



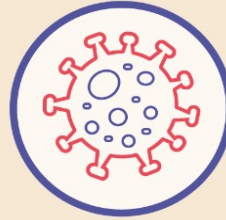
# Availability of medicines in the EU

## Panel I: Actions under the Pharmaceutical Strategy for Europe

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## PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from  
COVID-19,  
towards a crisis-  
resistant system



Ensuring  
accessibility and  
affordability of  
medicines



Supporting  
sustainable  
innovation,  
emerging science  
and digitalisation



Reducing medicines  
shortages and  
securing strategic  
autonomy

#EUPharmaStrategy



- Security of supply is one of the pillars of strategy:
- Two aspects:
  - Preventing and mitigating shortages;
  - Ensuring EU resilience and open strategic autonomy



# Flagships of the pharmaceutical strategy

## Ensuring availability and addressing shortages

### Secure the supply

- Revise the legislation to **enhance security of supply and address shortages** (2022)
- Launch a structured dialogue to **identify vulnerabilities** in the global supply chain (2021)
- Ensure **increased transparency of the industry** on the supply chains (2021)

### High quality, safe and environmentally sustainable

- revise manufacturing and supply provisions in the legislation to **ensure environmental sustainability, quality and preparedness** (2022)
- revise the legislation to strengthen **environmental risk assessment** requirements and conditions of use (2022)

### Crisis response mechanisms

- Proposal for an **EU Health Emergency Response Authority** (2021)

# Pharmaceutical strategy

## Shortages – systemic solutions:

- To consider systemic changes, creating regulatory environment ensuring security of supply and introducing mitigating and preventing shortages;
  - Strategy announces the **revision of the pharmaceutical legislation** to enhance security of supply and address shortages through specific measures including stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages;
    - Utilise outputs of **study on root causes of shortages** (*Future-Proofing pharmaceutical legislation – Study on medicine shortages*), due for completion Q3 2021.
- Encourage MS and provide support to engage in close cooperation.

# Study on shortages

- The goal of this study is to provide:
  - an overview of medicines in shortage in the EU, including their specific characteristics, as well as an analysis of the root causes of the shortages
  - an evidence-based assessment of whether the current framework (at EU and national level) to address the issue of shortages is fit for purpose, in line with the Better Regulation guidelines
  - an overview of potential solutions to address shortages, taking into account their root causes and the shortcomings of the current system, as identified by this study

# Study on shortages

## Complete

- Stakeholder surveys, interviews
- Literature review and shortage definition analysis
- Inventory and trend analysis of shortages
- Analysis of products in shortage – characteristics analysis

## In Progress

- Root cause analysis of shortages in EEA
- Evaluation of legal framework and efficiency analysis
- Evaluation of potential solutions

## Next Steps

- Focus groups with solution focus – **stakeholder** involvement (May)
- Longlisting and shortlisting of solutions – **stakeholder** involvement (May/ June)
- Draft final report and **consultation** workshop (End Q2)
- Final report (End Q3)
- Inform review of legislation under Pharmaceutical Strategy

# EU resilience and open strategic autonomy:

- Conclusions of the European Council of 2 October 2020:

*The European Council invites the Commission to identify strategic dependencies, particularly in the most sensitive industrial ecosystems such as for health, and to propose measures to reduce these dependencies, including by diversifying production and supply chains, ensuring strategic stockpiling, as well as fostering production and investment in Europe.*

- First step is to map vulnerabilities, including dependencies, of the supply chains and gain good understanding of the supply chain situation in order to propose concrete actions.
  - **Structured Dialogue** with industry representatives, Member States, patients and health professionals representatives and research community **launched on 26 February 2021.**

# Structured dialogue initiative

Involving actors of the pharmaceuticals manufacturing value chain, public authorities, patient and health non-governmental organisations and the research community in a process steered by the Commission

## Overall purpose

- Strengthen the resilience of the pharma supply chains
- Ensure the security of supply of medicines

## Phase 1 objectives

- Gain a better understanding of the functioning of global supply chains
- Identify the precise causes and drivers of different potential vulnerabilities

## Phase 2 objective

- Put forward a set of possible measures to address the identified vulnerabilities and formulate policy options to be considered by the Commission and other authorities in the EU



# Thank you



European Commission  
Public Health information:  
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