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

2008/0255(COD) - 24/11/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 564 votes to 41, with 45 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on 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.

It adopted its position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) in which it amends the Commission proposal as follows:

Patients' rights: Parliament considers that the Amending Directive has to focus on the patients and their interests and it has to be reflected in the Amending Regulation as well. The new provisions of the Amending Directive have to emphasise the right of patients for information instead of the right of the pharmaceutical companies to disseminate information.

Information: the resolution highlights the urgent need for a more precise distinction between advertising and information.

Non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

In this context, Parliament proposes an amendment relating to information not approved by competent authorities during the registration of medicinal products and is in fact hidden "push" information. Any relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics (SmPC), which is part of the registration file for approval.

Time-limit for information: The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within **90 days** (instead of 60 days) after receipt of the notification. If the Agency does not object within 90 days, the information shall be deemed accepted and may be published. The marketing authorisation holder shall remain fully liable and responsible for the information provided in all cases.

If the Agency asks for changes to be made to a document submitted by the marketing authorisation holder, and if the latter resubmits an improved proposal within 30 working days, the Agency shall communicate its response to the new proposal within 60 working days.

Database on medicinal products: the resolution underlines that strengthening the EMEA's role with regard to information for the public on medicinal products for which a medical prescription is required is crucial in order to ensure that all citizens have equal access to high-quality information. The management of the database of information for the public should comply with exemption criteria for that information.

The database on medicinal products should be accessible to the general public, in all official languages of the Union and should be managed independently of the commercial interests of pharmaceutical companies. It should be publicly accessible as a prime source of objective information. With this aim in

mind, the Member States, the Commission and the Agency itself should make every effort to ensure that proper use is made of this database.

Members insist on promoting existing sources of independent reliable health information. There are many sources of independent and evidence-based information on treatment choices available within the European Union. These resources take into account cultural specificities and contexts for the population, including health determinants. They are developed by health authorities, medical products agencies, healthcare assessment bodies, healthcare providers, healthcare professionals, consumer organisations, and independent patients' organisations. These information sources should be actively promoted to the general public.

Agency's budget: the resolution requests that in the event that the additional costs incurred by the Agency as a result of its preliminary checking of certain types of information pursuant to this Regulation are not covered by the fees payable by the marketing authorisation holders for this purpose, the amount of the European Union's contribution to the Agency's budget should be reviewed. Accordingly, efforts should be initiated at Member State level with a view to the possible amendment of the European Union's contribution to the Agency.