Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2008/0255(COD)	Procedure lapsed or withdrawn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		21/07/2009
		PPE FJELLNER Christofer	
		Shadow rapporteur	
		S&D PARGNEAUX Gilles	
		ALDE CHATZIMARKAKIS Jorgo	
		Verts/ALE SCHLYTER Carl	
		ECR YANNAKOUDAKIS Marina	
		EFD ROSBACH Anna	
	Former committee responsible		
	ENVI Environment, Public Health and Food Safety		
	ENVI Environment, Public Health and Food Safety		01/03/2012
		PPE FJELLNER Christofer	
	Committee for opinion	Rapporteur for opinion	Appointed
	ITRE Industry, Research and Energy		16/09/2009
		ALDE CHATZIMARKAKIS Jorgo	
	IMCO Internal Market and Consumer Protection		14/09/2009
		S&D CORREIA DE CAMPOS António Fernando	
	Former committee for opinion		
	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	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	3095	30/05/2011
	Employment, Social Policy, Health and Consumer Affairs	3053	06/12/2010
	Employment, Social Policy, Health and Consumer Affairs	2980	30/11/2009
European Commission	Commission DG	Commissioner	
	Health and Food Safety	BORG Tonio	
European Economic and Social Committee			
European Committee of the Regions			

Key events

10/12/2008	Legislative proposal published	COM(2008)0662	Summary
13/01/2009	Committee referral announced in Parliament, 1st reading		
19/10/2009	Committee referral announced in Parliament, 1st reading		
30/11/2009	Debate in Council	2980	Summary
28/09/2010	Vote in committee, 1st reading		Summary
19/10/2010	Committee report tabled for plenary, 1st reading	A7-0289/2010	
22/11/2010	Debate in Parliament		
24/11/2010	Results of vote in Parliament		
24/11/2010	Decision by Parliament, 1st reading	T7-0430/2010	Summary
06/12/2010	Debate in Council	3053	Summary
30/05/2011	Debate in Council	3095	
11/10/2011	Modified legislative proposal published	COM(2011)0632	Summary
10/02/2012	Formal reconsultation of Parliament		
10/02/2012	Amended legislative proposal for reconsultation published	COM(2012)0049	Summary
21/05/2014	Proposal withdrawn by Commission		Summary

Technical information

Procedure reference	2008/0255(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 159
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/7/09017; ENVI/7/00156

Documentation gateway

Legislative proposal		COM(2008)0662	10/12/2008	EC	Summary
Document attached to the procedure		SEC(2008)2667	10/12/2008	EC	
Document attached to the procedure		SEC(2008)2668	10/12/2008	EC	
Economic and Social Committee: opinion, report		CES1025/2009	10/06/2009	ESC	
Committee draft report		PE439.412	10/03/2010	EP	
Committee opinion	ITRE	PE430.863	24/03/2010	EP	
Committee opinion	IMCO	PE439.345	30/04/2010	EP	
Amendments tabled in committee		PE441.030	04/05/2010	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0289/2010	19/10/2010	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0430/2010	24/11/2010	EP	Summary
Commission response to text adopted in plenary		SP(2011)610	26/01/2011	EC	
Modified legislative proposal		COM(2011)0632	11/10/2011	EC	Summary
Amended legislative proposal for reconsultation		COM(2012)0049	10/02/2012	EC	Summary
Economic and Social Committee: opinion, report		CES0468/2012	22/02/2012	ESC	
Economic and Social Committee: opinion, report		CES0810/2012	28/03/2012	ESC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

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

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/2008/0256) 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

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

The Committee on the Environment, Public Health and Food Safety adopted the report drafted by Christofer FJELLNER (EPP, SE) 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.

The committee recommended that the European Parliament?s position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Patients? rights: Members consider 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 report 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, Members propose 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.

Extending the time-limit for information: Members propose extending the timeline for the tacit acceptance of the information from 60 to 120 days in order to meet the organisational needs of the Agency and to ensure that the companies remain fully liable for the information they provide to the general public. If the Agency asks for changes 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 report 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 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 report 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.

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

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.

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

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

The Commission presents an amended proposal for a Regulation of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. Incorporated within the amended proposal are amendments proposed by the European Parliament at its first reading which are acceptable to the Commission.

