European Medicines Agency

2020/0321(COD) - 08/07/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

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.