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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission

Delegations will find attached the presentation given by the Commission on DG SANTE's Staff Working Document on Critical Medicines Act at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025.

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Staff Working Document on Critical Medicines Act

Working Party on Pharmaceuticals and Medical Devices,

3rd September 2025

Director SANTE D

European Commission

Context

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- CMA proposal adopted on 11 March 2025
- No full impact assessment but SWD published subsequently
- This SWD summarises evidence supporting the CMA proposal, e.g.:
  - Study on medicine shortages in the EU
  - SWD on the vulnerabilities in global medicines supply chains published as a result of the Structured Dialogue on medicines supply security
  - Study on best practices in the public procurement of medicines
  - Work of the Critical Medicines Alliance and vulnerability assessment pilot
  - Call for evidence and exploratory study

Critical medicines

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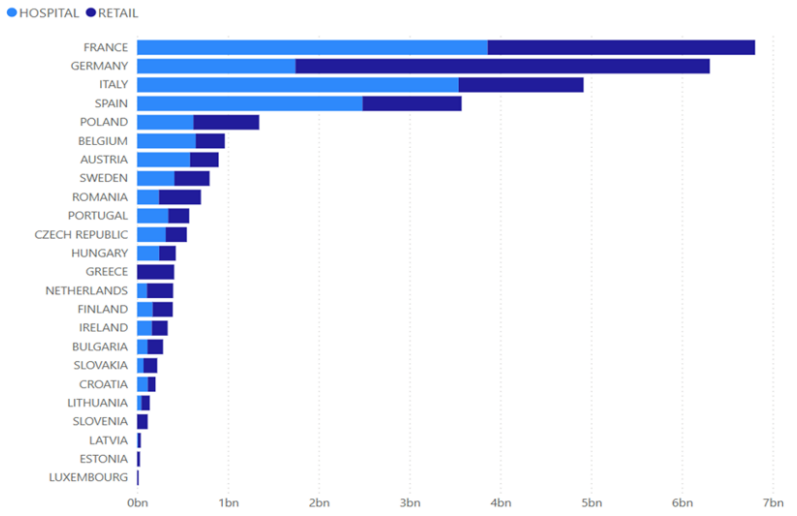
- Span a diverse spectrum of medicines for which continued supply is considered a priority in the EU
- 276 active substances currently included on the Union list, representing 18 700 medicinal products on the EU market
- Significant segment of EU pharmaceutical market: sales accounted for over EUR 30 bn in 2023
- Dispensed either in hospitals or in pharmacies: hospital sales accounted for slightly more than half (52%) of total EU sales in 2023
- Substantial disparities across MS, reflecting the varying roles of healthcare systems and retail distribution channels in different countries

Figure 3 - Sales (EUR) of critical medicines in the EU, by year and distribution channel



Source: Ecorys based on IQVIA MIDAS®: value sales data of critical medicines in the EU for period January 2019 to December 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

Figure 4 - EU sales (EUR) of critical medicines, by country and distribution channel (2023)



Source: Ecorys Study based on IQVIA MIDAS®: value sales data for period January 2023 to December 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. *Note: for Greece and Estonia only retail data are available.

Medicines of common interest

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- Cover a wide range of therapeutic areas, from orphan medicines to novel antibiotics
- Policy actions related to medicines of common interest restricted to those medicines where there is a need for EU intervention
- Market failures may arise from various structural factors, for example:
  - limited population size (e.g., orphan medicines)
  - nature of some medicines that are intended to be used only sparingly (novel antimicrobials)

Problem definition

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- Problem 1: Shortages of medicines affecting security of supply and availability of critical medicines
  - Multifactorial and complex root causes (incl. manufacturing issues, unexpected increase in demand, commercial reasons, etc.)
  - Potential impact includes reduced quality of life, increased healthcare costs and additional burden on healthcare systems
- Problem 2: Market failures affecting the availability of and accessibility to medicines of common interest
  - Significant delays or even no accessibility to potentially lifesaving treatments for some EU patients
  - Major disparities btw MS in terms of market uptake (e.g. orphan medicines)

Problem drivers (1)

