Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2023/0132(COD)	Awaiting Council's 1st reading position
Medicinal products for human use Repealing Directive 2001/83 1999/0134(COD) Repealing Directive 2009/35 2008/0001(COD) Subject 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry Legislative priorities Joint Declaration 2023-24		

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		15/05/2023
	WEISS Pernille	
	Shadow rapporteur	
	BEŇOVÁ Monika	
	AMALRIC Catherine	
	AUKEN Margrete	
	TARDINO Annalisa	
	KOPCIŃSKA Joanna	
	KONEČNÁ Kateřina	

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy		05/10/2023
	VIRKKUNEN Henna	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
JURI Legal Affairs (Associated committee)	Chair on behalf of committee	14/12/2023
	VÁZQUEZ LÁZARA Adrián	

Council of the European Union European Commission	Commission DG	Commissioner
	Health and Food Safety	KYRIAKIDES Stella
European Economic and Social Committee European Committee of the Regions		

Key events

26/04/2023	Legislative proposal published	COM(2023)0192	Summary
14/09/2023	Committee referral announced in Parliament, 1st reading		
14/09/2023	Referral to associated committees announced in Parliament		
19/03/2024	Vote in committee, 1st reading		
21/03/2024	Committee report tabled for plenary, 1st reading	A9-0140/2024	
10/04/2024	Debate in Parliament		
10/04/2024	Decision by Parliament, 1st reading	T9-0220/2024	Summary

Technical information

Procedure reference	2023/0132(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealing Directive 2001/83 1999/0134(COD) Repealing Directive 2009/35 2008/0001(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4; Rules of Procedure EP 57
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	Awaiting Council's 1st reading position
Committee dossier	ENVI/9/11861

Documentation gateway

Legislative proposal		COM(2023)0192	26/04/2023	EC	Summary
Document attached to the procedure		SEC(2023)0390	26/04/2023	EC	
Document attached to the procedure		SWD(2023)0191	26/04/2023	EC	
Document attached to the procedure		SWD(2023)0192	26/04/2023	EC	

Document attached to the procedure		SWD(2023)0193	26/04/2023	EC	
Committee draft report		PE753.470	03/10/2023	EP	
Amendments tabled in committee		PE754.916	21/11/2023	EP	
Amendments tabled in committee		PE754.917	21/11/2023	EP	
Amendments tabled in committee		PE756.260	21/11/2023	EP	
Amendments tabled in committee		PE756.261	21/11/2023	EP	
Specific opinion	JURI	PE758.884	13/02/2024	EP	
Committee opinion	ITRE	PE754.773	22/02/2024	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0140/2024	21/03/2024	EP	
Text adopted by Parliament, 1st reading/single reading		T9-0220/2024	10/04/2024	EP	Summary

Additional information

Research document	Briefing	03/04/2024

Medicinal products for human use

PURPOSE: to review pharmaceutical legislation with a view to establishing rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market.

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

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: EU pharmaceutical legislation has enabled the authorisation of safe, efficacious and high-quality medicinal products. However, patient access to medicinal products across the EU and security of supply are growing concerns. There is also a growing problem of shortages of medicinal products for many EU/EEA countries. Consequences of such shortages include decreased quality of treatment received by patients and increased burden on health systems and on healthcare professionals, who need to identify and provide alternative treatments. While the pharmaceutical legislation creates regulatory incentives for innovation and regulatory tools to support timely authorisation of innovative and promising therapies, these medicinal products do not always reach the patient, and patients in the EU have differing levels of access.

Moreover, innovation is not always focused on unmet medical needs, and there are market failures, especially in the development of priority antimicrobials that can help address antimicrobial resistance. Scientific and technological developments and digitalisation are not fully exploited, while the environmental impact of medicinal products needs attention.

The Pharmaceutical Strategy for Europe marks a turning point with the addition of further key objectives and by creating a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.

The proposed revision of the pharmaceuticals legislation consists of this proposal for a new directive and a proposal for a new regulation, which will also cover orphan and paediatric medicinal products.

CONTENT: the overall pharmaceutical framework needs to be simplified, adapted to scientific and technological changes, and contribute to reducing the environmental impact of medicinal products. This proposed reform is comprehensive but targeted and focuses on provisions relevant to achieving its specific objectives; therefore it covers all provisions apart from those concerning advertising, falsified medicinal products, and homeopathic and traditional herbal medicinal products.

The proposed Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use. It will apply to medicinal products for human use intended to be placed on the market. It will also apply to starting materials, active substances, excipients and intermediate products.

Objectives

The objectives of the proposal are the following:

- guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients;

- harmonise the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States;

- make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines;

- enhance security of supply and ensure medicines are always available to patients, regardless of where they live in the EU;

- offer an attractive innovation-and competitiveness friendly environment for research, development, and production of medicines in Europe;

- make medicines more environmentally sustainable.

The proposed Directive includes the following main areas of revision:

- promoting innovation and access to affordable medicinal products - creating a balanced pharmaceutical ecosystem;

- introduction of variable incentives related to regulatory data protection and rewarding of innovation in areas of unmet medical needs: companies marketing innovative medicines will benefit from a minimum regulatory protection period of 8 years, including 6 years of data protection and 2 years of market protection. They will be eligible for additional periods of data protection if they launch the medicinal products in all Member States covered by the marketing authorisation (+2 years), if the medicinal product meets an unmet medical need (+6 months) or if comparative clinical trials are conducted (+6 months);

- measures that will facilitate faster market entry of generics and biosimilars, thereby increasing competition;

- increased transparency on the contribution of public funding to research & development costs;

- strengthening the requirements for environmental risk assessment (ERA) in the marketing authorisation of medicines;

- reducing the regulatory burden and providing a flexible regulatory framework to support innovation and competitiveness;

- specific provisions for new platform technologies;

- specific measures related to quality and manufacturing: a flexible, risk-based approach will enable the manufacture or testing of a wide range of medicinal products in close proximity to the patient.

