Questions and answers: Addressing Medicine Shortages in the EU

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What are "critical medicines" and "critical shortages" and how do they differ?

Critical medicines are medicines for which no appropriate alternative is available and for which insufficient supply would result in a serious harm or risk of harm to patients. These medicines are considered to be essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. A union list of critical medicines is currently under development and will be published by the end of the year.

A **shortage** occurs when the supply of a medicine does not meet the demand for that medicine. Many shortages are managed and resolved at national level. However certain shortages require coordinated action at the European level, with close involvement of the European Medicines Agency (EMA) and Member States, to resolve the situation. These are called **critical shortages**.

Why has the Commission come forward with this Communication now, and what concrete actions are proposed?

Everyone must have **timely and equal access to critical medicines**. This is the very premise of the European Health Union, including the pharmaceutical reform presented in spring of this year. As part of this goal, **addressing shortages and strengthening security of supply** is a top political priority for the Commission. The Commission stands ready to take every measure possible to address this.

Today's Communication sets out the existing and planned measures, including those set out in the pharmaceutical reform. It proposes a **toolbox of measures** for the immediate and short-to-medium term to enhance security of supply of critical medicines and make supply of medicines to Europe more resilient.

These measures include a strengthened, coordinated system for critical shortage management at EU level, including tools that can be deployed such as a **new Voluntary Solidarity Mechanism** established by the EMA and Member States. This mechanism will facilitate the redistribution of medicines available on the European market from one Member State to another experiencing a critical shortage.

In advance of the adoption of the proposed pharmaceutical legislation, the Commission is working with the EMA and Member States to develop a Union list of critical medicines and plan to analyse the vulnerabilities in the supply chain of those medicines. A first version of the list will be available by the end of 2023. The Communication sets out regulatory and industrial policy measures that will be available to address those vulnerabilities. These measures – together with all those already taken - will better equip the EU to anticipate and mitigate shortages, and ultimately ensure that medicines are available for patients across the EU.

What is the link between this Communication and the EU's Pharmaceutical Reform?

This Communication complements the regulatory and legislative efforts already made, in particular the extended mandate of the EMA and the **Pharmaceutical Reform** proposal from last spring. This proposal focuses on **longer term, structural measures** to ensure the availability of accessible and affordable medicines.

Following the pharmaceutical reform, however, Member States, EMA and the Commission have already started actions that go in the direction of this reform, including the earlier adoption of the Union list of critical medicines.

In that context, **today's Communication includes immediate short- and mid-term actions** to enhance the security of supply of critical medicines, by addressing identified vulnerabilities in their supply chains in a targeted way.

It also responds to calls from the public, the European Parliament and Member States for more immediate action to ensure the availability of critical medicines in the EU. It reinforces the

voluntary cooperation and establishes a **European Solidarity Mechanism** to support Member States in tackling shortages of medicines in a timely and coordinated manner.

Furthermore, the Commission intends to set up a **Critical Medicines Alliance** to be operational in early 2024, adding an industrial policy pillar to the European Health Union. This will allow national authorities, industry, civil society representatives, the Commission and EU agencies to coordinate action at the EU level against the shortages of medicines and to address supply chain vulnerabilities, in compliance with competition rules. It is the direct policy response to enhancing security of supply and it could pave the way for a possible "Critical Medicines Act" in the future, subject to the results of a dedicated preparatory study and the impact assessment.

What has already been done to address the issue of shortages of critical medicines?

The **mandate of the European Medicines Agency** has been extended, as part of the EU Health Union, to **improve coordination with Member States** and interactions with industry, in preparation for and during crises.

That way, when critical shortages occur, authorities can engage quickly with the companies responsible for those medicines, to mitigate the effects of the shortages and reduce the impact on patients, citizens and health systems.

The added value of this enhanced cooperation has already been shown in recent cases of shortages of a medicine dissolving blood clots and a medicine against vision loss.

The Commission's **Health Emergency Preparedness and Response Authority** (HERA) is also supporting with foresight and emergency preparedness to ensure the availability of medical countermeasures, notably through joint procurement of medicines.

The pharmaceutical reform proposal extends those processes and contains a series of measures to **strengthen shortage management and boost the security of supply of medicines**, in a structural way. There is however a lot more that can be done, which is why this Communication looks beyond the existing and proposed regulatory and legislative framework to consider additional tools, in particular industrial policy tools, that can be activated.

How will the proposed reform of the pharmaceutical legislation, tabled last spring, help stabilise supply chain issues and the availability of medicines?

The Pharmaceutical reform focuses on **structural measures** which will make the supply chains of critical medicines more resilient **in the medium to long term**. It will improve the prevention and mitigation of medicine shortages.

The reform proposes earlier notification of shortages and withdrawals, a requirement for shortage prevention plans for all medicines and stronger EU coordination mechanisms for the management of shortages and security of supply of critical medicines.

The reform will also improve the enforceability of companies' compliance with their obligation to ensure appropriate and continued supply. Where necessary, legally binding obligations to strengthen security of supply of specific critical medicines will be enforced, including a requirement for certain companies to hold contingency stocks. The reform will also facilitate the use of electronic product information and multi-country packages.

