Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2014/0256(COD)
Medicinal products for human and veterinary use Amending Directive 2001/83/EC 1999/0134(COD) Amending Regulation (EC) No 726/2004 2001/0252(COD) Amending Regulation (EC) No 1901/2006 2004/0217(COD) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20.01 Medicine, diseases 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		25/11/2014
		S&D TĂNĂSESCU Claudiu Ciprian	
		Shadow rapporteur	
		epp CIRIO Alberto	
		ECR PIECHA Bolesław G.	
		MEISSNER Gesine	
		HÄUSLING Martin	
		EFD PEDICINI Piernicola	
	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		22/10/2014
		epp POLČÁK Stanislav	
Council of the European Union	Council configuration	Meeting	Date
	Education, Youth, Culture and Sport	3653	26/11/2018
European Commission	Commission DG	Commissioner	
	Health and Food Safety	BORG Tonio	
European Economic and Social Committee			
European Committee of the Regions			

Key events

10/09/2014	Legislative proposal published	COM(2014)0557	Summary
20/10/2014	Committee referral announced in Parliament, 1st reading		
17/02/2016	Vote in committee, 1st reading		
23/02/2016	Committee report tabled for plenary, 1st reading	A8-0035/2016	Summary
09/03/2016	Debate in Parliament		
10/03/2016	Results of vote in Parliament		
10/03/2016	Decision by Parliament, 1st reading	T8-0088/2016	Summary
10/03/2016	Matter referred back to the committee responsible		
24/10/2018	Debate in Parliament		
25/10/2018	Decision by Parliament, 1st reading	T8-0420/2018	Summary
26/11/2018	Act adopted by Council after Parliament's 1st reading		
11/12/2018	Final act signed		
11/12/2018	End of procedure in Parliament		
07/01/2019	Final act published in Official Journal		

Technical information

Procedure reference	2014/0256(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 2001/83/EC 1999/0134(COD) Amending Regulation (EC) No 726/2004 2001/0252(COD) Amending Regulation (EC) No 1901/2006 2004/0217(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 59-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/8/01656

Documentation gateway

Legislative proposal		COM(2014)0557	10/09/2014	EC	Summary
Economic and Social Committee: opinion, report		CES6070/2014	21/01/2015	ESC	

Committee draft report		PE552.048	14/04/2015	EP	
Amendments tabled in committee		PE560.745	22/06/2015	EP	
Committee opinion	AGRI	PE552.060	23/07/2015	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0035/2016	23/02/2016	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T8-0088/2016	10/03/2016	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0420/2018	25/10/2018	EP	Summary
Commission response to text adopted in plenary		SP(2018)755	21/11/2018	EC	
Draft final act		00044/2018/LEX	12/12/2018	CSL	

Additional information

European Commission	EUR-Lex

Final act

Regulation 2019/5
OJ L 004 07.01.2019, p. 0024 Summary

Final legislative act with provisions for delegated acts

Medicinal products for human and veterinary use

PURPOSE: to amend 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.

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

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) 726/2004 of the European Parliament and of the Council constituted the Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products.

In the light of the experience acquired and following the assessment by the Commission of the functioning of the internal market for veterinary medicinal products, the Commission has presented a proposal that will repeal and replace Directive 2001/82/EC on veterinary medicinal products. This proposal lays down procedures for the authorisation and supervision of medicinal products for human and veterinary use. It is therefore necessary to amend Regulation (EC) No 726/2004 to take account of the fact that centralised marketing authorisation for veterinary products is being decoupled from that for medicines for humans.

IMPACT ASSESSMENT: the consultation and a study, An assessment of the impact of the revision of veterinary pharmaceutical legislation, formed the basis of an impact assessment carried out for the Commission between November 2009 and June 2011. The Commissions Impact Assessment Board (IAB) released its final opinion in September 2013.

CONTENT: the proposal seeks to amend Regulation (EC) No 726/2004 so as to:

- delete from Regulation (EC) No 726/2004 the provisions regarding granting and maintaining marketing authorisations for veterinary medicinal products. The rules on marketing authorisations valid in all EU Member States are part of the proposal for a Regulation on veterinary medicinal products. The new Regulation on veterinary medicinal products will cover all routes granting marketing authorisations for veterinary medicinal products in the Union both at centralised and national level;
- establish certain principles applicable to fees payable to the Agency, including the need to take into account, as appropriate, the specific needs for SMEs. The provisions regulating fees should be brought into line with the Treaty of Lisbon;
- align the powers conferred on the Commission under Regulation (EC) No 726/2004 to Articles 290 and 291 (delegated and implementing acts) of the Treaty on the Functioning of the European Union.

BUDGETARY IMPLICATION: the costs for the EMA for implementing and applying the new rules are entirely covered by fees charged to industry. Therefore, the proposal is not expected to have any financial impact on the budget of the EU.

As set out in the legislative financial statement the additional resource needs for EMA are approximately 8 staff plus expenditure for meetings, translation, IT, etc. The level of fees, their structure and modalities and exceptions will be set at a later stage by the Commission by way of

implementing acts.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the treaty on the Functioning of the European Union.

