

European Medicines Agency

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 EU's 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 EU's 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 EU's 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.