






Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> <p>2020/0321(COD)</p>	Preparatory phase in Parliament
<p>Reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices</p> <p>Subject</p> <p>4.20.01 Medicine, diseases</p> <p>4.20.04 Pharmaceutical products and industry</p> <p>4.20.05 Health legislation and policy</p> <p>8.40.08 Agencies and bodies of the EU</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health and Food Safety	 GONZÁLEZ CASARES Nicolás	25/11/2020
	Committee for opinion	Rapporteur for opinion	Appointed
	 Budgets	The committee decided not to give an opinion.	
Council of the European Union	 Industry, Research and Energy		03/12/2020
	 Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	Commission DG Health and Food Safety	Commissioner	KYRIAKIDES Stella
European Economic and Social Committee European Committee of the Regions			

Key events			
11/11/2020	Legislative proposal published	COM(2020)0725	Summary

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 168-p4; Treaty on the Functioning of the EU TFEU 114-p1

Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions				
Stage reached in procedure	Preparatory phase in Parliament				
Documentation gateway					
Legislative proposal		COM(2020)0725	11/11/2020	EC	Summary

2020/0321(COD) - 11/11/2020 Legislative proposal

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.