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

2008/0255(COD) - 10/02/2012 - Amended legislative proposal for reconsultation

The Commission presents, **for re-consultation**, an amended proposal for a Regulation of the European Parliament and the Council on information to the general public on medicinal products subject to medical prescription. The amended proposal incorporates the amendments proposed by the European Parliament at first reading on 24 November 2010 as the Commission considers them acceptable.

The general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are in line with the overall objectives of the EU pharmaceutical legislation. This amended proposal is in line with those objectives to include measures setting high standards of safety for medicinal products. Therefore, in view of the entry into force of the Treaty of Lisbon since the adoption of the Commission proposal, **article 168(4)** of the Treaty on the Functioning of the European Union is added as legal basis to the amended proposal.

Moreover, this amended proposal further reinforces the rights of patients. In particular, the marketing authorisation holders will have the **obligation**, and no longer the possibility, to make available certain information, such as the labelling and the package leaflet.

The amendments introduced by the Commission in light of the European Parliament's amendments aim to :

- recall that in the Commission Communication 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**;
- specify that the new Title introduced in Directive 2001/83/EC is intended to place emphasis on the rights and interests of patients;
- specify 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;
- provide for the **procedure** regarding cases when the Agency requests for 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;
- provide that the **EudraPharm database should be available in all EU languages**. Such a change has been introduced as regards the lay-out of the database; on the other hand, the information contained in the database will be available in the languages of Member States where the medicinal product is authorised;
- provide that 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.

The proposal has no implication for the budget of the Union.

For legal clarity and in order to facilitate the ordinary legislative procedure, this text replaces COM(2011) 632 final, presented on 11/10/2011, which is consequently withdrawn.