide on a case-by-case basis whether to make public the fact that products are subject to strengthened surveillance. For the sake of fuller transparency as regards products under special surveillance, the text is modified to systematically include medicinal products that are subject to conditions and requirements with regard to safety;
- a new provision is introduced to avoid a situation where the voluntary withdrawal of a marketing authorisation or product by the holder could lead to safety issues not being addressed in the EU. It clarifies the information obligations of the marketing authorisation holder.

Lastly, the text clarifies the scope of this provision and the EU procedures set out in Directive 2001/83/EC.