Commission proposal for a Critical Medicines Act

30th June 2025

Context

President von der Leyen:
"… we will propose a Critical Medicines Act to reduce dependencies relating to critical medicines and ingredients, particularly for products where there are only a few supplying manufacturers or countries."

- Increasing attention and pressure (COVID-19, geopolitical context)
- Complex and multifactorial root causes
- 23 Member States call for an EU Critical Medicines Act
- Recent and ongoing EU initiatives, *e.g.*:
  - Reform of the EU pharmaceutical legislation (chapter X on shortages)
  - Communication on addressing medicine shortages in the EU
  - Critical Medicines Alliance

Comprehensive approach to ensure availability of critical medicines

REGULATION ON EMA'S ROLE IN CRISIS PREPAREDNESS

Shortage management in crisis times

- Creation of dedicated groups (MSSG and SPOC)

- Shortage reporting and monitoring (ESMP)

GENERAL EU PHARMA LEGISLATION

Shortage management at all times

- Reinforced supply obligation (early notification and shortage prevention plans)

- Preventive approach (Union List and MSSG recommendations)

STRUCTURED DIALOGUE

Methodology to identify critical medicines & supply chain vulnerabilities

Critical Medicines Alliance

Recommendations for industrial policy measures

CRITICAL MEDICINES ACT

Preventive approach

mainly industrial policy measures to support:

- Investment in EU manufacturing capacity

- Supply chain diversification and resilience

- Leveraging aggregated demand

Objectives and scope

Strenghtening security of supply and availability of critical medicines

Critical medicines on the Union list as envisaged in the Pharma Reform

Improved availability and accessibility of other medicines where a market failure exists

Medicines of common interest (e.g. orphans, novel antimicrobials)

KEY ELEMENTS OF THE ACT

ENSURING

SECURITY OF SUPPLY AND AVAILABILITY OF CRITICAL MEDICINES

ACCESSIBILITY AND **AVAILABILITY** OF OTHER KEY MEDICINES

STRATEGIC PROJECTS	PUBLIC PROCUREMENT	COLLABORATIVE PROCUREMENT	STRATEGIC PARTNERSHIPS
Facilitate investments in manufacturing in the EU	Incentivise supply chain diversification and resilience	Harness the combined demand and buying-power of Member States	Support the diversification of supply chains

Strategic projects

- Projects that create, increase or modernise **EU manufacturing capacity** of critical medicines, their active substances and other key inputs
- Benefits:
  - **Fast-tracking of administrative procedures** *(permit granting, environmental assessment)*
  - **Regulatory and scientific support** *(incl. EMA advice & prioritised GMP inspections)*
  - **Facilitated financial support,** including through the STEP Seal
- **State aid Guidance** to assist Member States
- Obligation: **Prioritise EU supply** if received financial support
- Recognition at Member States' level (lean, decentralised approach)
- Exchanges and coordination *via* Critical Medicines Group

Public procurement

- **Mandatory use of other requirements than price** for critical medicines (*e.g. stockholding obligations, number of diversified suppliers, monitoring of supply chains*)
- Obligation for **procurers to favour EU production** for specific critical medicines with high dependencies
- When justified, possibility to favour EU production for other medicines of common interest
- Member States to develop strategy (**national programmes**) covering procurement practices *(incl. multi-winner approaches)* and possibly pricing and reimbursement measures
- Commission guidelines on procurement practices

Contingency stocks

- Dedicated article on **safeguards related to national measures on security of supply**, in particular contingency stock requirements
- Contingency stocks = an obligation imposed on supply chain actors to establish buffer stocks of certain medicines to mitigate the risk of supply disruption
- To be distinguished with ‘stockpiling’ by a (public) health institution in order to anticipate and manage a specific crisis
- **No negative impact of national measures on security of supply** on other Member States
- Member States to respect **principles of proportionality, transparency and solidarity**
- Complementary to measures foreseen in the pharma reform (possibility for EC to impose EU wide contingency stocks)

