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	

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; Rules of Procedure EP 57; Treaty on the Functioning of the EU TFEU 168-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	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	

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.

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	
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	
WINZIG Angelika	Member	04/03/2024	SANOFI	