12 amendments on the proposal were adopted by Parliament at first reading. The Commission considers that a majority of 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 incorporates in full or in part, the following amendments of the European Parliament in the amended proposal:

- it underlines that in the Commission Communication transmitted on 20 December 2007 concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" the need for a more precise distinction between advertising and information was highlighted;
- it is specified that the new Title introduced in Directive 2001/83/EC is intended to place emphasis on the rights and interests of patients. It also states that although the pre-control of information is performed by the Agency for centrally approved medicinal products, the monitoring of the information rests with Member States. It is appropriate to ensure consistently that the Agency is also responsible for the control of the information made available through Internet websites registered in the Member States. Specific provisions are introduced to clarify the operation of this control mechanism in such case of information made available through Internet websites registered with the Member States. The Commission acknowledges that a number of Member States have expressed concerns regarding 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 Regulation;
- it provides for the procedure regarding cases when the Agency requests changes within the information submitted for control and for the fees applicable which should be proportionate to the additional work. Considering that the normal delay is 60 days, the subsequent delay should be of 30 days;
- the text provides that the EudraPharm database it should be available in all EU languages. Such a change has been introduced as regards the lay-out of the database. However, the information contained in the database will be available in the languages of Member States where the medicinal product is authorised. In another respect, it is not necessary to further specify that the information provided is designed for non-experts, as it is already provided that it should be worded in an appropriate and comprehensible manner.

EudraPharm should be actively promoted to European citizens. This should be done through the development of the European medicines web-portal established by Regulation (EU) No 1235/2010 as the central point of access to information about medicinal products. However, it is not appropriate that information available on marketing authorisation holder websites is reproduced on EudraPharm, which is a public database.

Pharmacovigilance: in addition to the changes introduced on the basis of the European Parliament resolutions regarding the Commission proposals on information to patients, the Commission considers that limited changes to Regulation (EC) No 726/2004 in the area of pharmacovigilance should be introduced. Regulation (EC) No 726/2004 has been recently amended by Regulation (EU) No 1235/2010 to revise the EU pharmacovigilance system. Since Regulation (EU) No 1235/2010 has as legal basis Article 168(4)(c) of TFUE, the amended proposal should also be based on Article 168(4)(c) of TFUE.

Regulation (EU) No 1235/2010 substantially strengthens the legal framework for the surveillance of medicinal products in the EU. However, in view of recent pharmacovigilance events in the EU, the Commission has detected certain areas where the legislation could be further strengthened.

Therefore:

- the new public list of medicinal products subject to additional monitoring introduced by Regulation (EU) No 1235/2010 will not necessarily include all medicinal products subject to post-authorisation safety conditions. Competent authorities will have to decide on a case-by-case basis whether to make public the fact that products are subject to strengthened surveillance. For the sake of fuller transparency as regards products under special surveillance, the text is modified to systematically include medicinal products that are subject to conditions and requirements with regard to safety;
- a new provision is introduced to avoid a situation where the voluntary withdrawal of a marketing authorisation or product by the holder could lead to safety issues not being addressed in the EU. It clarifies the information obligations of the marketing authorisation holder.

Lastly, the text clarifies the scope of this provision and the EU procedures set out in Directive 2001/83/EC.

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

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 amendments introduced by the Commission in light of the European Parliaments amendments aim to :

- recall that in the Commission Communication concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" the need for a more precise distinction between advertising and information was highlighted;
- specify that the new Title introduced in Directive 2001/83/EC is intended to place emphasis on the rights and interests of patients;
- specify that although the pre-control of information is performed by the Agency for centrally approved medicinal products, the monitoring of the information rests with Member States. It is appropriate to ensure consistently that the Agency is also responsible for the control of the information made available through Internet websites registered in the Member States. Specific provisions are introduced to clarify the operation of this control mechanism in such case of information made available through Internet websites registered with the Member States;
- provide for the procedure regarding cases when the Agency requests for changes within the information submitted for control and for the fees applicable which should be proportionate to the additional work. Considering that the normal delay is 60 days, the subsequent delay should be of 30 days;
- provide that the EudraPharm database should be available in all EU languages. Such a change has been introduced as regards the lay-out of the database; on the other hand, the information contained in the database will be available in the languages of Member States where the medicinal product is authorised;
- provide that EudraPharm should be actively promoted to European citizens. This should be done through the development of the European medicines web-portal established by Regulation (EU) No 1235/2010 as the central point of access to information about medicinal products.

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

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

As announced in Official Journal C 153 of 21 May 2014, the Commission decided to withdraw this proposal, which had become obsolete.