Medicinal products for human and veterinary use

The Committee on the Environment, Public Health and Food Safety adopted the report by Claudiu Ciprian T?N?SESCU (S&D, RO) on the proposal for a regulation of the European Parliament and of the Council amending 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 Parliament make the following amendments to the Commission proposal:

Fees: Members clarified and separated the Agencys sources of revenue, stating that revenue will consist of:

- a contribution from the Union;
- a contribution from any European third country with which the Union has concluded agreements;
- the fees paid by undertakings for obtaining and maintaining Union marketing authorisations for human and veterinary medicinal products and for other services provided by the Agency;
- charges for any other services provided by the Agency; and
- other sources of income, including any ad-hoc grants within the scope of Regulation (EU, Euratom) No 966/2012 on the general budget of the Union.

The European Parliament and the Council will re-examine, when necessary, the level of the Union contribution on the basis of an evaluation of needs and by taking account of the level of fees.

Reserve fund: in order to safeguard fluctuations in fee revenue, any positive budget outturn of a financial year will be set aside as assigned revenue and serve as a reserve in the event that actual fee revenue be below budgeted appropriations.

Co-decision rather than an implementing act: Members felt that matters relating to the structure and level of fees should be decided through the co-decision procedure rather than through implementing acts. Accordingly, they deleted the relevant parts of the text that empowered the Commission to adopt implementing acts relating to fees.

Centralised procedure: the committee referred to the new Veterinary Medicines Regulation, and stressed the role of the EMA in the authorisation and supervision of veterinary products through the centralised procedure.

Alternative models: the Agency shall develop a framework for the regulatory acceptance of alternative models and take into consideration the opportunities presented by new concepts which aim at providing for more predictive medicines.

Transitional arrangements: with regard to the level and the structure of the fees, Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 will be applicable until an amendment of Regulation (EC) No 297/95 or any other relevant provisions on fees are adopted and become applicable.

Report: a report on the experience acquired through the Regulation will be published every five years (rather than every ten years).

Medicinal products for human and veterinary use

The European Parliament adopted amendments to the proposal for a regulation of the European Parliament and of the Council amending 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 matter has been referred back to the committee. The vote on the legislative resolution has been postponed to a subsequent sitting.

The main elements adopted in plenary are as follows:

Fees: Members clarified and separated the Agencys sources of revenue, stating that revenue will consist of:

- a contribution from the Union;
- a contribution from any European third country with which the Union has concluded agreements;
- the fees paid by undertakings for obtaining and maintaining Union marketing authorisations for human and veterinary medicinal products and for other services provided by the Agency;
- charges for any other services provided by the Agency; and
- other sources of income, including any ad-hoc grants within the scope of Regulation (EU, Euratom) No 966/2012 on the general budget of the Union (Financial Regulation).

The European Parliament and the Council will re-examine, when necessary, the level of the Union contribution on the basis of an evaluation of needs and by taking account of the level of fees.

Reserve fund: in order to safeguard fluctuations in fee revenue, any positive budget outturn of a financial year will be set aside as assigned revenue and serve as a reserve in the event that actual fee revenue be below budgeted appropriations. The total amount of such a safeguard fund shall not exceed the Agency's appropriations for the fee revenue of the past year.

Financial provisions: the Executive Director shall implement the budget of the Agency. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's Accounting Officer and to the Court of Auditors.

By 31 March of the following financial year, the Executive Director shall send the report on the budgetary and financial management to the

European Parliament, the Commission, the Council and the Court of Auditors.

Structure and level of fees: Members felt that matters relating to the structure and level of fees should be decided through the co-decision procedure rather than through implementing acts. Accordingly, they deleted the relevant parts of the text that empowered the Commission to adopt implementing acts relating to fees.

Centralised procedure: in the interest of public health, authorisation decisions adopted under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy. It is proposed for reference to be made to the new Veterinary Medicines Regulation, and that the role of the EMA in the authorisation and supervision of veterinary products through the centralised procedure should be stressed.

Alternative models: the Agency shall develop a framework for the regulatory acceptance of alternative models and take into consideration the opportunities presented by new concepts which aim at providing for more predictive medicines. These concepts may be based on human-relevant computer or cellular models, pathways of toxicity, or adverse outcome pathways.

Transitional arrangements: with regard to the level and the structure of the fees, Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 will be applicable until an amendment of Regulation (EC) No 297/95 or any other relevant provisions on fees are adopted and become applicable.

Report: a report on the experience acquired through the Regulation will be published every five years (rather than every ten years).

Medicinal products for human and veterinary use

The European Parliament adopted by 563 votes to 48, with 10 abstentions, a legislative resolution on the proposal for a Regulation of the European Parliament and of the Council amending 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 European Parliaments position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Marketing authorisation: for certain categories of medicinal products for human use, the amended text provides for the possibility of granting marketing authorisations before comprehensive clinical data are provided in order to meet the unmet medical needs of patients and in the interest of public health.

