Basic information

2014/0257(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Veterinary medicinal products Repealing Directive 2001/82/EC 1999/0180(COD) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20 Public health 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Climate and Food Safety	GROSSETÊTE Françoise (PPE)	13/11/2014
	Shadow rapporteur TNSESCU Claudiu Ciprian (S&D) PIECHA Bolesaw G. (ECR) FEDERLEY Fredrick (ALDE) KYLLÖNEN Merja (GUE/NGL) HÄUSLING Martin (Verts/ALE) PEDICINI Piernicola (EFDD)	

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	MÜLLER Ulrike (ALDE)	07/11/2014

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	3547	2017-06-12
Agriculture and Fisheries	3437	2015-12-08
Education, Youth, Culture and Sport	3653	2018-11-26

European Commission	**Commission DG** / **Commissioner** Health and Food Safety / ANDRIUKAITIS Vytenis Povilas
European Economic and Social Committee	
European Committee of the Regions	

Key events

Date	Event	Reference	Summary
10/09/2014	Legislative proposal published	COM(2014)0558	Summary
20/10/2014	Committee referral announced in Parliament, 1st reading		
08/12/2015	Debate in Council		
17/02/2016	Vote in committee, 1st reading		
29/02/2016	Committee report tabled for plenary, 1st reading	A8-0046/2016	Summary
09/03/2016	Debate in Parliament	CRE link	
10/03/2016	Decision by Parliament, 1st reading	T8-0087/2016	Summary
10/03/2016	Results of vote in Parliament		
10/03/2016	Matter referred back to the committee responsible		
12/06/2017	Debate in Council		
20/06/2018		PE623.768	
20/06/2018		PE623.781	
24/10/2018	Debate in Parliament	CRE link	
25/10/2018	Decision by Parliament, 1st reading	T8-0421/2018	Summary
25/10/2018	Results of vote in Parliament		
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	2014/0257(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 2001/82/EC 1999/0180(COD)
Legal basis	Rules of Procedure EP 61 Treaty on the Functioning of the EU TFEU 114 Treaty on the Functioning of the EU 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/8/01652

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE551.951	14/04/2015	
Amendments tabled in committee		PE551.949	17/06/2015	
Amendments tabled in committee		PE560.753	17/06/2015	
Amendments tabled in committee		PE560.760	17/06/2015	
Committee opinion	AGRI	PE552.056	23/07/2015	
Committee report tabled for plenary, 1st reading/single reading		A8-0046/2016	29/02/2016	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T8-0087/2016	10/03/2016	Summary
Committee letter confirming interinstitutional agreement		PE623.781	13/06/2018	
Text agreed during interinstitutional negotiations		PE623.768	04/07/2018	
Text adopted by Parliament, 1st reading/single reading		T8-0421/2018	25/10/2018	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00045/2018/LEX	12/12/2018	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2014)0558	10/09/2014	Summary
Document attached to the procedure	SWD(2014)0273	10/09/2014	
Document attached to the procedure	SWD(2014)0274	10/09/2014	
Commission response to text adopted in plenary	SP(2018)755	21/11/2018	
Follow-up document	COM(2023)0009	13/01/2023	
Follow-up document	COM(2023)0295	07/06/2023	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2014)0558	26/11/2014	

Contribution	IT_SENATE	COM(2014)0558	03/12/2014	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
ESC	Economic and Social Committee: opinion, report	CES5960/2014	21/01/2015	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2019/0006
OJ L 004 07.01.2019, p. 0043 Summary

Delegated acts

Reference	Subject
2022/2526(DEA)	Examination of delegated act
2021/2718(DEA)	Examination of delegated act
2021/2532(DEA)	Examination of delegated act
2021/2533(DEA)	Examination of delegated act
2021/2592(DEA)	Examination of delegated act
2023/2581(DEA)	Examination of delegated act
2022/2971(DEA)	Examination of delegated act

Veterinary medicinal products

2014/0257(COD) - 25/10/2018 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 583 votes to 16, with 20 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Purpose: the Regulation shall establish rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products. It shall set **high standards of quality, safety and efficacy for veterinary medicinal products** in order to meet common concerns as regards the protection of public and animal health and of the environment. At the same time, it shall harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.

It shall not apply to veterinary medicinal products which have not undergone an industrial process such as, for example, non-processed blood.

Marketing authorisations: a veterinary medicinal product may only be placed on the market when a marketing authorisation for that product has been granted by a competent authority or by the Commission. Authorisations may only be granted to applicants established in the Union. Decisions to grant, **refuse, suspend, revoke or amend** a marketing authorisation shall be made public.

