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

2008/0256(COD) - 24/11/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 558 votes to 42, with 53 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

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

Patients' rights: Parliament considers that this Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and 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).

Patients should have the right to easily access certain information such as a summary of product characteristics and the package leaflet in electronic and printed form. Certified and registered websites for independent, objective and non-promotional information are therefore necessary. A leaflet containing information for the patient which accompanies the medicinal product and which corresponds to patients' real needs. The package leaflet shall include a short paragraph which sets out the benefit and potential harm of a medicinal product as well as a short description of further information aiming at safe and effective use of a medicinal product.

Distinction between the interpretation of information and advertising: the resolution underlines that disparities in the interpretation of the Community rules on advertising, and between national provisions on information have a negative impact on the uniform application of Community rules on advertising, and on the effectiveness of the provisions on product information contained in the summary of products' characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the making available of such key information are allowed.

Informing patients and the general public: Parliament is of the opinion that the focus of the Directive should be not on advertising but on making information available to the public. The information provided to patients and the general public needs to meet the core quality criteria in order to ensure patient safety and safeguard public health.

The marketing authorisation holder shall, in respect of authorised medicinal products subject to medical prescription, make available to the general public or members thereof the following information: the most recent summary of product characteristics as approved by the competent authorities during the course of marketing authorisation and authorisation renewal; the most recent labelling and package leaflet as approved by the competent authorities during the course of marketing authorisation or authorisation variation; and the most recent, publicly accessible version of the assessment report as drawn up by the competent authorities during the course of marketing authorisation and authorisation updates.

The information shall be presented in a format that faithfully represents the officially approved information drawn up by the competent authorities. The information shall be made available both in electronic and printed form, and in formats appropriate for the **blind and partially-sighted**.

The marketing authorisation holder may, in respect of authorised medicinal products subject to medical prescription, make available to the general public or members thereof the following information: information on prices; information on pack changes; adverse-reaction warnings; instructions for use of the medicinal product. This information may be completed, where necessary, with still or moving images of a technical nature demonstrating the proper way of using the product; the pharmaceutical and pre-clinical tests and the clinical trials of the medicinal product concerned presented in factual, non-promotional listings of summary information; a summary of the frequently submitted requests for information, and the subsequent answers; other types of information agreed by the competent authority that are relevant to support the appropriate use of the medicinal product.

National competent authorities and health care professionals: Members consider that these should remain the main source of information on medicinal products for the general public. While there is already a lot of independent information on pharmaceuticals, for example information provided by national authorities or healthcare professionals, the situation differs very much between Member States and among the different products available. Member States and Commission should make much greater efforts to facilitate the access of citizens to high-quality information through appropriate channels.

Advertising of prescription-only medicinal products: given that marketing authorisation holders may be an additional source of non-promotional information on their medicinal products, Members consider that this Directive should therefore establish a legal framework for the making available of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Limitation of the scope of the Directive: the resolution underlines that it is appropriate to limit the scope of this Directive to the making available of information on prescription-only medicinal products as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions. The provisions of this Directive are without prejudice to the right of any other person or organisation, in particular the press or patients and patient organisations, to express their views on prescription-only medicinal products, provided that they are acting independently and not directly or indirectly on behalf of, on the instructions of, or in the interest of the marketing authorisation holder.

Use of the written press to inform the public: information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall not be made available on television, radio or any other instrument of dissemination to the general public, including Internet radio or television channels, or in general newspapers and magazines or in the form of inserts or supplements to them. A different type of channel shall be used.

An amendment stipulates that health professionals who deliver information on medicinal products or medical devices during a public event, in print or broadcast media shall declare publicly their interests, for example any financial ties with marketing authorisation holders or with third parties working on their behalf.

Information campaign on falsified medicinal products: Members consider that information campaigns aimed at raising awareness among the general public and members thereof about the risks of falsified medicinal products should be organised. Such information campaigns may be conducted by national competent authorities in collaboration with industry, healthcare professionals and patient organisations.

An amendments stipulates that such campaigns shall be approved by the competent authorities of the Member States only if it is ensured that objective, non-biased information is provided in the frame of the campaign by the industry on the causes of the disease, the efficacy of the vaccine, the adverse reactions and contra-indications of the vaccination.

Monitoring of information: the proposal provides that Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Members call for these rules to be harmonised at Union level so as to ensure consistency. In cases of non-compliance, procedures should be put in place for marketing authorisation holders to be represented and heard in the course of the consideration of their case. Monitoring should be based on the control of information prior to its being made available. Only information that has been approved in advance by the competent authorities should be provided and it should be provided in an approved form only.

Association of patient organisations: the Commission should consult independent patient, health and consumer organisations and healthcare professionals on issues relating to the implementation of this Directive and its application by the Member States.

Delegated acts: the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the quality criteria of information provided to the general public, and web accessibility guidelines.