Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0131(COD)	Awaiting Council's 1st reading position

Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

Repealing Regulation 2000/141 1998/0240(COD)
Repealing Regulation 2004/726 2001/0252(COD)
Repealing Regulation 2006/1901 2004/0217(COD)
Amending Regulation 2007/1394 2005/0227(COD)
Amending Regulation 2014/536 2012/0192(COD)

Subject
4.20.01 Medicine, diseases
4.20.04 Pharmaceutical products and industry
4.60.08 Safety of products and services, product liability
8.40.08 Agencies and bodies of the EU

Legislative priorities
Joint Declaration 2023-24

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		11/05/2023
		S&D WÖLKEN Tiemo	
		Shadow rapporteur	
		epp SOKOL Tomislav	
		renew europe. RIES Frédérique	
		METZ Tilly	
		VISTISEN Anders	
		ECR SLABAKOV Andrey	
		KONEČNÁ Kateřina	
	Committee for opinion	Rapporteur for opinion	Appointed
	BUDG Budgets		23/05/2023
		ECR VAN OVERTVELDT Johan	
	CONT Budgetary Control	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy (Associated committee)		05/10/2023

		VIRKKUNEN Henna	
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	AGRI Agriculture and Rural Development		23/05/2023
		LINS Norbert	
	LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	
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)0193	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	A9-0141/2024	
10/04/2024	Debate in Parliament		
10/04/2024	Decision by Parliament, 1st reading	T9-0221/2024	Summary

Technical information

Procedure reference	2023/0131(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Regulation 2000/141 1998/0240(COD) Repealing Regulation 2004/726 2001/0252(COD) Repealing Regulation 2006/1901 2004/0217(COD) Amending Regulation 2007/1394 2005/0227(COD) Amending Regulation 2014/536 2012/0192(COD)
Legal basis	Rules of Procedure EP 57; 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 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/9/11874

Documentation gateway

Legislative proposal		COM(2023)0193	26/04/2023	EC	Summary
Document attached to the procedure		SWD(2023)0192	26/04/2023	EC	
Document attached to the procedure		SWD(2023)0193	26/04/2023	EC	
Document attached to the procedure		SWD(2023)0194	26/04/2023	EC	
Document attached to the procedure		N9-0082/2023 OJ C 000 14.11.2023, p. 0000	19/06/2023	EDPS	
Committee draft report		PE753.550	20/10/2023	EP	
Amendments tabled in committee		PE756.131	21/11/2023	EP	
Amendments tabled in committee		PE756.132	21/11/2023	EP	
Amendments tabled in committee		PE756.133	21/11/2023	EP	
Amendments tabled in committee		PE756.134	21/11/2023	EP	
Amendments tabled in committee		PE756.135	21/11/2023	EP	
Amendments tabled in committee		PE756.136	21/11/2023	EP	
Amendments tabled in committee		PE756.137	21/11/2023	EP	
Amendments tabled in committee		PE756.138	21/11/2023	EP	
Specific opinion	AGRI	PE757.314	17/01/2024	EP	
Committee opinion	ITRE	PE754.772	22/02/2024	EP	
Specific opinion	BUDG	PE759.054	23/02/2024	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0141/2024	21/03/2024	EP	
Text adopted by Parliament, 1st reading/single reading		T9-0221/2024	10/04/2024	EP	Summary

Additional information

Research document	Briefing	03/04/2024

Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

PURPOSE: to ensure the authorisation of high-quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union.

PROPOSED ACT: Regulation 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: the Union pharmaceutical framework has enabled the authorisation of safe, efficacious and high-quality medicines in the Union, contributing to a high level of public health and a smooth functioning of the internal market of these products.

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.

Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.

Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.

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

CONTENT: this proposal lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency (EMA).

This Regulation will not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.

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 regulation includes the following main areas of revision:

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

- modulation of the length of the market exclusivity for orphan medicinal products. For rare disease medicines, the standard duration of market exclusivity would be 9 years with the possibility of granting a one-year extension of market exclusivity, based on patient access in all Member States concerned;

- paediatric investigation plans for medicinal products for children, based on a medicinal products mechanism of action;

- measures related to antimicrobials and provisions on transferable data exclusivity vouchers. A voucher system will provide transferable data exclusivity vouchers under strict conditions to developers of new antimicrobials. Such a voucher will grant an additional year of regulatory data protection to the developer of the priority antimicrobial, which the developer can either use for any product in their own product portfolio or sell it to another marketing authorisation holder;

- strengthening the scientific and regulatory support of the European Medicines Agency, in particular for developers of medicines that address unmet medical needs;

- enhanced pre-authorisation scientific and regulatory support;

- temporary emergency marketing authorisation;

- improving security of supply of medicines;

- a framework for activities to be undertaken by Member States and the Agency to improve the EU's ability to respond in an effective and coordinated manner to support the management of medicines shortages at all times;

- EMA capacity to inspect sites located in non-EU countries;

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

- improved structure and governance of EMA and the regulatory network.

Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

The European Parliament adopted by 488 votes to 67, with 34 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No

536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

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

Subject matter and scope

The proposed regulation: (i) lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, (ii) establishes rules and procedures at Union and at Member State level relating to the monitoring and management of shortages and critical shortages and the security of supply of medicinal products and (iii) lays down the governance provisions of the European Medicines Agency.

Environmental risk assessment

The environmental risk assessment of medicinal products consisting of or containing genetically modified organisms should include the identification and characterisation of risks to the environment, animals and human health throughout the life-cycle of the medicinal product, including its production, and the risk reduction and mitigation strategies proposed to address the identified risks.

Combating antimicrobial resistance (AMR)

In order to support the development of antimicrobials and address existing market failures, Members wish to introduce market entry rewards and intermediate reward payment systems. Accordingly, they suggested developing a milestone payment reward scheme, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that delink volumes sold from payment received.

Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase.

Granting the right to a transferable data exclusivity voucher

Following a request by the applicant for a marketing authorisation, made before the marketing authorisation is granted, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a priority antimicrobial, under certain conditions based on a scientific assessment by the Agency. The voucher should give the right to its holder to a maximum of additional 12 months of data protection for one authorised medicinal product.

The Commission should adopt delegated acts by setting up the eligibility of pathogens for the protection periods referred to in the regulation in accordance with the WHO priority pathogens list or an equivalent established at Union level, with 12 months of data protection for an authorised product ranked critical, 9 months of data protection for those ranked high and 6 months of data protection for those ranked medium.

A voucher should only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. The voucher should not be used for a product which already benefited from the maximum regulatory data protection period.

By five years from the date of entry into force of this regulation, the Commission should submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards in this regulation.

Agencys scientific advice

The Agency should, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product. The Agency should ensure that at least one of the two rapporteurs for a marketing authorisation application has not taken part in any pre-submission activities concerning the medicinal product.

Orphan drugs

Orphan drugs (medicines developed to treat rare diseases) would benefit from up to 11 years of market exclusivity if they address a high unmet medical need. By 24 months from the date of entry into force of this regulation, the Commission should, following a consultation with the Member States, patient organisations and other relevant stakeholders, propose a needs-driven and goals-based Union Framework for Rare Diseases with a view to better framing and coordinating Union policies and programmes.

Transparency

To increase transparency of scientific assessments and all other activities, a user-friendly European medicines web-portal should be created and maintained by the Agency. The portal should provide information for all centrally authorised medicinal products, inter alia on safety, efficacy, environmental risk, patient populations, and where relevant information on antimicrobial resistance, shortages, and pending obligations for marketing authorisation holders. Sufficient budgetary resources should be allocated to the Agency to ensure its transparency obligations and commitments are appropriately implemented.

Medicine shortages

The marketing authorisation holder should notify and explain its decision to temporarily suspend the marketing of a medicinal product in that Member State as soon as possible and no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder.

The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. Information on such shortages should be made available on the European medicines web-portal provided for in this regulation.

When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to communicate the necessary information to patients, consumers and healthcare professionals, including on the estimated duration of the shortage and available alternatives, and manage those critical shortages.

Transparency

WÖLKEN Tiemo	Rapporteur	ENVI	08/04/2024	MEDEV
METZ Tilly	Shadow rapporteur	ENVI	11/03/2024	BEAM Alliance
RIES Frédérique	Shadow rapporteur	ENVI	07/03/2024	Acumen Public Affairs
RIES Frédérique	Shadow rapporteur	ENVI	07/03/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
WÖLKEN Tiemo	Rapporteur	ENVI	06/03/2024	Beglian PermRep
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	European Confederation of Pharmaceutical Entrepreneurs
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	Eurordis - Rare Disease Europe
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	European Patients' Forum (EPF)
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	GARDP Foundation
METZ Tilly	Shadow rapporteur	ENVI	23/02/2024	European Society of Cardiology
ECKE Matthias	Member	28/03/2024	European Federation of Pharmaceutical Industries and Associations GSK	
KNOTEK Ond?ej	Member	20/03/2024	BioMarin UK Limited	
GUALMINI Elisabetta	Member	19/03/2024	European Confederation of Pharmaceutical Entrepreneurs	
ZAMBELLI Stefania	Member	13/03/2024	Assosalute	
GLAVAK Sun?ana	Member	29/02/2024	Bayer AG	
	Member	27/02/2024	European Society of Cardiology	
LIESE Peter	Member	23/02/2024	European Federation of Pharmaceutical Industries and Associations	
CLUNE Deirdre	Member	21/02/2024	Bristol-Myers Squibb Company	
SIDL Günther	Member	21/02/2024	AOP Orphan Pharmaceuticals GmbH	
	Member	21/02/2024	La Roche - Hoffmann	