Basic information

2008/0256(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure lapsed or withdrawn
Medicinal products for human use: information on products subject to medical prescription **Subject** 4.20.04 Pharmaceutical products and industry 4.60.02 Consumer information, advertising, labelling	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	FJELLNER Christofer (PPE)	21/07/2009
	Shadow rapporteur PARGNEAUX Gilles (S&D) CHATZIMARKAKIS Jorgo (ALDE) SCHLYTER Carl (Verts/ALE) YANNAKOUDAKIS Marina (ECR) MAŠTÁLKA Jiří (GUE/NGL) ROSBACH Anna (EFD)	

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	FJELLNER Christofer (PPE)	01/03/2012
ENVI Environment, Public Health and Food Safety		

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	CHATZIMARKAKIS Jorgo (ALDE)	16/09/2009
IMCO Internal Market and Consumer Protection	BUŞOI Cristian-Silviu (ALDE)	14/09/2009

Former committee for opinion	Former rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection		
ITRE Industry, Research and Energy		
IMCO Internal Market and Consumer Protection		

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	2980	2009-11-30
Employment, Social Policy, Health and Consumer Affairs	3053	2010-12-06
Employment, Social Policy, Health and Consumer Affairs	3095	2011-05-30

European Commission

Commission DG	Commissioner
Health and Food Safety	BORG Tonio

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
10/12/2008	Legislative proposal published	COM(2008)0663	Summary
13/01/2009	Committee referral announced in Parliament, 1st reading		
19/10/2009	Resumption of business from the previous parliamentary term		
30/11/2009	Debate in Council		Summary
28/09/2010	Vote in committee, 1st reading		Summary
19/10/2010	Committee report tabled for plenary, 1st reading	A7-0290/2010	
22/11/2010	Debate in Parliament		
24/11/2010	Decision by Parliament, 1st reading	T7-0429/2010	Summary
24/11/2010	Results of vote in Parliament		
06/12/2010	Debate in Council		Summary
30/05/2011	Debate in Council		

11/10/2011	Modified legislative proposal published	COM(2011)0633	Summary
10/02/2012	Amended legislative proposal for reconsultation published	COM(2012)0048	Summary
15/02/2012	Formal reconsultation of Parliament		
21/05/2014	Proposal withdrawn by Commission		Summary

Technical information

Procedure reference	2008/0256(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	Treaty on the Functioning of the European Union TFEU 114-p1 Treaty on the Functioning of the European Union TFEU 168-p4
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	ENVI/7/08859 ENVI/7/00159

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE439.410	04/03/2010	
Committee opinion	ITRE	PE430.857	24/03/2010	
Committee opinion	IMCO	PE439.346	18/05/2010	
Amendments tabled in committee		PE441.215	25/05/2010	
Committee report tabled for plenary, 1st reading/single reading		A7-0290/2010	19/10/2010	
Text adopted by Parliament, 1st reading/single reading		T7-0429/2010	24/11/2010	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0663	10/12/2008	Summary
Document attached to the procedure	SEC(2008)2667	10/12/2008	
	SEC(2008)2668		

Document attached to the procedure		10/12/2008	
Commission response to text adopted in plenary	SP(2011)610	26/01/2011	
Modified legislative proposal	COM(2011)0633	11/10/2011	Summary
Amended legislative proposal for reconsultation	COM(2012)0048	10/02/2012	Summary

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2012)0048	12/04/2012	
Contribution	PT_PARLIAMENT	COM(2012)0048	12/04/2012	
Contribution	LU_CHAMBER	COM(2012)0048	25/04/2012	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1022/2009	10/06/2009	
EESC	Economic and Social Committee: opinion, report	CES0469/2012	22/02/2012	
EESC	Economic and Social Committee: opinion, report	CES0809/2012	28/03/2012	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

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.

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.

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

2008/0256(COD) - 30/11/2009

On the basis of progress reports, the Presidency informed the Council of the **state of play in the negotiations** on two parts of the "pharmaceutical package": preventing falsified medicines from entering into the legal supply chain of medicinal products and the strengthening and rationalising of the current pharmacovigilance system.

Under the Swedish Presidency, the preparatory bodies of the Council pursued their work with high priority on these two parts of the package.

1) Concerning the draft directive on preventing the entry into the legal supply chain of falsified medicinal products, the working group reached tentative agreement on a number of technical aspects, including:

- the definition of "falsified medicinal products";
- the proposed definition of "trading of medicinal products" has been changed to "brokering of medicinal products" and amended, thereby clarifying which actors in the supply chain should be subject to the responsibilities of brokers. The proposed introduction of obligations for brokers aim to reinforce the traceability of medicinal products;
- a clarification of the relationship between the proposed new provisions in Directive 2001/83/EC and Community legislation on intellectual property rights.

Other elements of the proposal still need further discussion, notably with regard to the strengthening of controls of non active substances used in pharmaceuticals (excipients) and the proposed safety features aiming to render falsification more difficult.

