

Reinforced role for European Medicines Agency

As part of building a European Health Union, as well as in response to the Covid-19 pandemic, the European Commission proposed in November 2020 to reinforce the European Medicines Agency's role in crisis preparedness and the management of medicines and medical devices. The proposed regulation seeks to better anticipate possible shortages and to ensure timely development of high-quality medicinal solutions, to allow the EU to react to health crises more quickly, efficiently, and in a coordinated manner. The agreement on the proposal reached in trilogue negotiations now needs to be confirmed by the European Parliament.

Background

The Commission proposal on the extension of the mandate of the European Medicines Agency (EMA) forms part of the [European Health Union](#) package, which includes a [communication](#), a [proposal](#) for a reinforced mandate for the European Centre for Disease Prevention and Control, and a [proposal](#) for a new regulation on serious cross-border threats to health. This was complemented by a proposal for the establishment of a Health Emergency Preparedness and Response Authority ([HERA](#)), put forward by the Commission on 16 September 2021. The [EMA](#) was set up in 1995, and relocated (from London) to Amsterdam in 2019, as a result of the United Kingdom's withdrawal from the EU.

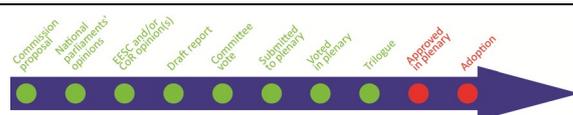
European Commission proposal

The [proposal for a regulation](#) aims to reinforce the EMA so that it can facilitate a coordinated EU-level response to health crises, by monitoring and mitigating potential and actual shortages of medicines and medical devices considered as critical in addressing public health emergencies; providing advice on medicines that may have the potential to treat, prevent or diagnose the diseases causing those crises; and coordinating clinical trials. The proposed regulation would, among other things, create new structures within the EMA, such as steering groups on shortages and an emergency task force.

European Parliament position and outcome of the negotiations

Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) adopted its [report](#) on the proposal on 22 June 2021, on the basis of which, the Parliament's [position](#) for trilogue was adopted in plenary on 8 July. Interinstitutional negotiations began on 13 July 2021. After three trilogue meetings, the European Parliament and Council reached a provisional agreement on [28 October 2021](#). Among other things, they agreed on: setting up a platform to monitor shortages; the definition of a 'major event' (that is likely to pose a serious risk to public health requiring medicines); transparency; data protection; and on funding for the work of the steering groups, task force, working parties and expert panels that are to be established. The [agreed text](#) was endorsed by Coreper, for the Council, on [10 November 2021](#), and then approved at the ENVI committee meeting of [30 November 2021](#). The text now needs to be formally adopted by Parliament, and is scheduled to be voted during the January 2022 plenary session. Once adopted, the regulation would apply from 1 March 2022.

First-reading report: [2020/0321\(COD\)](#); Committee responsible: ENVI; Rapporteur: Nicolás González Casares (S&D, Spain). For further information see our European Parliament '[Legislative Train Schedule](#)'.



EPRS | European Parliamentary Research Service

Author: Laurence Amand-Eeckhout, Members' Research Service
PE 698.871 – January 2022



This document is prepared for, and addressed to, the Members and staff of the European Parliament as background material to assist them in their parliamentary work. The content of the document is the sole responsibility of its author(s) and any opinions expressed herein should not be taken to represent an official position of the Parliament. Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy. © European Union, 2022

eprs@ep.europa.eu (contact) <http://www.eprs.ep.parl.union.eu> (intranet) <http://www.europarl.europa.eu/thinktank> (internet) <http://epthinktank.eu> (blog)