Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2008/0045(COD)
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	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PPE-DE GROSSETÊTE Françoise	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.	
AGRI Agriculture and Rural Development	PPE-DE STAVREVA Petya	31/03/2008
JURI Legal Affairs	The committee decided not to give an opinion.	

Council of the European Union

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

European Commission

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

Key events

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	2876	

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	Results of vote in Parliament		
22/10/2008	Debate in Parliament		
22/10/2008	Decision by Parliament, 1st reading	T6-0510/2008	Summary
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
	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

Legislative proposal		COM(2008)0123	04/03/2008	EC	Summary
Document attached to the procedure		SEC(2008)0273	04/03/2008	EC	
Document attached to the procedure		SEC(2008)0274	04/03/2008	EC	
Committee draft report		PE409.420	26/06/2008	EP	
Economic and Social Committee: opinion, report		CES1194/2008	09/07/2008	ESC	
Amendments tabled in committee		PE409.694	18/07/2008	EP	
Committee opinion	AGRI	PE407.833	09/09/2008	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0346/2008	15/09/2008	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0510/2008	22/10/2008	EP	Summary
Commission response to text adopted in plenary		SP(2008)6664	12/11/2008	EC	
Draft final act		03713/2008/LEX	18/06/2009	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2009/53
OJ L 168 30.06.2009, p. 0033 Summary

Medicinal products for human and veterinary use: marketing authorisations

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.

Medicinal products for human and veterinary use: marketing authorisations

The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Francoise GROSSETETE (PES, FR) and amended 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 main amendments are as follows:

- the possibility of filing a single application for one or more identical changes to the terms of a number of marketing authorisations must be extended to all the types of change in order to simplify and optimise the procedures;

- under the current system, Regulations (EC) No 1084/2003 and No 1085/2003 provide for the possibility, in the case of an extension of a marketing authorisation, of filing a complete, separate request for authorisation for a medicinal product that has already been authorised, but under another name and with a different product characteristic summary. It is essential that this possibility should be retained. Some names of medicines have strong associations to a certain pathology, and it could have a damaging effect on patients if the same name were kept when the pathology treated by the medicine had changed completely;

- the appropriate arrangements adopted by the Commission must take the following considerations into account: for practical reasons of efficiency, the possibility should be extended to all the categories of change of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations. As regards extensions of marketing authorisations, the possibility should be provided, on the basis of arguments in justification, of submitting a complete, separate application for authorisation for a medicinal product that has already been authorised under another name and with a different product characteristic summary;

- a new clause states that Member States may continue to apply national provisions on variations applicable at the time of entry into force of this 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;

- the committee deleted the provisions in the proposal which were intended solely to bring Directive 2001/82/EC into line with the relevant new comitology procedure (the regulatory procedure with scrutiny). It stated that those provisions were not directly related to the subject of the proposal, that is to say, changes to marketing authorisations. They already appear, moreover, in the Commission's 'all-inclusive' proposal (see COD/2008/0032) and are consequently redundant in this proposal;

- transposition should be 18 months (rather than 12 months) after entry into force of the Directive.

Medicinal products for human and veterinary use: marketing authorisations

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

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.