Marketing authorisations granted shall be subject to specific obligations, including being required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is favourable. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

When the specific obligations have been fulfilled, the Commission may, following an application by the marketing authorisation holder, and after receiving a favourable opinion from the Agency, grant a marketing authorisation valid for five years and renewable.

Surveillance: variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved.

A marketing authorisation may be transferred to a new marketing authorisation holder. Such a transfer shall not be considered to be a variation. The transfer shall be subject to prior approval by the Commission, following the submission of an application for the transfer to the Agency.

Where the Agency concludes that a holder of a marketing authorisation granted failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly. The Commission shall adopt a decision to vary, suspend or revoke that marketing authorisation.

European Medicines Agency: the Agency shall be responsible for coordinating the existing scientific resources put at its disposal by the Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products. Each of the Agency's committees shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

The Agency shall perform, among other things, the following tasks:

- coordinate the scientific evaluation of the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products which are subject to Union marketing authorisation procedures;
- transmit on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for the medicinal products for human use;
- coordinate the monitoring of medicinal products for human use and of veterinary medicinal products which have been authorised in the Union and providing advice on the measures necessary to ensure the safe and effective use of those products;
- ensure the collation and dissemination of information on suspected adverse reactions to medicinal products for human use and to veterinary medicinal products authorised in the Union by means of databases that are permanently accessible to all Member States;
- assist Member States with the rapid communication of information on pharmacovigilance concerns;
- distribute appropriate information on pharmacovigilance concerns relating to medicinal products for human use to the general public, in particular by setting up and maintaining a European medicines web-portal;
- coordinate the monitoring of compliance with the standards of good manufacturing practice;
- advise undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medecines.

Considering the seriousness of the threat from antimicrobial resistance, it is appropriate that the Agency continue to contribute to periodic

reporting on antimicrobial resistance at least every three years.

The Executive Director shall be appointed by the Management Board, on a proposal from the Commission, for a period of five years on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the Official Journal of the European Union and, as appropriate, by other means. Before appointment, the candidate nominated by the Management Board shall be immediately invited to make a statement to the European Parliament and to answer any questions put by its Members.

Penalties: the Commission may impose financial penalties for non-compliance with the obligations set out in Annex II in the context of marketing authorisations. It may also impose the financial penalties on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder.

Medicinal products for human and veterinary use

PURPOSE: to amend Regulation (EC) No 726/2004 establishing the European Medicines Agency and the centralised authorization and monitoring procedure for medicinal products, in order to avoid any overlap with the procedures laid down in the new Regulation on veterinary medicinal products.

LEGISLATIVE ACT: Regulation (EU) 2019/5 of the European Parliament and of the Council amending 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, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.

CONTENT: this Regulation amends Regulation (EC) No 726/2004 by removing from Regulation (EC) No 726/2004 the provisions on the granting and maintenance of authorisations for the placing on the market of veterinary medicinal products as these procedures now fall under the new Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products.

The amending Regulation clarifies the following points:

Marketing authorisation

For certain categories of medicinal products for human use intended to treat, prevent and diagnose seriously debilitating or life-threatening diseases, the amending Regulation provides for the possibility of issuing marketing authorisations before comprehensive clinical data is available, to meet unmet medical needs of patients and in the interest of public health. These authorisations will only be issued if they comply with specific obligations, in particular to complete the studies in progress or to conduct new studies in order to confirm that the benefit / risk ratio is favourable.

Variations

Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to the terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved.

The transfer of marketing authorisation to a new holder will not be considered as a variation. It will be subject to prior approval by the Commission after submission of a transfer request to the European Medicines Agency.

European Medicines Agency

The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products for human use or veterinary medicinal products.

The new rules provide that the Agency will:

- provide advice for the regulatory acceptance of innovative development methods in the context of research and development of medicinal products for human use and veterinary medicinal products;

- contribute to the development of joint reporting with the European Food Safety Authority and the European Centre for Disease Prevention and Control on the sale and use of antimicrobials in the fields of human and veterinary medicine, and on antimicrobial resistance in the Union, based on contributions received from Member States. Such joint reporting will be carried out at least every three years.

The Executive Director will be appointed by the Management Board, on a proposal from the Commission, for a period of five years (renewable once), on the basis of a list of candidates proposed by the Commission following publication in the Official Journal of the European Union. Before being appointed, the candidate selected by the Management Board will be invited to make a statement to the European Parliament and to answer questions put by Members.

Fees

The Regulation lays down certain principles applicable to fees payable to the Agency.

By 2019 at the latest, the Commission will review the regulatory framework governing the fees collected by the Agency in the field of medicinal products for human use and veterinary medicinal products. The Commission will present, as appropriate, legislative proposals to update this framework. When reviewing the regulatory framework, the Commission will pay attention to any risks arising from the fluctuations in the fee revenue of the Agency.

Lastly, the Directive aligns the powers conferred on the Commission by Regulation (EC) No 726/2004 with Articles 290 and 291 of the Treaty on the Functioning of the European Union (delegated and implementing powers).

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2019 and from 28.1.2022 depending on the provisions.