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

2008/0256(COD) - 11/10/2011 - Modified legislative proposal

The Commission presents an amended proposal amending Directive 2001/83/EC, as regards information to the general public on medicinal products subject to medical prescription and as regards pharmacovigilance. It notes that on 24 November 2010, the European Parliament adopted 78 amendments on the proposal and the Commission considers that a majority of the European 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 accepts in full or in part, the following amendments of the European Parliament:

Amendments of a general nature: some of the amendments use more appropriate wording, and clarify the text. These changes have been incorporated within the whole revised text. The text also contains a re-worded recital calling for a distinction between advertisement and information in order that all citizens have access to information in all Member States.

Scope of title VIII "Advertising": Directive 2001/83/EC currently identifies types of information which are not covered by the Directive's title on advertising. The amended proposal contains some drafting amendments and clarifies the elements listed in the Commission proposal as not covered by the advertisement title. In particular, it adds to the fact that information to the general public should comply with Title VIIIa, the requirement for such information to be approved by the authorities and to respect quality criteria. It also:

- adds to the list of elements which should not be covered by the advertisement title, factual, informative announcements for investors and employees on significant business developments provided they are not used to promote the product to the general public;
- further specifies, however, that if the information concerns individual medicinal products, the conditions of Title VIIIa should apply to ensure that the provisions of information to investors and employees is not used to circumvent the provisions of the Directive;
- clarifies that in cases not covered by the advertising title, the marketing authorisation holder and any third party acting on behalf of the marketing authorisation holder making available the information should be identified as such.

Exception to advertising: the text now provides conditions that must be fulfilled by industry in order to be authorised to conduct advertising on vaccination campaigns. However the information should refer only to the vaccines and not to the diseases concerned as the scope of Directive 2001/83/EC is limited to medicinal products.

Advertising to healthcare professionals: the amended proposal modifies the current text which regulates the advertising to healthcare professionals. It specifies that the rules should apply to direct or indirect promotion by marketing authorisation holder or a third party acting on its behalf or following its instructions. The Commission supports this clarification, which should not be restricted to one specific article. It should concern all Articles on advertising.

Scope of the new title VIIIa: Parliament’s amendment modifying the content of the information makes the distinction between information that marketing authorisation holders should make available and

information that he may make available. By creating this distinction, the European Parliament re-orientates the text from the right of marketing authorisation holders to make available some information to the right of the patients to have information. This re-orientation should also be reflected in the scope of the Title.

Parliament also wanted healthcare professionals who deliver information on medicinal products during public events to declare their financial interests with marketing authorisation holders. The Commission supports this amendment, which can only concern medicinal products and not medical devices in view of the scope of the Directive. In addition, the amended text excludes from the scope of the Directive information made available by third parties acting independently from the marketing authorisation holder in order for them to express their views on prescription-only medicinal products. In order to ensure transparency about information provided by third parties, they should declare their interests when making available information on medicinal products.

Content of the information: information regarding adverse-reaction warnings should be excluded from the scope of the Directive's Title on information, as it is specifically addressed by the Title on pharmacovigilance.

Channels of information: Parliament's amendments delete the possibility of making available information through health-related publications and provide that it cannot be made available through newspapers, magazines and similar publications. However, the amendments introduce the possibility of making information available through printed materials about a medicinal product prepared by marketing authorisation holders upon specific request by a member of the general public. The Commission accepts these changes.

Quality criteria and statements: the Commission supports most of the amendments made by Parliament particularly on the requirement of a statement containing contact information allowing members of the public to contact competent authorities, and a statement containing a reference to the most recent package leaflet or an indication as to where that text can be found.

Control of the information: the Commission accepts the principle of pre-control of information by competent authorities and the possibility for derogations. An additional derogation should be included for cases where Member States cannot introduce a system of pre-control for constitutional reasons related to the principles of freedom of expression and of the press. However, the Commission should not be tasked with verifying and approving alternative national systems.

As the possibility of opting for voluntary control by self-regulatory or co-regulatory bodies are deleted in the new proposal, the provisions for a code of conduct adopted by the Commission has been deleted, while maintaining provisions for Commission guidelines.

The Commission **acknowledges that a number of Member States have expressedconcerns** in relation to 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 Directive. As some of the provisions introduced by this Directive may interfere with national constitutional rules relating to freedom of the press and freedom of expression in the media, the Commission introduces a recital clarifying that this Directive does not prevent Member States from applying these constitutional rules.

Internet websites: the Commission agrees to the linkage of marketing authorisation holder websites to EU databases and portals on medicinal products, but feels it is more appropriate to link marketing authorisation holder websites to the EU medicines web-portal established by Regulation (EU) No 1235 /2010 than to the EudraPharm database, as that portal is intended to become the central point of access to information on medicines.

Penalties: the Commission has modified the text on penalties in order to provide for the possibility of publishing the name of marketing authorisation holders who have published information on a medicinal product which is non-compliant with the Directive.

Pharmacovigilance: in addition to the changes introduced on the basis of the European Parliament's resolution, the Commission considers that certain changes to Directive 2001/83/EC in the area of pharmacovigilance should be introduced.

Directive 2001/83/EC has been recently amended by Directive 2010/84/EU to revise the EU pharmacovigilance system. Since Directive 2010/84/EU has as its legal basis Article 168(4)(c) of TFUE, the amended proposal should also be based on Article 168(4)(c) of TFUE. Directive 2010/84/EU substantially strengthens the legal framework for the surveillance of medicinal products authorised by the Member

States, with provisions to reinforce the coordinating role of the Agency, the possibilities for signal detection, and the operation of coordinated procedures at European level to respond to safety concerns. However, in view of recent pharmacovigilance events in the EU, the Commission has detected certain areas where the legislation could be further strengthened. Therefore:

- Articles 107i is modified in order to provide for an automatic procedure at European level in the cases of specific serious safety issues with nationally authorised products, with a view to ensuring that the matter is assessed and addressed in all Member States where the medicinal product is authorised;
- Articles 31 and 34 are also modified to clarify the respective scopes of this provision and the revised automatic procedure, as well as the links between these procedures and procedures involving medicinal products authorised in accordance with Regulation (EC) No 726/2004.

Lastly, Articles 23a and 123 are modified to avoid the voluntary withdrawal of a marketing authorisation or product by the holder leading to safety issues not being addressed in the EU, by clarifying information obligations for the marketing authorisation holder.