Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2012/0023(COD)
Pharmacovigilance: transparency and efficiency of the system. Regulation Amending Regulation (EC) No 726/2004 2001/0252(COD) See also 2012/0025(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	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		20/12/2011
		S&D MCAVAN Linda	
		Shadow rapporteur	
		PPE AYUSO Pilar	
		ALDE PARVANOVA Antonyia	
		Verts/ALE RIVASI Michèle	
		ECR YANNAKOUDAKIS Marina	
	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	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	3188	04/10/2012
European Commission	Commission DG	Commissioner	
	Health and Food Safety	DALLI John	
European Economic and Social Committee			
European Committee of the Regions			

Key events

10/02/2012	Legislative proposal published	COM(2012)0051	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	A7-0164/2012	
10/09/2012	Debate in Parliament		
11/09/2012	Results of vote in Parliament		
11/09/2012	Decision by Parliament, 1st reading	T7-0314/2012	Summary
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		
14/11/2012	Final act published in Official Journal		

Technical information

Procedure reference	2012/0023(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 726/2004 2001/0252(COD) See also 2012/0025(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1; Treaty on the Functioning of the EU TFEU 168-p4
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 completed
Committee dossier	ENVI/7/08833

Documentation gateway

Legislative proposal		COM(2012)0051	10/02/2012	EC	Summary
Economic and Social Committee: opinion, report		CES0812/2012	28/03/2012	ESC	
Committee draft report		PE486.166	03/04/2012	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0164/2012	12/07/2012	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0314/2012	11/09/2012	EP	Summary
Commission response to text adopted in plenary		SP(2012)665	11/10/2012	EC	
Draft final act		00042/2012/LEX	25/10/2012	CSL	

Additional information

National parliaments	IPEX

Final act

Regulation 2012/1027
OJ L 316 14.11.2012, p. 0038 Summary

Pharmacovigilance: transparency and efficiency of the system. Regulation

PURPOSE: to amend Regulation (EC) No 726/2004 as regards pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system.

PROPOSED ACT: Regulation 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 Mediatorcase, 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 Directive 2001/83/EC.

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:

Reasons for withdrawal: 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.

Accordingly, provision is made for the marketing authorisation holder to inform the Agency 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.

Transparency: the public list of medicinal product subject to additional monitoring provided for in Article 23 of Regulation (EC) No 726/2004 will include certain medicinal products subject to post-authorisation safety conditions. Those products will be included in the list, following consultation with the Pharmacovigilance Risk Assessment Committee, only if the Commission or a Member States' competent authorities make a request. Therefore, 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.

The proposal provides that, in order to ensure transparency on the surveillance of authorised medicinal products, the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004 should systematically include medicinal products that are subject to post-authorisation safety conditions.

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. Regulation

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance.

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

List of products: the list of products subject to additional monitoring should only include products subject to the most serious conditions and safety concerns, as otherwise the list becomes too long and loses meaning. It should automatically include all new products containing new active substances, as well as all new biosimilars, for the first five years.

Fees: in order to ensure full implementation of the new provisions related to pharmacovigilance the European Medicines Agency must be empowered to charge fees to marketing authorisation holders for the fulfilment of the pharmacovigilance tasks.

Consequently, the Commission should be empowered to adopt a delegated act in order to supplement the provisions in Article 67(3) as regards services provided by the Agency or the coordination group with respect to pharmacovigilance.

The power to adopt the delegated acts shall be conferred on the Commission for a period of 5 years from 1 July 2012. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it.

Pharmacovigilance: transparency and efficiency of the system. Regulation

The European Parliament adopted by 665 votes to 9, with 10 abstentions, a legislative resolution on the proposal for a Regulation of the European Parliament and of the Council amending Regulation No 726/2004 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:

Information requirements: the marketing authorisation holder shall notify the Agency forthwith of any action the holder takes 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. He shall in particular declare if such action is based on any of the grounds set out in Directive 2001/83/EC. He shall also make the notification if the action is taken in a third country.

List of medicinal products: the Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.

The amended text stipulates that, at the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation and subject to certain conditions may also be included in the list.

Tasks of the Agency: the Agency will assume, among other things, the following tasks:

- coordinating the monitoring of medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;
- ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products authorised in the Union by means of a database which is permanently accessible to all Member States.

Marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised in the Union, using the format referred to in the Regulation.

Pharmacovigilance: transparency and efficiency of the system. Regulation

PURPOSE: determination of precise rules on pharmacovigilance and the improvement of medicines for human use in accordance with Regulation (EC) No 726/2004.
LEGISLATIVE ACT: Regulation (EC) No 1027/2012of the European Parliament and of the Council amending Regulation (EC) No 726/2004 relating to pharmacovigilance.
CONTENT: following a first reading agreement with the European Parliament, the Council adopted this Regulation as well as a Directive to improve medicines for human use (pharmacovigilance) so as to further improve general patient safety.

The main changes introduced to the legislation in force are as follows:

Information requirements:

- if the product ceases to be placed on the market of a Member State, either temporarily or permanently. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product;
- the marketing authorisation holder shall notify the Agency forthwith of any action the holder takes 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. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 116 or Article 117(1) of Directive 2001/83/EC. They shall also make the notification if the action is taken in a third country.

List of medicinal products: the Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring. The list referred to shall include an electronic link to the product information and to the summary of the risk management plan.

At the request of the Commission, medicinal products that are authorised pursuant to this Regulation, subject to certain conditions may also be included in the list.

By 5 June 2018, the Commission shall present to the European Parliament and the Council a report on the use of the list, based on the experience and data provided by the Member States and the Agency.

Missions of the Agency: the Agency will ensure, inter alia, the following functions:

- coordinating the monitoring of medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;
- ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products authorised in the Union by means of a database which is permanently accessible to all Member States.

Marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised in the Union, using the format referred to in the Regulation.

ENTRY INTO FORCE: 04/12/2012.

APPLICATION: from 05/06/2013, with the exception of some sections which shall apply from 04/12/2012.