Basic information

2025/0102(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Awaiting Parliament's position in 1st reading
Critical Medicines Act Amending Regulation 2024/795 2023/0199(COD) **Subject** 4.20 Public health 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry 4.20.05 Health legislation and policy **Legislative priorities** Joint Declaration 2026	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
SANT Public Health	SOKOL Tomislav (EPP)	02/05/2025
	Shadow rapporteur WÖLKEN Tiemo (S&D) KNOTEK Ondřej (PfE) VERYGA Aurelijus (ECR) VASILE-VOICULESCU Vlad (Renew) METZ Tilly (Greens/EFA) MARTINS Catarina (The Left) ANDERSON Christine (ESN)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Climate and Food Safety	PICARO Michele (ECR)	18/06/2025
ITRE Industry, Research and Energy	SCHENK Oliver (EPP)	15/04/2025
IMCO Internal Market and Consumer Protection	WALSMANN Marion (EPP)	23/06/2025

Committee for budgetary assessment	Rapporteur for budgetary assessment	Appointed
BUDG Budgets	The committee decided not to give an opinion.	

Council of the European Union	
European Commission	

Commission DG	Commissioner
Health and Food Safety	VÁRHELYI Olivér

European Economic and Social Committee

Key events

Date	Event	Reference	Summary
11/03/2025	Legislative proposal published	COM(2025)0102	Summary
21/05/2025	Committee referral announced in Parliament, 1st reading		
15/12/2025	Vote in committee, 1st reading		
19/12/2025	Committee report tabled for plenary, 1st reading	A10-0272/2025	
19/01/2026	Debate in Parliament		
20/01/2026	Decision by Parliament, 1st reading	T10-0001/2026	Summary
20/01/2026	Results of vote in Parliament		
20/01/2026	Matter referred back to the committee responsible for interinstitutional negotiations		

Technical information

Procedure reference	2025/0102(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation 2024/795 2023/0199(COD)
Legal basis	Rules of Procedure EP 58 Treaty on the Functioning of the European Union TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Parliament's position in 1st reading
Committee dossier	SANT/10/02427

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE775.742	18/07/2025	
Amendments tabled in committee		PE778.025	26/09/2025	
Amendments tabled in committee		PE778.031	13/10/2025	
Amendments tabled in committee		PE778.032	13/10/2025	
Committee opinion	ENVI	PE775.606	06/11/2025	
Committee opinion	ITRE	PE774.586	11/11/2025	
Committee opinion	IMCO	PE776.854	11/11/2025	
Committee report tabled for plenary, 1st reading/single reading		A10-0272/2025	19/12/2025	
Text adopted by Parliament, partial vote at 1st reading /single reading		T10-0001/2026	20/01/2026	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2025)0102	11/03/2025	Summary
Document attached to the procedure	SWD(2025)0263	02/09/2025	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2025)0102	17/06/2025	
Contribution	IT_CHAMBER	COM(2025)0102	24/06/2025	
Contribution	CZ_SENATE	COM(2025)0102	24/06/2025	
Contribution	RO_SENATE	COM(2025)0102	25/06/2025	
Reasoned opinion	SE_PARLIAMENT	PE774.572	10/07/2025	
Contribution	IT_SENATE	COM(2025)0102	15/07/2025	
Reasoned opinion	FR_SENATE	PE775.747	24/07/2025	
Contribution	IT_SENATE	COM(2025)0102	28/07/2025	
Reasoned opinion	IT_SENATE	PE776.742	29/07/2025	
Contribution	DE_BUNDESRAT	COM(2025)0102	11/08/2025	

Contribution	FR_SENATE	COM(2025)0102	10/11/2025	
Contribution	RO_CHAMBER	COM(2025)0102	27/12/2025	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1074/2025	18/06/2025	
CofR	Committee of the Regions: opinion	CDR1935/2025	10/12/2025	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Critical Medicines Act

2025/0102(COD) - 11/03/2025 - Legislative proposal

PURPOSE: to establish a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States.

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 EU has a strong and competitive pharmaceutical sector, which is a global leader in the production of medicines and a major contributor to the EU economy and directly employs around 800 000 people. However, in recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients. Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can **reduce its risk of exposure to shortages** of medicinal products.

CONTENT: the Commission proposal consists of a proposal for a new regulation. It seeks to strengthen the **security of supply and the availability of critical medicinal products within the Union**, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to **improve the availability and accessibility of other medicinal products**, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

To achieve the objectives, the proposed Regulation sets out a framework to:

- **facilitate investments** in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;

- **lower the risk of supply disruptions** and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;

- leverage the aggregated demand of participating Member States through **collaborative procurement procedures**, and;

- support the **diversification of supply chains** also by facilitating the conclusion of strategic partnerships.

Key elements of the Critical Medicines Act include:

Strategic Projects

Strategic Projects will create, increase or **modernise EU manufacturing capacity** for critical medicines or their ingredients. These industrial projects may benefit from easier access to funding and fast-tracked administrative, regulatory and scientific support.

Financial incentives

It should be possible for Member States to prioritise financial support for strategic projects that address a supply chain vulnerability and requires due consideration to the outcome of vulnerability evaluations and the strategic orientations of the Critical Medicines Group. Strategic projects may be supported by EU funding under the current MFF, if strategic projects fulfil the conditions and requirements of the calls under the available programmes.

