Basic information

2012/0025(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Pharmacovigilance: transparency and efficiency of the system. Directive Amending Directive 2001/83/EC 1999/0134(COD) See also 2012/0023(COD) **Subject** 4.20.04 Pharmaceutical products and industry 4.20.05 Health legislation and policy 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	MCAVAN Linda (S&D)	20/12/2011
	Shadow rapporteur AYUSO Pilar (PPE) PARVANOVA Antonyia (ALDE) RIVASI Michèle (Verts/ALE) YANNAKOUDAKIS Marina (ECR) MAŠTÁLKA Jiří (GUE/NGL)	

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

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	3188	2012-10-04

European Commission

Commission DG	Commissioner

	Health and Food Safety	DALLI John
European Economic and Social Committee		
European Committee of the Regions		

Key events

Date	Event	Reference	Summary
10/02/2012	Legislative proposal published	COM(2012)0052	Summary
16/02/2012	Committee referral announced in Parliament, 1st reading		
08/05/2012	Vote in committee, 1st reading		
12/07/2012	Committee report tabled for plenary, 1st reading	A7-0165/2012	Summary
10/09/2012	Debate in Parliament		
11/09/2012	Decision by Parliament, 1st reading	T7-0313/2012	Summary
11/09/2012	Results of vote in Parliament		
04/10/2012	Act adopted by Council after Parliament's 1st reading		
25/10/2012	Final act signed		
25/10/2012	End of procedure in Parliament		
27/10/2012	Final act published in Official Journal		

Technical information

Procedure reference	2012/0025(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 2001/83/EC 1999/0134(COD) See also 2012/0023(COD)
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 completed
Committee dossier	ENVI/7/08830

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE486.167	03/04/2012	
Committee report tabled for plenary, 1st reading/single reading		A7-0165/2012	12/07/2012	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0313/2012	11/09/2012	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00043/2012/LEX	25/10/2012	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2012)0052	10/02/2012	Summary
Commission response to text adopted in plenary	SP(2012)665	11/10/2012	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2012)0052	12/04/2012	
Contribution	PT_PARLIAMENT	COM(2012)0052	12/04/2012	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0811/2012	28/03/2012	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2012/0026
OJ L 299 27.10.2012, p. 0001 Summary

Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 25/10/2012 - Final act

PURPOSE: to strengthen the rules on pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system, and amending Directive 2001/83/EC.

LEGISLATIVE ACT: Directive 2012/26/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance.

CONTENT: following agreement at first reading, the European Parliament and the Council adopted this Directive aimed at strengthening the post-authorisation monitoring of medicines for human use ("pharmacovigilance"), thereby further improving patient safety.

The new legislation focuses in particular on obligations on marketing authorisation holders in relation to adverse reactions to medicinal products and clarifies the procedures when competent authorities follow up such reporting.

The main points of the Directive are as follows:

Automatic assessment at EU level: recent pharmacovigilance incidents in the Union have shown the need for an automatic procedure at Union level in cases of specific safety issues to ensure that a matter is assessed and addressed in all Member States where the medicinal product is authorised. The Directive clarifies the scope of different Union procedures concerning products authorised at national level, as laid down in Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Clarification of Normal Procedure and Urgent Procedure: these procedures are strengthened in order to ensure coordination, swift assessment in case of urgency and the possibility of taking immediate action, where necessary to protect public health, before a decision is taken at Union level.

- The Normal Procedure should be initiated for matters concerning quality, safety or efficacy of medicinal products where the interests of the Union are involved.
- The Urgent Union Procedure should be initiated when there is a need to swiftly assess concerns resulting from the evaluation of data from pharmacovigilance activities.

Regardless of whether the Urgent Union Procedure or the Normal Procedure is applied, and regardless of the procedure by means of which the medicinal product was authorised, be it centralised or otherwise, the Pharmacovigilance Risk Assessment Committee must always give its recommendation when the reason for taking action is based on pharmacovigilance data.

Member States must bring cases concerning new contraindications, reductions in the recommended dose or restrictions to the indication for medicinal products authorised in accordance with the decentralised procedure and the mutual recognition procedure to the attention of the coordination group when the Urgent Union Procedure is not initiated. In order to ensure harmonisation for those products, the coordination group may discuss whether any action is necessary in the event that no Member State has triggered the Normal Procedure.

Notification to competent authorities where product is withdrawn: voluntary action by the marketing authorisation holder should not lead to a situation where concerns relating to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, the **Directive requires marketing authorisation holder to inform the relevant competent authorities and the European Medicines Agency** of the reasons for with-drawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing auth-orisation be revoked, or for not renewing a marketing authorisation. This also applies if the marketing authorisation holder withdraws a medicine from a third country market.

Transparency: each year, the European Medicines Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or which have been withdrawn from the market, including the reasons for such action.

Wholesale distribution of medicinal products: the Directive further strengthens the rules concerning wholesale distribution of medicinal products to third countries.

ENTRY INTO FORCE: 16 November 2012.

TRANSPOSITION: 28 October 2013.

APPLICATION: from 28 October 2013.

Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 10/02/2012 - Legislative proposal

PURPOSE: to amend Directive 2001/83/EC as regards pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system.

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

BACKGROUND: in December 2010, the European Parliament and the Council adopted Directive 2010/84/EU and Regulation (EU) No 1235/2010 ("2010 pharmacovigilance legislation") amending respectively, as regards pharmacovigilance, Directive 2001/83/EC and Regulation (EC) No 726/2004. The new legislation will apply from July 2012.