Exemptions may be granted for veterinary medicinal products for animals that are exclusively pets, provided that these medicinal products are not subject to a veterinary prescription.

Decisions to grant marketing authorisations: a marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period. By way of derogation, a marketing authorisation for a limited market shall be valid for five years.

Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission, as applicable, may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive given the potential development of antimicrobial resistance.

A marketing authorisation shall be refused if: (i) the applicant has not sufficiently demonstrated efficacy on the target species; (ii) the risks to public or animal health or the environment are not sufficiently addressed; (iii) the medicinal product is an antimicrobial veterinary medicinal product presented for use as a **performance promoter to accelerate the growth or increase the yield of treated animals**; (iv) the active substance contained in the medicinal product meets the criteria to be considered persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.

Responsibilities of marketing authorisation holders: the marketing authorisation holder shall be responsible for the placing on the market of his veterinary medicinal product. The designation of a representative shall note relieve the marketing authorisation holder of legal liability. In particular, the authorisation holder shall:

- ensure, within the limits of its responsibilities, an appropriate and continuous supply of its veterinary medicinal products;
- ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with current scientific knowledge;
- not place generic veterinary medicinal products and hybrid veterinary medicinal products on the Union market until the period of the protection of technical documentation for the reference veterinary medicinal product has elapsed;
- record in the product database the dates when its authorised veterinary medicinal products are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned;
- record in the product database the annual volume of sales for each of its veterinary medicinal products.

Prudent use of antibiotics: given that resistance to antimicrobial drugs for human and veterinary use is a growing health problem in the EU and worldwide, the amended text emphasised the need to **limit the veterinary use of critically important antimicrobial agents** to the prevention or treatment of life-threatening human infections and to encourage and facilitate the development of new antimicrobials.

According to the amended text:

- antimicrobial drugs shall only be used for **prophylactic purposes** (as a preventive measure) in **well-defined cases** of treatment of an animal or a limited number of animals, if the risk of infection is very high or if the consequences of such infection can have serious consequences. Antibiotic drugs shall only be used for prophylactic purposes in **exceptional cases** and only for a specific animal;
- antimicrobial drugs should only be used for **metaphylaxis** (e. g. to treat a group of animals, one of which shows signs of infection) if there is a **high risk of spreading** an infection or infectious disease in a group of animals and no other solution exists.

Veterinarians shall always issue a veterinary prescription when supplying a veterinary medicinal product subject to a veterinary prescription only and not administering it themselves. Whenever the veterinarians administer such medicinal products themselves it shall be left up to national provisions to specify whether a veterinary prescription needs to be issued. However, veterinarians shall always keep records of the medicinal products that they have administered.

The amended text provides that **third country** operators will have to comply with certain basic conditions relating to antimicrobial resistance for animals and products of animal origin exported to the Union. It also provides incentives to encourage **research and innovation**, in particular on antimicrobials.

Veterinary medicinal products

2014/0257(COD) - 11/12/2018 - Final act

PURPOSE: to adopt new rules on veterinary medicinal products with a view to ensuring a high level of protection of human and animal health and the environment and the proper functioning of the internal market.

LEGISLATIVE ACT: Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC.

CONTENT: the Regulation lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. It sets high standards of quality, safety and efficacy of veterinary drugs. At the same time, it harmonises the rules on the authorisation of veterinary medicinal products and their placing on the Union market.

Marketing authorisations

The new rules clarify and simplify the procedures for granting a marketing authorization for new medicines, which reduces the administrative burden for businesses, especially small businesses. Member States will have to take the necessary measures to advise SMEs on compliance with the requirements of the Regulation.

A veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a marketing authorisation for that product. A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. It shall be valid for an unlimited period of time. Decisions to grant, refuse, suspend, revoke or amend by way of a variation a marketing authorisation shall be made public.

A marketing authorisation will be refused if, in particular:

- the benefit-risk balance of the veterinary medicinal product is negative;

- the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;

- the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;

- the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health

Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission, as applicable, may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive given the potential development of antimicrobial resistance.

Improving the operation of the pharmacovigilance system

Holders of marketing authorisations will be responsible for continuously carrying out pharmacovigilance in order to ensure the continuous evaluation of the benefit-risk balance of the veterinary medicinal products they place on the market. They will, in particular:

- collect reports on suspected adverse events relating to their veterinary medicinal products;

- ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with current scientific knowledge, and

- record in the product database the dates when its authorised veterinary medicinal products are placed on the market, and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned.