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- High dependency on third countries especially for API production (generics):
  - ~ 75% of API production sites located outside the EU, notably in India and China (EDQM certification database analysis) and no API production at all within the EU for approx. 21%
- Lack of diversification and market concentration
  - Over 30% supply coming from a single country or manufacturer for all CM covered by the vulnerability assessment pilot
- Increased complexity and specialisation of pharmaceutical supply chains
  - Specific challenges such as the difficulty of dual sourcing or to make manufacturing adjustments for innovative medicines with novel innovative manufacturing processes

Problem drivers (2)

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- Fragmented procurement practices and pricing policies
  - Impact of practices based on the lowest price and “winners-takes-all” approaches
- Limited market size and other external factors
  - Impact of targeted population size or limited intended use of the medicine, leading to a limited attractiveness of certain markets and/or reduced bargaining power

Intervention logic

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PROBLEMS	DRIVERS	GENERAL OBJECTIVES	SPECIFIC OBJECTIVES	ACTIONS	RESULTS	IMPACTS
Shortages of medicines affecting the security of supply and availability of critical medicines	EU dependency on 3rd countries for CM and API production	Strengthen the security of supply and availability of critical medicines	Facilitate investments in EU manufacturing capacity	Fast-tracking of administrative procedures and financial support to strategic projects	Increased EU manufacturing capacity	Reduced number of shortages and increased security of supply for critical medicines
Market failures affecting the availability of and accessibility to medicines of common interest	Fragmented procurement practices and pricing policies	Improve the availability and accessibility of medicines of common interest	Incentivise supply chain resilience	Smart public procurement	Greater resilience and diversification of supply chains	Increased EU autonomy
	Lack of diversification and market concentration		Support supply chain diversification	Strategic partnerships with 3rd countries	Better predictability of demand	Better availability of and accessibility to medicines of common interest
	Limited market size		Leverage the aggregated demand of Member States	Collaborative procurement		

Analysis of the main impacts

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- Qualitative assessment complemented by, where possible, disaggregated quantitative evidence and illustrations
- Quantification limitations:
  - differing national health systems and market dynamics
  - very different market realities for the many medicines in scope
  - multi-faceted nature of interventions
- Importance to compare the expected impacts with the current **burden of medicine shortages** (baseline)

Burden of medicine shortages (baseline)

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- For individual patients (**patient health impact**):
  - impact on quality of life and potential deterioration of their health status due to delays in treatment and suboptimal care
- For the society (**price increases**, **administrative costs** and **use of healthcare resources**):
  - additional costs of treatment,
  - workload of healthcare providers (pharmacists) and
  - administrative costs for EU administrations, NCA and businesses

Economic impacts

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- **Security of supply and resilience:** increase domestic production capabilities and reduce external dependencies, foster supply chain diversification
- **Competitiveness of EU pharma sector:** encouraging investments in EU manufacturing, innovative processes and new production technologies
- **Functioning of the Single Market**: coordination btw national authorities on financial support to Strategic Projects and public procurement strategies + preventing negative impact of national measures (contingency stocks)
- **Affordability of medicines:** impact on pharma prices will depend on a large number of factors, incl. type of CM, market situation, specific non-price criteria used by the procurer and their weight (PP measure), etc.

Social and environnemental impacts

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- **Health impacts**
  - Decreased occurrence and impact of critical medicines shortages in the medium to long-term: **reduced burden of shortages** (admin costs and HCP workload) and **better patients' health** (preventing deterioration of health status due to sub-optimal care or delayed treatment)
  - Improved **availability and accessibility** of medicines of common interest, particularly for smaller and lower-income MS
- Environmental impact
  - Potential reduction of long-haul freight emissions but increase of energy consumption and emissions in the EU, particularly related to energy-intensive API synthesis.

Other impacts

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- **Costs and benefits**:
  - For **businesses**: facilitate creation or expansion of EU manufacturing capacities and incentivise supply chain resilience without entailing significant additional regulatory burden
  - For **national authorities**: certain compliance costs and reporting obligations are foreseen but synergies and efficient coordination btw MS are expected
  - For **patients and health systems**: medium to long-term benefits on availability of medicines
- Digital readiness:
  - Data interoperability and ‘only-once principle’ for data collection (identification of critical medicines and vulnerability evaluation)

Thank you





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