These measures have substantially strengthened the legal framework for the surveillance of medicinal products, 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, recent pharmacovigilance events in the European Union, in particular the “Mediator case”, have shown the **need for a further improvement of the pharmacovigilance system**. Following an analysis of the Mediator case in the light of the 2010 pharmacovigilance legislation ("Stress test"), the Commission has detected certain weaknesses in the pharmacovigilance system that need to be addressed.

It should be noted that this proposal is closely linked to the proposal to amend Regulation (EC) No 726/2004.

IMPACT ASSESSMENT: no impact assessment has been undertaken.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the EU.

CONTENT: the general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are to ensure the proper functioning of the internal market for medicinal products for human use and to protect better the health of EU citizens. Following this line, the proposals aim specifically to address weaknesses identified in the EU pharmacovigilance system and provide for more transparency and efficiency of the system in cases where safety concerns are identified.

The main amendments to the Regulation are as follows:

Automatic assessment at EU level: Directive 2001/83/EC provides for an automatic assessment at Union level when specific serious safety issues have been identified with regard to nationally authorised products. In the 2010 pharmacovigilance legislation, changes to the Commission's proposal during co-decision have led to the automatic assessment being lost, as the initiation of the procedure is linked to an appreciation by the Member State or the Commission as to whether an urgent action is considered necessary. Thus, when a Member State considers suspending, revoking or refusing renewal of a marketing authorisation, but does not consider that urgent action is needed, no evaluation of the safety concern will be conducted at Union level.

Recent pharmacovigilance events in the Union have shown the need for an automatic procedure at Union level in the cases of specific safety issues to ensure that a matter is assessed and addressed in all Member States where the medicinal product is authorised. The scope of different Union procedures concerning nationally authorised products is clarified in the text.

Transparency: marketing authorisation holders are not required to declare the reasons for the withdrawal of a marketing authorisation or product. Therefore, it cannot be ruled out that voluntary withdrawal of a marketing authorisation or product by the marketing authorisation holder could lead to safety issues being missed, in particular if the company is not transparent about possible safety concerns.

Voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, provision is made for the marketing authorisation holder to **inform competent authorities of the reasons for the withdrawal of a medicinal product**, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation.

BUDGETARY IMPLICATIONS: the proposal has no implication for the budget of the Union. It makes minor changes to the system set forth by the 2010 pharmacovigilance legislation, and does not require additional human or administrative resources.

Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 12/07/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance.

The committee recommends that the European Parliament’s position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Obligations regarding information: Members want to reinsert two obligations which make the referral procedure work more smoothly. Accordingly:

- the Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or marketing authorisation holder accordingly;
- the Member States and the applicant or marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.

Drug-Fact-Box: the notice must include a Drug-Fact-Box - a brief description of essential/necessary facts and details of the medicinal product, which are required by the patient to understand the usefulness as well as possible risks of the medicinal product and to use it in a safe and proper way. The information contained in the Drug-Fact-Box shall be presented in a clear and legible way, and shall be distinguishable from the rest of the text form.

Third countries: the marketing authorisation holder shall also make the notification to Member States and the Agency of action to suspend the marketing of a medicinal product, or the non-renewal of a marketing authorization if the action is taken in a third country.

Notification to the Agency: the marketing authorisation holder shall be obliged to notify the Agency as well as Member States forthwith of any action taken by him to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action.

Transparency: the Agency shall not only make public annually a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended, whose supply has been prohibited or which have been withdrawn from the market, but also the reasons for such action.

Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 11/09/2012 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 659 votes to 9, with 9 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance.

Parliament adopted its position on first reading following the ordinary legislative procedure. The agreement was the result of a compromise negotiated between Parliament and Council. The main amendments are as follows:

Obligations regarding information: the marketing authorisation holder shall be obliged to inform the relevant competent authorities and the European Medicines Agency of the reasons for withdrawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing authorisation be revoked, or for not renewing a marketing authorisation.

Normal Procedure and Urgent Union Procedure: the amended text clarifies and further strengthens the normal procedure and the urgent Union procedure in order to ensure coordination, swift assessment in case of urgency and the possibility to take immediate action, where necessary to protect public health, before a decision is taken at Union level.

- The Normal Procedure should be initiated for matters concerning quality, safety or efficacy of medicinal products where the interests of the Union are involved.
- The Urgent Union Procedure should be initiated when there is a need to swiftly assess concerns resulting from the evaluation of data from pharmacovigilance activities.

Regardless of whether the Urgent Union Procedure or the Normal Procedure is applied, and regardless of the procedure by means of which the medicinal product was authorised, be it centralised or otherwise, the **Pharmacovigilance Risk Assessment Committee** should always give its recommendation when the reason for taking action is based on pharmacovigilance data. The coordination group and the Committee for Medicinal Products for Human Use shall rely on that recommendation when carrying out the assessment of the issue.

Drug-Fact-Box: the package leaflet must be written and designed in such a way as to be **clear and understandable**, enabling users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market

Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, **grant an exemption to the obligation** that certain particulars should appear on the labelling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market.

Wholesale distribution of medicinal products to third countries: in this case, wholesale distributors shall ensure that the medicinal products are obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the third country concerned.