## Basic information

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| **2020/0321(COD)**<br><br>COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | Procedure completed |
| European Medicines Agency<br><br>**Subject**<br><br>4.20.01 Medicine, diseases<br>4.20.04 Pharmaceutical products and industry<br>4.20.05 Health legislation and policy<br>8.40.08 Agencies and bodies of the EU<br><br>**Legislative priorities**<br><br>Joint Declaration 2021 | |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | GONZÁLEZ CASARES Nicolás (S&D) | 25/11/2020 |
| | Shadow rapporteur<br><br>BUŞOI Cristian-Silviu (EPP)<br><br>RIES Frédérique (Renew)<br><br>METZ Tilly (Greens/EFA)<br><br>KOPCIŃSKA Joanna (ECR)<br><br>MÉLIN Joëlle (ID)<br><br>KONEČNÁ Kateřina (The Left) | |

| Committee for opinion | Rapporteur for opinion | Appointed |
|---|---|---|
| BUDG Budgets | The committee decided not to give an opinion. | |
| ITRE Industry, Research and Energy | MÉLIN Joëlle (ID) | 03/12/2020 |
| IMCO Internal Market and Consumer Protection | The committee decided not to give an opinion. | |

### Council of the European Union

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| European Commission | **Commission DG** | **Commissioner** |
| | Health and Food Safety | KYRIAKIDES Stella |
| European Economic and Social Committee | | |
| European Committee of the Regions | | |

**Key events**

| Date | Event | Reference | Summary |
|---|---|---|---|
| 11/11/2020 | Legislative proposal published | COM(2020)0725 | Summary |
| 14/12/2020 | Committee referral announced in Parliament, 1st reading | | |
| 22/06/2021 | Vote in committee, 1st reading | | |
| 25/06/2021 | Committee report tabled for plenary, 1st reading | A9-0216/2021 | |
| 07/07/2021 | Debate in Parliament | | |
| 08/07/2021 | Decision by Parliament, 1st reading | T9-0351/2021 | Summary |
| 08/07/2021 | Matter referred back to the committee responsible for interinstitutional negotiations | | |
| 30/11/2021 | Approval in committee of the text agreed at 1st reading interinstitutional negotiations | | |
| 19/01/2022 | Results of vote in Parliament | | |
| 20/01/2022 | Decision by Parliament, 1st reading | T9-0006/2022 | Summary |
| 20/01/2022 | Results of vote in Parliament | | |
| 25/01/2022 | Act adopted by Council after Parliament's 1st reading | | |
| 25/01/2022 | Final act signed | | |
| 31/01/2022 | Final act published in Official Journal | | |

**Technical information**

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|---|---|
| **Procedure reference** | 2020/0321(COD) |
| **Procedure type** | COD - Ordinary legislative procedure (ex-codecision procedure) |
| **Procedure subtype** | Legislation |
| **Legislative instrument** | Regulation |
| **Legal basis** | Treaty on the Functioning of the European Union TFEU 114-p1<br>Treaty on the Functioning of the European Union TFEU 168-p4 |
| **Other legal basis** | Rules of Procedure EP 165 |
| **Mandatory consultation of other institutions** | European Economic and Social Committee<br>European Committee of the Regions |
| **Stage reached in procedure** | Procedure completed |

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| **Committee dossier** | ENVI/9/04630 |

## Documentation gateway

**European Parliament**

| Document type | Committee | Reference | Date | Summary |
|---|---|---|---|---|
| Committee draft report | | PE680.818 | 31/03/2021 | |
| Amendments tabled in committee | | PE691.443 | 28/04/2021 | |
| Committee opinion | ITRE | PE689.565 | 27/05/2021 | |
| Committee report tabled for plenary, 1st reading/single reading | | A9-0216/2021 | 25/06/2021 | |
| Text adopted by Parliament, partial vote at 1st reading /single reading | | T9-0351/2021 | 08/07/2021 | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T9-0006/2022 | 20/01/2022 | Summary |

**Council of the EU**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Draft final act | 00076/2021/LEX | 25/01/2022 | |

**European Commission**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Legislative proposal | COM(2020)0725 | 11/11/2020 | Summary |
| Commission response to text adopted in plenary | SP(2022)66 | 24/02/2022 | |

**National parliaments**

| Document type | Parliament /Chamber | Reference | Date | Summary |
|---|---|---|---|---|
| Contribution | ES_PARLIAMENT | COM(2020)0725 | 22/02/2021 | |
| Contribution | PT_PARLIAMENT | COM(2020)0725 | 25/02/2021 | |
| Contribution | CZ_SENATE | COM(2020)0725 | 24/03/2021 | |
| Reasoned opinion | FR_SENATE | PE691.143 | 30/03/2021 | |
| Contribution | IT_SENATE | COM(2020)0725 | 19/05/2021 | |

**Other institutions and bodies**

| Institution/body | Document type | Reference | Date | Summary |
|---|---|---|---|---|
| EESC | Economic and Social Committee: opinion, report | CES5933/2020 | 27/04/2021 | |
| CofR | Committee of the Regions: opinion | CDR5525/2020 | 07/05/2021 | |

| Additional information | | |
|---|---|---|
| **Source** | **Document** | **Date** |
| European Commission | EUR-Lex | |

| Final act |
|---|
| Corrigendum to final act 32022R0123R(03)<br>OJ L 071 09.03.2023, p. 0037<br><br>Regulation 2022/0123<br>OJ L 020 31.01.2022, p. 0001 |

# 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.

# 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.

# 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).