Collaborative procurement

- Possibility to use different tools of collaborative procurement (each subject to specific conditions and thresholds):
  - **Member States' cross-border procurement** facilitated by the Commission *(available only for other medicines of common interest)*
  - **Commission procurement** on behalf or in the name of Member States
  - **Joint procurement** by the Commission (lead) and Member States

Collaborative procurement

Collaborative procurement type	Cross-border procurement	Procurement on behalf or in the name of MS	Joint Procurement
Legal basis	Article 39 Directive 2014/24/EU (Public Procurement Directive)	Article 168 (3) Regulation 2024/2509 (Recast Financial Regulation)	Article 168 (2) Regulation 2024/2509 (Recast Financial Regulation)
Scope	Other medicinal products of common interest (OMPCI)	- Critical Medicines with vulnerability or MSSG recommendation - OMPCI with JCA	
MS threshold	3 or more	9 or more	
Other conditions	N.A.	Demonstrated improvement access/availability/security of supply	
Procedure	- MS: reasoned request - EC: informs other MS, assesses and decides	- MS request - EC: informs and invites other MS, assesses and decides	- MS request OR at EC initiative - idem
EC role	- Facilitating communication and cooperation - Secretariat and logistics - Advice on EU procurement rules and regulatory matters	- Carries out procurement procedure - Upon acceptance of participating MS, can be conditioned to exclusivity / minimum binding quantities	

International cooperation

- Commission to explore possibilities for:
  - Establishing **strategic partnerships** aiming at **diversification of supply chains**
  - Building on existing cooperation forms
- Critical Medicines Coordination Group to periodically discuss:
  - Potential contribution of strategic partnerships to CMA objectives
  - Prioritisation of third countries
  - Consistency and synergies between national and EU actions

Coordination

- Establishment of a **Critical Medicines Coordination Group**
- Composed of EC and Member States' representatives
- Main tasks:
  - Facilitate coordination on strategic orientation for financial support of Strategic Projects
  - Enable exchanges, cooperation and coordination on public procurement policies
  - Facilitate discussion on collaborative procurement needs
  - Advise MSSG to prioritise, review and update vulnerability evaluations
  - Discuss periodically on international cooperation

Interplay with pharma package

- **Pharma package:**
  - Union List & vulnerability evaluation: EU methodology and adoption process
  - Contingency stocks: Implementing act to impose EU wide contingency stock requirements for critical medicines

- **Critical Medicines Act**
  - Scope: refers to critical medicines on the Union List in pharma package
  - Vulnerability evaluation as performed in pharma package (aggregated level)
  - Contingency stocks: obligation to avoid negative impact of national measures on other MS, principles of proportionality, transparency and solidarity

Vulnerability evaluation in CMA

- Most measures apply to all critical medicines with some exceptions:
  - Member States may prioritise Strategic Projects (SP) that address a supply chain vulnerability
  - STEP objectives deemed to be fulfilled for SP addressing a supply chain vulnerability
  - EU preference in public procurement if **high dependency on single or limited number of third countries**
  - Collaborative procurement if vulnerability identified by a vulnerability evaluation (or MSSG recommendation)
- CMG can ask MSSG to prioritise/review/update the vulnerability evaluation
- Obligation to provide data upon request of EC or NCAs (article 29)

New tasks for EMA/NCAs resulting from CMA

- EMA:
  - Upon request of project promotors of Strategic Projects, advise on innovative manufacturing processes
  - Support aggregated level vulnerability evaluation
- Member States / Medicines Agencies:
  - Regulatory support for Strategic Projects, incl. GMP inspection prioritisation
  - Potential role as designated authorities
- MSSG:
  - Provide vulnerability analysis at aggregated level, based on analysis performed under pharma package
  - Prioritisation, review and update of vulnerability analysis when advised by CMG
  - Possible recommendations for collaborative procurement of critical medicines

Thank you

European Commission