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New recommendations to strengthen supply chains of critical medicines

23 April 2024

EMA has published a number of recommendations to address vulnerabilities in the production and delivery of medicines included in the Union list of critical medicines and strengthen their supply chain.

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These [recommendations](#) have been developed by EMA's Medicines Shortages Steering Group (MSSG) and will facilitate the availability and supply of critical human medicines for which vulnerabilities in the supply chain have been identified.

Measures considered by the MSSG will be selected according to the risks posed to the supply chain and the type of medicine, and include:

- Possible recommendations to marketing authorisation holders (MAHs) to increase manufacturing capacity and diversify the suppliers in the supply chain (for example through the addition of alternative manufacturing sites), and to monitor forecasts of supply and demand of medicines and available stocks in the entire supply chain.
- Recommendations to certain actors in the supply chain, such as MAHs, and the European Commission to stockpile medicines to protect against fluctuations in demand or supply.
- The possibility to request a MAH to establish a shortage prevention plan for medicines in the Union list of critical medicines. EMA will publish guidance and templates for shortage prevention plans in June 2024.
- Provision of scientific and regulatory support to address vulnerabilities in the supply chain, including assistance to small and medium-sized enterprises.

Use of work-sharing procedures or other types of reliance on assessments conducted by another recognised authority, and accelerated timetables for required variations to address supply chain vulnerabilities of critical medicines.

The MSSG will work closely with the European Commission's [Critical Medicines Alliance \(CMA\)](#). The MSSG will develop regulatory and governmental policy recommendations focused on short- to medium-term actions, while the CMA will focus on long-term measures in the field of industrial policy to address vulnerabilities in the supply chain of critical medicines.

In case of critical shortages of medicinal products included in the Union list, the MSSG Toolkit on recommendations on tackling shortages of medicinal products would apply.

More about the MSSG

The MSSG was established under [Regulation \(EU\) 2022 / 123](#), which reinforces the role of the Agency in crisis preparedness and management for medicines and medical devices in order to monitor shortages and ensure a robust response to major events or public health emergencies and to coordinate urgent actions on the supply of medicines within the EU.

More about the Union list of critical medicines

The Union list of critical medicines identifies medicines for human use for which continuity of supply in the European Union (EU) is a priority and shortages should be avoided as they are critical for EU healthcare systems to function properly and shortages leading to interruption in treatment could result in serious harm to patients. The European medicines regulatory network will prioritise critical medicines for EU-wide actions aiming at strengthening their supply chain and minimise the risk of supply disruptions.

Related documents



MSSG recommendations to strengthen supply chains of critical medicinal products

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- [Availability of critical medicines: Union list of critical medicines](#)
- [Medicine shortages and availability issues](#)

External links

- [Critical Medicines Alliance \(CMA\)](#)
- [EUR-Lex: regulation \(EU\) 2022 /123](#)

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