The proposal includes provisions requiring the accreditation of third party auditors of Good Manufacturing Practices and Good Distribution Practices. A majority of delegations object to accreditation, since they maintain that such a system could result in a transfer of responsibility from manufacturers and importers as well as make enforcement by national competent authorities more difficult. The Presidency has therefore proposed to delete the provisions regarding accreditation from the text. Some delegations have expressed an interest in the possibility of establishing third party accreditation at a national level.

2) Concerning the proposals for a regulation and a directive on strengthening the EU system for the safety monitoring of medicinal products ("pharmacovigilance"), the working group reached tentative agreement on a number of questions including:

- a clarification of the relation between the proposed new provisions in Directive 2001/83/EC and Regulation (EC) 726/2004 on the one hand and the Community legislation on protection of personal data on the other hand;
- a strengthening of the role of the Pharmacovigilance Risk Assessment Committee (PRAC) in relation to the Committee for Medicinal Products for Human Use and to the Coordination Group set up by Article 27 of Directive 2001/83/EC (CMD), including an obligation for these last two bodies to explain any differences in opinion compared to the PRAC;
- a change in the composition of the PRAC and in the method for nominating the PRAC members so that all Member States will be represented;
- the inclusion of a requirement for the Agency, in collaboration with the Member States and the Commission, to draw up functional specifications for the Eudravigilance database which will take account of the role and experience of national competent authorities for pharmacovigilance. The new reporting obligations to Eudravigilance will not apply until these specifications are met and to this end a transitional period is envisaged;
- the legal status of CMD opinions and how they are implemented in Member States. Here, text redrafting proposals are under legal scrutiny.

The Working Party has continued to discuss other central provisions of the proposals, mainly in relation to the Community Procedure and Referrals, the Recording and Reporting of adverse reactions, the Periodic Safety Update Reports and the Post Authorisation Safety Studies.

A number of issues still require further examination, such as the recording and reporting of adverse reactions and the proposed list of medicinal products for human use under intensive monitoring.

At this stage, all delegations have a general scrutiny reservation on the entire proposal while the Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

3) With regard to the third part of the "pharmaceutical package", the proposals for a regulation and a directive concerning information for the general public on medicinal products, the Presidency recalled the strong concerns of many Member States. The Commission made it clear that it is prepared to show flexibility in order to find a common basis for the future negotiations.

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

2008/0256(COD) - 06/12/2010

The Commission expressed its willingness to **modify its proposal concerning information to the general public on medicinal products for human use** which are subject to prescription in order to take into account the concerns of the Member States.

The incoming Hungarian Presidency announced its willingness to address this file as a matter of priority as soon as the modified proposal has been presented.

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

2008/0256(COD) - 10/12/2008 - Legislative proposal

PURPOSE: to promote public health in the Community by establishing harmonised rules on the provision of information on medicinal products subject to medical prescription.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: Directive 2001/83/EC on the Community code relating to medicinal products for human use provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States. This legislation prohibits the advertising to the general public of medicines subject to prescription.

However, neither the Directive nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Therefore, Community legislation does not prevent Member States from establishing their own approaches regarding the provision of information on medicinal products as long as the above mentioned rules on advertising are respected. In addition, the boundaries between advertising and information, and therefore the field of application of the legislation's restrictions on advertising, are not interpreted consistently across the Community.

Pursuant to Directive 2001/83/EC, a Communication from the Commission to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" (see COD/1999/0134 under "*Follow-up documents*") was adopted and submitted to the European Parliament and the Council on 20 December 2007. According to the Report, rules and practices on what information can be made available vary significantly among Member States. Moreover, divergences in terms of rules and practices on what information can be made available have a negative impact on legal certainty for marketing authorisation holders with cross-border activity.

CONTENT: the Commission proposes to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 (see also COD/2008/0255) to address the gap in the current pharmaceutical legislation as regards the provision of information to the general public on prescription-only medicinal product for human use. The aim is to enhance the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

The main elements of the proposals can be summarised as follows:

- clarifying that **the provision of information** on prescription-only medicines directly to the public by marketing authorisation holders is allowed, without prejudice to the prohibition on advertising, provided that clearly defined conditions are fulfilled;
- establishing **harmonised conditions on the content of information** which marketing authorisation holders are allowed to disseminate (information approved by the competent authorities for granting marketing authorisation, whether used literally or presented in a different way, and other limited medicine-related information);
- establishing harmonised **quality standards** for such information, to ensure that it is of high-quality and non-promotional;
- determining the **authorised channels of information provision**, in order to exclude unsolicited means of dissemination;
- introducing the obligation for Member States to establish a **monitoring system** to ensure that the abovementioned provisions on content of information, quality standards and dissemination channels are complied with and ensure enforcement in case of non-compliance. The proposal leaves it up to the Member States to decide the most appropriate monitoring mechanisms, but lays down a general rule that monitoring should take place after dissemination of information, with certain exceptions (where prior approval would be necessary) in the case of certain modalities of information where the distinction between advertising and non-promotional information is more difficult to establish. For products authorised in accordance with Regulation (EC) No 726/2004, certain approval tasks are given to the European Medicines Agency;
- establishing specific monitoring rules for **information disseminated through websites**, to take account of the cross-border nature of information provided over the Internet and to allow Member State cooperation and avoid duplication of monitoring.

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:

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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.