Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2020/0321(COD)	Awaiting Parliament's position in 1st reading
European Medicines Agency Subject 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry 4.20.05 Health legislation and policy 8.40.08 Agencies and bodies of the EU Legislative priorities Joint Declaration 2021		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		25/11/2020
		S&D GONZÁLEZ CASARES Nicolás	
		Shadow rapporteur	
		epp BUŞOI Cristian-Silviu	
		renew europe. RIES Frédérique	
		METZ Tilly	
		MÉLIN Joëlle	
		ECR 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		03/12/2020
		MÉLIN Joëlle	
	IMCO Internal Market and Consumer Protection	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

14/12/2020	Committee referral announced in Parliament, 1st reading		
22/06/2021	Vote in committee, 1st reading		
25/06/2021	Committee report tabled for plenary, 1st reading	A9-0216/2021	
07/07/2021	Debate in Parliament		
08/07/2021	Decision by Parliament, 1st reading	T9-0351/2021	Summary
08/07/2021	Matter referred back to the committee responsible		

Technical information

Procedure reference	2020/0321(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1; 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 Parliament's position in 1st reading
Committee dossier	ENVI/9/04630

Documentation gateway

Legislative proposal		COM(2020)0725	11/11/2020	EC	Summary
Reasoned opinion	FR_SENATE	PE691.143	30/03/2021	NP	
Committee draft report		PE680.818	31/03/2021	EP	
Amendments tabled in committee		PE691.443	28/04/2021	EP	
Committee opinion	ITRE	PE689.565	27/05/2021	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0216/2021	25/06/2021	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		T9-0351/2021	08/07/2021	EP	Summary

European Medicines Agency

PURPOSE: to reinforce the role of the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices.

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 unprecedented experience of the COVID-19 pandemic has demonstrated that the EUs ability to coordinate work to ensure the availability of medicinal products and medical devices and facilitate their development is currently limited.

The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the EUs ability to rapidly and effectively react to such challenges during public health crises.

The proposal is part of a package of closely associated measures that aim to reinforce the crisis preparedness and response and enhance the role of the European Centre for Disease Prevention and Control (ECDC). Together, they form part of the EUs overall health response to COVID-19 as well as an improved crisis management framework.

CONTENT: the proposed Regulation should develop the core tasks already given to the EMA to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies.

It would complement the measures directed at improving the overall EU crisis management framework by addressing the specific issues related to medicinal product and medical device sectors and the tasks of the Agency. It would thus introduce new rules for the Agency with the objective to provide mechanisms within the Agency to:

- monitor and mitigate the risk of shortages of critical medicines and medical devices;
- provide scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises;
- coordinate studies to monitor the effectiveness and safety of vaccines;
- coordinate clinical trials.

Budgetary implications

The financial impact of this proposal on the EU budget should be part of the next Multiannual Financial Framework 2021-2027. The budgetary implications should relate mainly to administrative, scientific and IT support.

European Medicines Agency

The European Parliament adopted by 587 votes to 28, with 81 abstentions, amendments to the proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

The matter was referred back to the committee responsible for inter-institutional negotiations.

The main amendments adopted in plenary are the following:

Learning from the COVID-19 pandemic

Parliament stressed that the unprecedented experience of the COVID-19 pandemic has highlighted the difficulties of the EU and Member States in dealing with such a public health emergency. It also demonstrated the need to strengthen the role of the EU to increase its effectiveness in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health from an early stage.

Framework and means of the European Medicines Agency

Members considered that the proposed regulation should provide a framework and the necessary means within the Agency for:

- preparing for, preventing, coordinating and managing the impact of major events and public health emergencies on medicinal products for human use and medical devices at EU level;

- the prevention, monitoring and reporting of shortages of medicinal products for human use and critical medical devices;

- the creation of an interoperable and digital database at EU level to monitor and report on shortages of medicines.

In addition to a common definition of shortage, Members introduced a definition of supply and demand for a medicinal product or medical device.

Executive Steering Group on Shortages and Safety of Medicinal Products

Members suggested that the Executive Steering Group on Shortages and Safety of Medicinal Products should meet at regular intervals either in person or remotely, and whenever the situation requires, in preparation for or during a public health emergency or following a request for assistance.

The Medicines Steering Group should guarantee an open communication and close cooperation with marketing authorisation holders, manufacturers, relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals, patients and consumers with a view to enabling early notification or identification of potential or actual shortages of medicinal products considered as critical during a major event or a public health emergency.

The Medicines Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.

Emergency task force

Members suggested that the task force should convene in preparation for and during public health emergencies, either in person or remotely. They proposed strengthening the links between the Medicines Steering Group and the Task Force, whose work should be used by the Steering group when developing and/or updating the list of critical medicines.

European medicines supply database

Parliament proposed that the Agency should set up and manage a European medicines supply database in collaboration with the Commission and the Member States, to:

- enable the monitoring of supply and demand of medicinal products at EU and Member State level;

- enable the monitoring and reporting of shortages of medicinal products at EU and Member State level;

- enable marketing authorisation holders and wholesalers to comply with information obligations;

- enable the Commission, the Agency and the national competent authorities to carry out their tasks under the Regulation on a well-informed basis and to enhance cooperation between them.

The database would allow the Agency and the national competent authorities to simultaneously access and share the information provided in the database.

Each Member State should develop an electronic platform with a view to establishing real-time monitoring of the supply of medicinal products, capable of determining the volume of supply of each medicinal product existing at any given moment, and detecting, predicting and preventing shortages of medicinal products.

Electronic platforms should provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors, community pharmacies and hospital pharmacies at national level. Those platforms should also allow marketing authorisation holders to report any medicinal products supply problems, including manufacturing problems.

Information obligations

The Agency should establish a publicly accessible webpage containing information on actual shortages of critical medicines.

For the duration of a public health emergency, sponsors of clinical trials conducted in the EU should publish the study protocol in the EU clinical trials register at the start of the trial and publish a summary of the results.

Where a medicinal product has been granted a marketing authorisation, the Agency should publish product information with details of the conditions of use as soon as the marketing authorisation is granted.