Procurement requirements

The proposal imposes the use of procurement requirements other than price in the context of public procurement procedures by contracting authorities in the Member States, unless justified by market analysis and considerations related to the financing of health services. The proposal also requires, in specific cases, when justified by a **vulnerability analysis**, that the contracting authorities apply procurement requirements that favour suppliers that manufacture a significant portion of these critical medicines in the EU. The compliance with Union's international commitments should be ensured.

Furthermore, Member States will be required to develop national programmes to ensure security of supply of critical medicines via procurement, and, possibly, pricing and reimbursement practices. When imposing contingency stocks on supply chain actors, Member States will ensure these requirements are proportionate and respect the principles of transparency and solidarity.

Collaborative procurements

It is proposed that the Commission should support **collaborative procurement** among different Member States at the request of Member States, to address availability and access disparities of critical medicines and other medicines of common interest throughout the EU.

Critical Medicines Coordination Group

A Critical Medicines Coordination Group is established, which is composed of the Commission and Member States' representatives. Its main task being to facilitate the application of the Regulation including by facilitating: (i) discussion on strategic orientation for financial support of Strategic Projects; (ii) exchanges and, where appropriate, cooperation on national procurement policies; (iii) discussion on a need for collaborative procurement initiatives; (iv) advice on the order of priority for the vulnerability evaluation of critical medicines.

International cooperation

The proposal requires the Commission to investigate the possibility of establishing strategic partnerships with a view to broadening the supply chain and reducing dependencies on single or limited numbers of suppliers.

Critical Medicines Act

2025/0102(COD) - 20/01/2026 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 503 votes to 57 and 108 abstentions **amendments** on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795.

The issue has been referred to the relevant committee for interinstitutional negotiations.

The main amendments adopted in plenary session concern the following points:

Objectives

Members clarified that the regulation aims to **strengthen the security of supply and the availability of critical medicinal products within the Union**, thereby reducing its dependency on third countries and thereby ensuring a high level of public health protection, maintaining patient safety and supporting the security of the Union. Strengthening manufacturing capacities and the resilience of supply chains, as well as competitiveness, strategic autonomy and innovation in the Union's pharmaceutical sector, is also an objective of this Regulation.

In order to achieve these objectives, the regulation should:

- **facilitate, support and incentivise investments in new manufacturing capacity** and strengthen existing manufacturing capacity for critical medicinal products and, where applicable, medicinal products of common interest, with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain, by making available any accelerated permit granting processes related to the strategic projects;

- **prevent shortages and strengthen availability of medicinal products** by facilitating the adoption of common standards governing contingency stocks and national stockpiles of critical medicinal products and medicinal products of common interest, and by enhancing transparency and coordination among Member States in this regard;

- **facilitate investments in critical distribution infrastructure capacity** for critical medicinal products ensuring security of supply, availability and accessibility in the Union;

- **strengthen the resilience of supply chains** and maintain a continuous and demand-oriented supply of medicinal products, active substances, API starting materials, and key inputs in the Union, even during disruptions or external shocks.

The security of supply, availability and affordability of critical medicinal products and, where applicable, medicinal products of common interest, for patients should be considered a strategic objective of the Union.

Strategic projects

Members support the creation of industrial 'strategic projects' within the EU to create, modernise, and improve production capacity. Companies benefiting from public financial support must meet clear obligations. If a project promoter has received financial support for a strategic project from Union funding, it should prioritise supply to the Union market and should ensure that the critical medicinal product or, where applicable, medicinal product of common interest, remains available in the Member States where it is being marketed.

Within three months of the entry into force of this regulation, each Member State must designate an authority responsible for assessing and verifying whether a project qualifies as a strategic project. The Commission should provide a simple, accessible, and user-friendly webpage serving as the central hub for project promoters. It should act as a coordinator for cross-border strategic projects and should ensure effective cooperation between the designated authorities of the Member States concerned, to avoid duplication of efforts in bordering Member States.

Where the development of Strategic Projects or their related infrastructure has potential cross-border implications, the Member States concerned should **coordinate their planning and assessment procedures**, with the support of the Commission, in order to avoid duplication of efforts.

EU financial support

Subject to a Council regulation laying down the multiannual financial framework for the years 2028 to 2034 (MFF 2028–2034), strategic projects may be supported by Union funding, including any relevant Union instrument financed within the limits of the ceilings established in the MFF 2028–2034, provided that such support is in line with the objectives set out in the regulations establishing any such relevant instrument.

A **critical medicines security fund** should be established within the framework of MFF 2028–2034, in coordination with other relevant Union instruments, to support the achievement of the objectives of this Regulation.

Where there is a substantiated risk that export of a critical medicinal product would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an **export authorisation** before transferring such products outside the Union.

Procurement by the Commission on behalf of or in the name of Member States

Members want to lower the number of countries that may engage in joint procurement procedures to at least **five** (compared to nine in the Commission' s initial proposal).

Improved coordination of national stockpiles

To better anticipate and manage shortages, Members called for the creation of a **European coordination mechanism** for national stockpiles and contingency stocks of critical medicines. They also want the Commission to have the power to decide on, as a last resort, the **redistribution** of medicines from one national stockpile to one or more other countries, in instances where a shortage or a supply disruption has been identified.

In order to ensure the timely and effective availability of critical medicinal products with identified vulnerabilities in their supply chains, a **Union Stockpile** may be established as a last-resort mechanism to be activated in situations where the Union coordination mechanism for critical medicinal products indicates the existence of a recurrent or persistent shortage in national stockpiles and contingency stocks.