Member States competent authorities will have the power to carry out inspections, including unannounced inspections, at all stages of the production, distribution and use of veterinary medicinal products. To ensure a harmonised approach to controls throughout the Union, the Commission will be able to carry out audits in the Member States to verify the functioning of national control systems.

Prudent use of antimicrobials

The new rules provide that certain critical antimicrobials are reserved for the treatment of certain infections in humans so that their effectiveness is preserved.

Furthermore, the Regulation provides a better framework for the use of antimicrobial agents to prevent their prophylactic (as a preventive measure) and metaphylactic use (for example to treat a group of animals, one of which presents signs of infection):

- antimicrobial medicinal products should not be used for prophylaxis other than in well-defined cases for the administration to an individual animal or restricted number of animals when the risk for infection is very high or its consequences are likely to be severe. Antibiotic medicinal products should not be used for prophylaxis other than in exceptional cases only for the administration to an individual animal;

- antimicrobial medicinal products should be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in a group of animals is high and where no appropriate alternatives are available.

A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian. It shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.

The Regulation also improves the protection of European consumers against the risk that antimicrobial resistance will spread through imports of animals and animal products.

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2022.

Veterinary medicinal products

2014/0257(COD) - 10/03/2016 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** to the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

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:

Aim: this Regulation aims at ensuring a high level of protection of both animal and human health while securing the protection of the environment. Therefore, the **precautionary principle** should be applied.

Member States may impose stricter conditions, justified on grounds of **public health, animal health and environmental protection**, for the use and retail of veterinary medicinal products on their territory, provided that these conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market

Antibacterial resistance: in order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, Members considered it necessary to reserve those antimicrobials **for humans only**. The Commission shall, by means of **implementing acts** and taking into consideration the scientific advice of the Agency as well as the work already carried out by the WHO, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Therefore, the Union should be active in advocating the creation of an **international strategy** to combat antimicrobial resistance, in line with the recent Global Action Plan adopted by the WHO.

Use of prophylactic and metaphylactic medicines: Members considered that the routine prophylactic (preventive) and metaphylactic (mass medication of a group of animals to eliminate or minimize an expected outbreak of disease) use of antimicrobials on groups of food-producing animals should be brought to an end. Disease should be prevented not by routine recourse to antimicrobials but by good hygiene, husbandry and housing and sound management practices.

Routine prophylactic use of antimicrobials is therefore prohibited. Prophylactic use of antimicrobial veterinary medicines will only be permitted on **single animals** and when fully justified by a veterinarian in exceptional indications, of which a list shall be drafted by the Agency.

Metaphylactic use of antimicrobial veterinary medicines will be **restricted to use in clinically-ill animals** and to those single animals that are identified as being at a high risk of contamination, to prevent further spread of the disease in the group.

According to the amended text, antimicrobial veterinary medicines **shall not under any circumstances serve to improve performance** or compensate for poor animal husbandry.

Research and innovation: to encourage research into new antimicrobials, Parliament advocated the following incentives:

- longer periods of protection for technical documentation on new medicines;
- commercial protection of innovative active substances, and
- protection for significant investments in data generated to improve an existing antimicrobial product or to keep it on the market.

A new article on the period of protection of new data packages related to existing veterinary medicinal products stipulated that any **new studies and trials**, submitted by the applicant for a marketing authorisation to the competent authorities for an existing veterinary medicinal product no longer covered by any protection period shall benefit from a **stand-alone period of protection of four years** under certain conditions.

Animals under the care of veterinary professionals: Parliament narrowed the definition of persons entitled to retail veterinary medicines and states that persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their immediate care, subject to an appropriate veterinary diagnosis and examination of the animals concerned, and only in the amount required for the treatment concerned. In the case of **food-producing animals**, the continuation of the treatment with antimicrobial products shall be decided based on a renewed clinical examination by a veterinarian

On-line sales: **antimicrobials, psychotropic and biological or immunological veterinary medicinal products may not be offered on the internet** . Other products may be sold online under strict criteria e.g that the veterinary medicinal products and the prescriptions comply with the law of the destination Member State.

The Commission shall adopt guidelines supporting the Member States in the development of a **harmonised system of digital prescription** across the Union, including measures for controlling cross-border veterinary prescriptions.

Environmental protection: no later than six months before the date of application of the Regulation, the Commission must present a report on a feasibility study of a substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.

