Press release

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COVID-19 lessons learned: stronger role for EU medicines regulator

- Improved capacity for crisis preparedness and management of medical devices and products
- New EU database to monitor and report medicine shortages
- Large-scale clinical trials and publication of marketing authorisation decisions

Public health MEPs agree to change the European Medicines Agency's mandate to reinforce its role and better equip the EU to manage future health crises.

The Committee on the Environment, Public Health and Food Safety (ENVI) adopted on Tuesday, with 68 votes in favour, 3 against and 8 abstentions, its negotiating position on the extension of the mandate of the European Medicines Agency (EMA). The position is scheduled to be voted on during the July plenary session.

A new European Medicines Supply Database

MEPs propose the creation of an interoperable digital EU database to monitor and report on shortages of medicinal products. The database would facilitate, on a permanent basis, access and exchange of information between the Agency and national authorities. Each EU country would develop a platform for the real-time monitoring of medicinal supply, aiming to detect, predict and prevent shortages.

Better coordination and transparency on clinical trials

MEPs want to implement coordinated, well-designed and large-scale clinical trials to obtain reliable evidence. Experience with clinical trials during the pandemic revealed many shortcomings, including duplication, the under-representation of important population subgroups, and a lack of collaboration.

In addition, MEPs want information on clinical trials and marketing authorisation decisions to be publicised.

Wider consultation and transparency of Agency steering groups

Newly established Agency bodies, such as the Medicines Steering Group and the Medical Devices Steering Group, should include permanent observers from bodies representing patients and medical professionals, as well as invite contributions from third parties including marketing authorisation holders, wholesale distributors, or other appropriate industry, patients', consumers' and healthcare professionals' groups. Members of these bodies must not have interests in related industry sectors that could affect their impartiality. The EMA should make these member lists and proceedings publicly available, MEPs add.

Quote

Rapporteur Nicolás González Casares (S&D, ES) said: "The pandemic has shown that the EU and its member states were not prepared to tackle a challenge of this magnitude. Agencies such as the EMA did not have an adequate mandate or sufficient resources. We are now strengthening the EMA's capacity to deal with future emergencies. Parliament wants to make the work of the steering groups more transparent and to strengthen the role of healthcare professionals, as well as encouraging synergies between EU agencies. Moreover, we want to promote clinical trials for the development of vaccines and treatments, reinforcing public information about them. We are committed to provide the Agency with new tools to enable it to carry out active monitoring in order to prevent medicines shortages. In short, more transparency, more participation, more coordination and more prevention."

Background

As part of building a European Health Union, the Commission proposed on 11 November 2020 a new health security framework fit for future health challenges, based on lessons learnt from combatting the coronavirus, which includes a proposal to reinforce the mandate of the European Medicines Agency.

Further information

Draft report
Compromise amendments
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Procedure file
Legislative train
Profile of the rapporteur: Nicolás González Casares (S&D, ES)
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