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

2008/0256(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 modifications introduced by the Commission in light of the European Parliament's amendments concern the following issues:

Amendments of a general nature: the Commission approves amendments aiming to: (i) replace the words "disseminate" by "making available" the information; (ii) stress that inequalities in accessing information are not acceptable and should be adjusted; (iii) make a distinction between advertisement and information in order that all citizens have access to information in all Member States; (iv) recognise that although some information is made available by national competent authorities and healthcare professionals, marketing authorisation holders may be an additional source of information.

Scope of title VIII "Advertising: Article 86(2) of Directive 2001/83/EC, as currently in force, identifies types of information which are not covered by the Directive's title on advertising. The Commission accepts in principle the amendment proposing to add to the list correspondence needed to answer a specific question about a medicinal product, and adds some factual, informative announcements. Another amendment adopted by the Commission stipulates 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.

Other amendments incorporated into the amended proposal are as follows:

- 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. It is further specified that, however, 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: Directive 2001/83/EC provides that the prohibition of advertising does not apply to vaccination campaigns carried out by industry and approved by the competent authorities of the Member States. The original proposals extended this exception to public health campaigns in general. An amendment deletes this proposed extension and imposes further requirements on possible vaccination campaigns. The amended proposal incorporates these changes; 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 Commission accepts the amendment aiming specify 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 "Information to the general public on medicinal products subject to medical prescription": Parliament's amendment makes a **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.

The Commission approves the amendments which:

- provide that healthcare professionals who deliver information on medicinal products during public events should **declare their financial interests** with marketing authorisation holders;

- modify the list of types of information which should not be covered by the Directive's title on information;

- exclude 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.

Content of the information: the Commission accepts the amendments aiming to make the distinction between information that marketing authorisation holders should make available and information that they may make available.

However, 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.

Lastly, according to the Commission the requirements linked to channels of information, persons with disabilities and control do not have to be specified in this Article as they are provided for in specific Articles.

Channels of information: Parliament's amendments delete the possibility to make 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 to make available information **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; however it is the issuing of these printed materials that should be on request, not their drafting.

Quality criteria and statements: the Commission accepts in principle the amendments aiming to add two statements accompanying the information: (i) a statement containing contact information allowing members of the public to contact competent authorities, and (ii) a statement containing a reference to the most recent package leaflet or an indication as to where that text can be found. The acts adopted by the Commission should be implementing acts and not delegated acts, as they are limited to the implementation of the quality criteria which are laid down in the proposal.

Persons with disabilities: one amendment aligns with the Treaty of Lisbon the delegation to the Commission to amend the Article to take account of technical progress.

Control of the information: the Commission accepts the principle of pre-control and the possibility for derogations. For the latter, in addition to the derogation for pre-existing systems foreseen by the amendments, 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 to verify and approve alternative national systems. As the possibility to opt 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 expressed concerns in relation to the 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 regards this

Directive, apart from the control mechanism, 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**.

However, 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 proposal is amended in order to provide for the possibility to publish the name of marketing authorisation holders who have published information on a medicinal product which is non-compliant with the Directive, to lay down the **right of appeal** of marketing authorisation holders and to introduce the **suspension** of the dissemination of the information while the proceedings are ongoing.

Monitoring of the information: the Commission accepts including an amendment into the proposal stipulating that **replies should be kept available** for inspections by national competent authorities.

Information provided by other sources than the marketing authorisation holder: the part of the amendment intended to task Member States with ensuring that objective, **unbiased information** is available to general public or members thereof has been introduced in the proposal.

Comitology alignment: Parliament's amendments are intended to include in Directive 2001/83/EC, in view of the entry into force of the Treaty of Lisbon, general provisions on the granting of delegated

powers to the Commission. However, these Articles have been introduced into the Directive by Directive 2010/84/EU. It is only necessary to adapt Article 121a on the exercise of the delegation to include the reference to Article 100f, paragraph 2 which provides for delegated acts.

Explanatory documents accompanying the notification of transposition measures: Directive 2001/83 /EC does not prevent Member States from establishing their own approaches regarding the provisions on information on medicinal products. Member States have different pre-existing national legislation, which the amended proposal aims to harmonise. Furthermore, the amended proposal provides for national obligations which may be transposed in various branches of the national legal order. In view of these elements, the Commission considers that explanatory documents from Member States are necessary for carrying out its task of overseeing the application of Union law.

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) 633 final, presented on 11/10/2011, which is consequently withdrawn.