Today's Communication identifies some of the actions within that reform package that could be further accelerated in the short-term, such as the establishment of a Union list of critical medicines.

These actions, combined with other measures to create the right environment to investment and innovation, can significantly tackle the problem of shortages in a systematic way.

Will the Commission provide funding to ensure the security of supply of medicines?

A number of EU financial instruments can already support critical medicines production, for instance the Recovery and Resilience Facility. The Strategic Technologies for Europe Platform (STEP), recently proposed as part of the mid-term review of the Multiannual Financial Framework, aims at boosting investments in critical technologies in Europe, either to promote innovation or to contribute to reduce or prevent strategic dependencies of the Union. STEP seeks to reinforce and leverage existing EU instruments for a quick deployment of financial support for the development or manufacturing in the Union of critical technologies in several fields, including biotechnology. More specifically, the Commission proposal covers pharmaceuticals and medical technologies vital for health security as examples of biotechnologies that should be covered by STEP. STEP projects could be supported through several programmes, such as Cohesion Policy programmes, the Recovery and Resilience Facility, EU4Health, Horizon Europe or InvestEU. Moreover, STEP also proposes to create a Sovereignty Seal, with the objective to promote synergies amongst existing programmes.

Will the Commission reshore production of all critical medicines to the EU?

Security of supply is a top priority when it comes to medicines, as well as the need to ensure sufficient production for the Union. The Commission's **open strategic autonomy** is a major political objective of this Commission, and a major lesson of the COVID-19 pandemic. The focus will be to **derisk** but not decouple from the global economy. The Commission continues to rely on the global supply chains of pharmaceutical companies, originator or generic, for the supply of active principal ingredients and medicines. The vulnerabilities analysis of the Union list of critical medicines, guided by evidence, will identify over-dependencies and, where relevant, define solutions (stockpiling, public procurement, increased and modernised manufacturing, strategic partnerships, etc.).

How is the Commission preparing for winter 2023-2024 on availability of antibiotics?

The Commission is working on multiple actions to ensure the availability of antibiotics for this winter. This includes the recommendations issued in July by the Commission, Head of Medicines Agencies and EMA on measures necessary to meet the forecasted demand for antibiotics. The information available today suggests that – if demand in the coming winter season does not differ significantly from the demand of recent years – the supply to the EU of key antibiotics seems to generally match demand. However, this depends on the compliance by relevant companies with their legal obligation to ensure supply and their ability to adapt.

Close collaboration with industry continues to ensure that production of key antibiotics meets demand, continuing to closely monitor supply and demand levels, and raising public awareness on the importance of prudent use of these antibiotics.

Is the Commission stockpiling antibiotics at risk of shortage?

The Commission is stockpiling a limited amount of antibiotics in case a cross-border health threat causes a critical shortage. This stockpile was established following a call for proposals for chemical, biological, radiological and nuclear (CBRN) threat stockpiling in 2022. Because of the long-term planning, manufacturers were able to factor in these amounts in their production capacity. The Commission is asking Member States not to stockpile antibiotics for this winter to avoid worsening the situation.

What are the next steps following the publication of the Union list of critical medicines?

The European Commission is currently establishing a robust methodology to increase supply chain transparency of critical medicines and of medical countermeasures to improve crisis response. The mapping of the supply chains is followed by a vulnerability analysis identifying potential bottlenecks, among others, high dependencies from few consolidated markets outside the EU and low diversification in suppliers. The work will guide EU-level actions to increase supply chain resilience and thus, to strengthen supply continuity of medical products to EU patients.

Will the Commission now start working on a "Critical Medicines Act"?

In the immediate, a Critical Medicines Alliance offers the opportunity to coordinate action at the EU level against shortages of medicines through the range of tools available at EU and national level. A legislative initiative for an EU "Critical Medicines Act" would require thorough preparation, including the assessment of economic aspects. The Commission will to that end launch a dedicated study, paving the way for an impact assessment. Concrete decisions on the need, content and feasibility of such an Act can only be taken when the evidence is available.

Public funding can help industry develop new medicines or improve production processes. But where a company receives government support, EU State aid rules could apply. Do these rules allow such aid?

EU State aid rules make sure that public support is necessary and proportionate and thus helps to achieve certain policy objectives while not distorting the marked. A number of EU State aid rules allow Member States to grant aid for developing medicines and enhance their availability, under certain conditions. Rules applicable to Important Project of Common European Interest (IPCEI) allow aid for entire value chains, for the development and deployment of breakthrough technologies including the health sector. A new IPCEI focusing on generic medicines could complement the ongoing work of the existing IPCEI in the health area, which aims to support the development of innovative treatments on antimicrobial resistance, rare diseases and cancer, as well as innovative production processes and products. Rules applicable to aid for services in the general economic interest (SGEI) may be used to limit the risk of critical medicines shortages at the EU level. Further examples include aid for implementing innovative production processes, for investing in new research, testing or production capacity. Specific rules on aid to SMEs and innovative start-ups can help bringing innovative ideas and technologies on the market or on support in less developed regions in line with the Regional Aid Guidelines (RAG). There is a broad margin for implementing aid

measures rapidly even without formal Commission approval, under the General Block Exemption Regulation (GBER).

For more information

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Press release

Factsheet

European Health Union

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