Medicinal products for human use

The European Parliament adopted by 495 votes to 57, with 45 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

The position adopted by the European Parliament at first reading under the ordinary legislative procedure is as follows:

Subject matter and scope

The proposed Directive should apply to medicinal products for human use intended to be placed on the market in Member States. Where questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation, the Agency should consult other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status of the substance or a product concerned.

Advanced therapy medicinal products prepared under hospital exemption

Member States should ensure that advanced therapy medicinal products prepared under hospital exemption comply with the good pharmacy preparation practices that are adapted to hospital processes while still equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products. This should include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical data generated by the applicant.

Any relevant data from patient follow-up for a sufficient period of time after the administration of the advanced therapy medicinal product should be collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually.

The Agency should, in collaboration with the competent authorities of Member States and the Commission, set up and maintain via regular updates a repository of that data as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which should be updated regularly. The repository should be publicly available except for personal data and commercially confidential information.

Animal testing

The marketing authorisation applicant should not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied with regard to any animal study conducted for the purpose of supporting the application.

Antimicrobials

The marketing authorisation holder should ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit, the marketing authorisation holder should ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment. Member States should promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.

The Commission should therefore issue, after consulting the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria.

Environmental risk assessment and other environmental information

Members insisted that risk mitigation measures (relating to the prevention and limitation of emissions into the air, water and soil) should cover the entire lifecycle of medicinal products.

Medicinal products subject to medical prescription

A medicinal product should be subject to medical prescription where it: (i) is an antibiotic or any other antimicrobial for which there is an identified risk of antimicrobial resistance; or (ii) contains an active substance, adjuvants or any other ingredients or constituent parts which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment.

A prescription for antibiotic products should: (a) be limited to the amount required for the treatment or therapy concerned; (b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis; (c) in the event that a diagnostic test has not been performed, a justification should be required.

Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.

Application for pricing and reimbursement

In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request. The application for pricing and reimbursement for the medicinal product should be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date in the case of SMEs.

Product information and labelling

Member States should make the package leaflet available electronically and in paper format, except where the Member State decides to make only the electronic product information available. The package leaflet should be easily legible, clearly comprehensible by users, including especially the target patient groups, and indelible.

With a view to combating misinformation, in particular during health pact of online pharmaceutical advertising and promotions and adopt specific rules to regulate such advertising and promotional practices. emergencies such as the COVID-19 pandemic, Member States should ensure that healthcare professionals are not hampered in their ability to communicate clear, impartial and independent information, whether in their dialogue with a patient or in broader communications.

Members States should introduce appropriate disposal systems for antimicrobials in the community setting and inform the general public on the correct disposal methods for antimicrobial. The Commission should assess the exposure and impact of pharmaceutical advertising and promotions online and adopt specific rules to regulate such advertising and promotional practices.

Pharmacovigilance

Member States should record all suspected adverse reactions occurring on their territory and brought to their attention by healthcare professionals or patients. They should endeavour to inform directly interested parties who have reported a suspected adverse reaction about decisions taken concerning the safety of the medicinal product. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product should be available in the Eudravigilance database and shall be included in periodic safety update reports.

Transparency

WEISS Pernille	Rapporteur	ENVI	05/04/2024	Novo Nordisk A/S
WEISS Pernille	Rapporteur	ENVI	03/04/2024	Alliance Promotion Microbiote
WEISS Pernille	Rapporteur	ENVI	27/03/2024	Confindustria
WEISS Pernille	Rapporteur	ENVI	21/03/2024	Novo Nordisk Foundation
WEISS Pernille	Rapporteur	ENVI	21/03/2024	Confederation of Danish Industry
WEISS Pernille	Rapporteur	ENVI	11/03/2024	European Federation of Pharmaceutical Industries and Associations
WEISS Pernille	Rapporteur	ENVI	08/03/2024	Novo Nordisk A/S
WEISS Pernille	Rapporteur	ENVI	07/03/2024	European Confederation of Pharmaceutical Entrepreneurs
WEISS Pernille	Rapporteur	ENVI	07/03/2024	Bayer AG
WEISS Pernille	Rapporteur	ENVI	06/03/2024	Lægemiddelindustriforeningen
?TEFANEC Ivan	Member	04/04/2024	Národný in?titút pre hodnotu a technológie v zdravotníctve	
JARUBAS Adam	Member	15/03/2024	Medicines for Poland The Employers' Union	

			of Innovative Pharmaceutical Companies polityka insight
BERNHUBER Alexander	Member	15/03/2024	Wirtschaftskammer Österreich
KNOTEK Ond?ej	Member	08/03/2024	GSK
BERNHUBER Alexander	Member	07/03/2024	Takeda Pharmaceuticals International AG
MONTSERRAT Dolors	Member	06/03/2024	Bayer AG
RASMUSSEN Bergur Løkke	Member	06/03/2024	The Danish Association of the Pharmaceutical Industry
JARUBAS Adam	Member	05/03/2024	The Employers' Union of Innovative Pharmaceutical Companies
POULSEN Erik	Member	05/03/2024	The Danish Association of the Pharmaceutical Industry
MONTSERRAT Dolors	Member	04/03/2024	Teva Pharmaceuticals Europe BV