Basic information

2008/0045(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Medicinal products for human and veterinary use: marketing authorisations Amending Directive 2001/83/EC 1999/0134(COD) Amending Directive 2001/82/EC 1999/0180(COD) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20.04 Pharmaceutical products and industry 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	GROSSETÊTE Françoise (PPE-DE)	14/04/2008

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.	25/03/2008
AGRI Agriculture and Rural Development	STAVREVA Petya (PPE-DE)	31/03/2008
JURI Legal Affairs	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	2876	2008-06-09
Competitiveness (Internal Market, Industry, Research and Space)	2945	2009-05-28

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter

Key events

Date	Event	Reference	Summary
04/03/2008	Legislative proposal published	COM(2008)0123	Summary
13/03/2008	Committee referral announced in Parliament, 1st reading		
09/06/2008	Debate in Council		
09/09/2008	Vote in committee, 1st reading		Summary
15/09/2008	Committee report tabled for plenary, 1st reading	A6-0346/2008	
22/10/2008	Decision by Parliament, 1st reading	T6-0510/2008	Summary
22/10/2008	Results of vote in Parliament		
22/10/2008	Debate in Parliament		
28/05/2009	Act adopted by Council after Parliament's 1st reading		
18/06/2009	Final act signed		
18/06/2009	End of procedure in Parliament		
30/06/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0045(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) Amending Directive 2001/82/EC 1999/0180(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/60575

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE409.420	26/06/2008	
Amendments tabled in committee		PE409.694	18/07/2008	
Committee opinion	AGRI	PE407.833	09/09/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0346/2008	15/09/2008	

Text adopted by Parliament, 1st reading/single reading		T6-0510/2008	22/10/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03713/2008/LEX	18/06/2009	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0123	04/03/2008	Summary
Document attached to the procedure	SEC(2008)0273	04/03/2008	
Document attached to the procedure	SEC(2008)0274	04/03/2008	
Commission response to text adopted in plenary	SP(2008)6664	12/11/2008	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1194/2008	09/07/2008	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2009/0053
OJ L 168 30.06.2009, p. 0033 Summary

Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 22/10/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 675 votes to 21 with 8 abstentions, a legislative resolution amending the proposal for a directive of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products.

The report had been tabled for consideration in plenary by Francoise **GROSSETETE** (PES, FR) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between the Council and the Parliament.

The main amendments - adopted under 1st reading of the codecision procedure - were as follows:

- Parliament considered that the rules on variations adopted by the Commission should pay particular attention to simplifying administrative procedures. To this effect, the Commission should foresee, when adopting these rules, certain possibilities of filing a single application for one or more identical changes to the terms of a number of marketing authorisations. Accordingly, the Commission shall make efforts to extend the possibility of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations;

- a Member State may continue to apply national provisions on variations applicable at the time of entry into force of the implementing regulation to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions is subsequently granted a marketing authorisation in another Member State, the implementing regulation shall apply to that medicinal product from that date;

- where a Member State decides to continue to apply national provisions it shall notify the Commission. If a notification has not been made by 18 months after entry into force of the directive, the implementing regulation shall apply.

Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 18/06/2009 - Final act

PURPOSE: to amend Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products.

LEGISLATIVE ACT: Directive 2009/53/EC of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products.

CONTENT: following a first reading agreement with the European Parliament, the Council adopted a directive amending two directives on the Community code relating to medicinal products. The German delegation abstained. The Directive aims to ensure that all medicinal products are subject to the same criteria for the evaluation, approval and administrative treatment of variations in the production process, in the packaging or in the address of the manufacturer.

Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, Directive 2001 /83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, lay down harmonised rules for the authorisation, supervision and pharmacovigilance of medicinal products within the Community.

Under those rules, marketing authorisations may be granted in accordance with harmonised Community procedures. The terms of those marketing authorisations may subsequently be varied where, for instance, the production process or the address of the manufacturer has changed.

The Directives empower the Commission to adopt an implementing regulation as regards variations subsequently made to marketing authorisations. The Commission therefore adopted Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

However, the majority of medicinal products for human or veterinary use currently on the market have been authorised under purely national procedures and, as such, fall outside the scope of Regulation (EC) No 1084/2003. Variations to marketing authorisations granted under purely national procedures are thus subject to national rules.

Consequently, while the granting of all marketing authorisations for medicinal products is subject to harmonised rules within the Community, this is not the case for variations to the terms of marketing authorisations.

For reasons of public health and legal consistency, and with a view to reducing the administrative burden and strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.

The rules on variations adopted by the Commission should pay particular attention to simplifying administrative procedures. To this effect, the Commission should provide, when adopting these rules, for the possibility of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations.

As part of the compromise between the European Parliament and the Council, the Directive stipulates that a Member State may continue to apply national provisions on variations applicable at the time of entry into force of the implementing regulation to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, the implementing regulation shall apply to that medicinal product from that date.

Where a Member State decides to continue to apply national provisions, it shall notify the Commission thereof. If a notification has not been made by 20 January 2011, the implementing regulation shall apply.

Directive 2001/82/EC and Directive 2001/83/EC is therefore amended accordingly.

ENTRY INTO FORCE: 20 July 2009.

TRANSPOSITION: 20 January 2011 at the latest.

Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 04/03/2008 - Legislative proposal

PURPOSE: to amend Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products.

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

CONTENT: within the European Community, medicinal products are regulated throughout their entire lifetime. Changes subsequent to their placing on the market, such as change in the production process, change in the packaging or change in the address of the manufacturer, are governed either by national provisions or by Community rules: Commission Regulations (EC) Nos 1084/2003 and 1085/2003 ("Variations Regulations"). These “Variation Regulations” are implementing measures adopted by the 'comitology' regulatory procedure.

However, the current Variations Regulations do not apply to changes to marketing authorisations for medicinal products which have been granted at a national level by a Member State competent authority under a national procedure. In the absence of Community harmonisation, changes affecting purely national authorisations are therefore subject to national rules. In some Member States, national requirements on changes to purely national authorisations nevertheless follow the Variations Regulations, by analogy. But in the majority of Member States there is no such alignment on Community legislation, which results in discrepancies between the rules of those Member States and may also have negative effects on public health, the administrative burden and the overall functioning of the internal market in pharmaceuticals.

The objective of this proposal is therefore to amend Directives 2001/82/EC and 2001/83/EC in order to empower the Commission to extend the scope of the corresponding Variations Regulation, namely Regulation (EC) No 1084/2003. The Commission may subsequently modify the scope of that Regulation by 'comitology' procedure. Enlarging the scope of Regulation (EC) No 1084/2003 will ensure that all medicinal products placed on the Community market -including those authorised at purely national level - are subject to the same criteria for the approval and administrative handling of changes, regardless of the procedure under which those medicines have been authorised.