European Medicines Agency

2020/0321(COD) - 20/01/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a legislative resolution on 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 European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Learning from the COVID-19 pandemic

The amended text stressed that the unprecedented experience of the COVID-19 pandemic has highlighted 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 respond to early public health threats in a harmonised manner.

Framework and means of the European Medicines Agency

The Regulation provides a framework and the necessary means within the Agency for:

- preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products and on medical devices at Union level. A '**major event**' is defined as an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State;

- monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices;

- setting up an interoperable information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;

- providing advice on medicinal products that have the potential to address public health emergencies;

- providing support for the expert panels.

Executive Steering Group on Shortages and Safety of Medicinal Products

The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) will be established within the Agency to ensure a **rapid response to major events and to coordinate urgent actions across the Union** in relation to the management of problems related to the supply of medicinal products. The Steering Group will be composed of one representative of the Agency, one representative of the Commission and one representative designated by each Member State. The list of members will be published on the Agency's web portal.

The MSSG should draw up a **list of critical medicines** to monitor them and should be able to advise and make recommendations on the measures needed to ensure the quality, safety and efficacy of medicines as well as to guarantee the supply of medicines and to ensure a high level of human health protection.

Representatives of national competent authorities for veterinary medicinal products, representatives of other relevant competent authorities and third parties, including representatives of interest groups, marketing authorisation holders, wholesalers, as well as representatives of health professionals, patients and consumers, may be invited to attend the meetings as observers and to provide expert advice.

European Shortages Monitoring Platform

The Agency will establish an IT platform that will be used to facilitate the collection of information on shortages, supply and demand of medicines, including information on whether the medicine is placed on the market or no longer placed or ceases to be placed on the market in a Member State. The information collected via the platform will be used to **monitor, prevent and manage actual or potential shortages of medicines** on the lists of critical medicines during public health emergencies or major events.

The Agency will need to ensure data **interoperability** between the European Shortage Monitoring Platform, Member States' IT systems and other relevant IT systems and databases.

Emergency Task Force (ETF)

The ETF will meet **in preparation** for and during public health emergencies. In liaison with the Agency's scientific committees, working groups and scientific advisory groups, it will provide scientific advice and scientific recommendations on the use of any medicinal product that may respond to a public health emergency. It will also provide advice on key aspects of clinical trial protocols.

Public information

For the duration of a public health emergency, sponsors of clinical trials conducted in the EU will have to **publish the clinical trial protocol at the start of the trial**, together with a summary of the results obtained. Where a medicinal product has been granted a marketing authorisation, the Agency will have to publish product information with details of the conditions of use as soon as the marketing authorisation is granted. The Agency will regularly publish on its web portal the list of ETF members, as well as the list of medicines under review.

Transparency and conflicts of interest

The Steering Group on Shortages of Medicines and the Steering Group on Shortages of Medical Devices should carry out their activities in an **independent, impartial and transparent manner**. Members and, where appropriate, observers should have no financial or other interest in the medicinal products industry or the medical devices industry that could affect their independence or impartiality.

Transfers of personal data under the Agency's new mandate will be subject to EU data protection rules, including the General Data Protection Regulation.

EU funding

Adequate staffing and funding should be allocated to the Agency, taking into account the specificities of the health sector in the different Member States. The EU will provide funding for the Agency's activities in support of the work of the Steering Groups on Medicines Shortages and on Medical Device Shortages, the ETF, working groups and expert groups that require cooperation with the Commission and the European Centre for Disease Prevention and Control (ECDC).