Veterinary medicinal products

2014/0257(COD) - 29/02/2016 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Françoise GROSSETÊTE (EPP, FR) on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

The committee recommended that Parliament make the following amendments to the Commission proposal:

Antibacterial resistance for humans only: the Committee agreed with the Commission that in order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, those antimicrobials should be reserved for humans only. By means of implementing acts and taking into consideration the scientific advice of the Agency as well as the work already carried out by the WHO, the Commission will designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Prophylactic use of medicines: Members considered that the routine prophylactic and metaphylactic use of antimicrobials on groups of food-producing animals should be brought to an end. Disease should be prevented not by routine recourse to antimicrobials but by good hygiene, husbandry and housing and sound management practices. **Routine prophylactic use of antimicrobials is therefore prohibited.** Prophylactic use of antimicrobial veterinary medicines will **only be permitted on single animals** and when fully justified by a veterinarian in exceptional indications, of which a list shall be drafted by the Agency.

Metaphylactic use of antimicrobial veterinary medicines will be restricted to use in clinically-ill animals and to those single animals that are identified as being at a high risk of contamination, to prevent further spread of the disease in the group.

Innovation: to encourage research into new antimicrobials, Members advocate incentives, including:

- longer periods of protection for technical documentation on new medicines;
- commercial protection of innovative active substances, and
- protection for significant investments in data generated to improve an existing antimicrobial product or to keep it on the market.

A new article on data protection for redevelopment of veterinary medicinal products states that where the data protection period has elapsed, any applicant may apply for a data protection period for additional innovations to existing veterinary medicinal products, which shall amount to **two years for an additional species and one year for an additional indication**, additional pharmaceutical form or new withdrawal period.

Any **new studies and trials**, submitted by the applicant for a marketing authorisation for an existing antimicrobial veterinary medicinal product no longer covered by any protection period shall benefit from a stand-alone period of protection of four years, provided that they fulfil certain conditions.

Animals under the care of veterinary professionals: the committee narrowed the definition of persons entitled to retail veterinary medicines and states that persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their immediate care, subject to an appropriate veterinary diagnosis and examination of the animals concerned, and only in the amount required for the treatment concerned. In the case of **food-producing animals**, the continuation of the treatment with antimicrobial products shall be decided based on a renewed clinical examination by a veterinarian.

On-line sales: Members tightened the rules on sales online. **Antimicrobials, psychotropic and biological or immunological veterinary medicinal products may not be offered on the internet**. Other products may be sold online under strict criteria e.g that the veterinary medicinal products and the prescriptions comply with the law of the destination Member State.

Environmental protection: no later than six months before the date of application of the Regulation, the Commission must present a report on a feasibility study of a substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.

Veterinary medicinal products

2014/0257(COD) - 10/09/2014 - Legislative proposal

PURPOSE: to ensure a high level of public health protection, high standards of quality and safety of veterinary medicinal products and the optimal functioning of the internal market.

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: in 2001, all the rules on production, marketing, distribution and use were consolidated in a veterinary medicines code (Directive 2001 /82/EC); this was followed by Regulation (EC) No 726/2004.

The current EU legislation on veterinary medicinal products provides the legal environment on authorisation, production, marketing, distribution and use of veterinary medicinal products. It brought some harmonisation to the procedures and rules required to place veterinary medicinal products on the EU market.

However, the Commission considers that there is evidence that the existing provisions do not deliver a functioning internal market:

- **diverging or incomplete transposition** of the rules and the existence of numerous national requirements imply that companies are confronted with different rules and interpretation in countries and have also led to different levels of public and animal health protection;
- that **needs of the veterinary sector differ substantially from those of the human sector in relation to medicines:** in the veterinary sector there are **many different animal species**, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another;
- the **price-setting mechanisms** in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use;
- the size of **the animal pharmaceutical industry** is only a small fraction of the size of the pharmaceutical industry for human medicines.

The Commission considers that it is critically important to **have a single market for veterinary medicinal products**. The current confined and fragmented markets do not allow the pharmaceutical sector to have a positive return on investments for developing new products for certain animal species.

The ambition to improve the availability of medicines in the Union and the functioning of the internal market and market competition can only be carried out at EU level.

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 Commission's Impact Assessment Board (IAB) released its final opinion in September 2013.

CONTENT: the **revision of Directive 2001/82/EC** and other legislation on veterinary medicinal products seek to put in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector.

Specific objectives aim to:

- expand the market beyond the top four animal species,
- simplify procedures for obtaining a marketing authorisation in multiple national markets,
- review data requirements in marketing authorisation procedures,
- simplify post authorisation requirements,
- review incentives for breakthrough medicines.

The proposal also tackles the issue of **antimicrobial resistance** and introduces provisions to minimise risks to public health arising from the use of antimicrobials in veterinary medicine.

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**.

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.