EMA
EUROPEAN MEDICINES AGENCY

Proposed Critical Medicines Act

EMA annual Meeting with all eligible EU Patients, Consumers, and Healthcare Professional Organisations

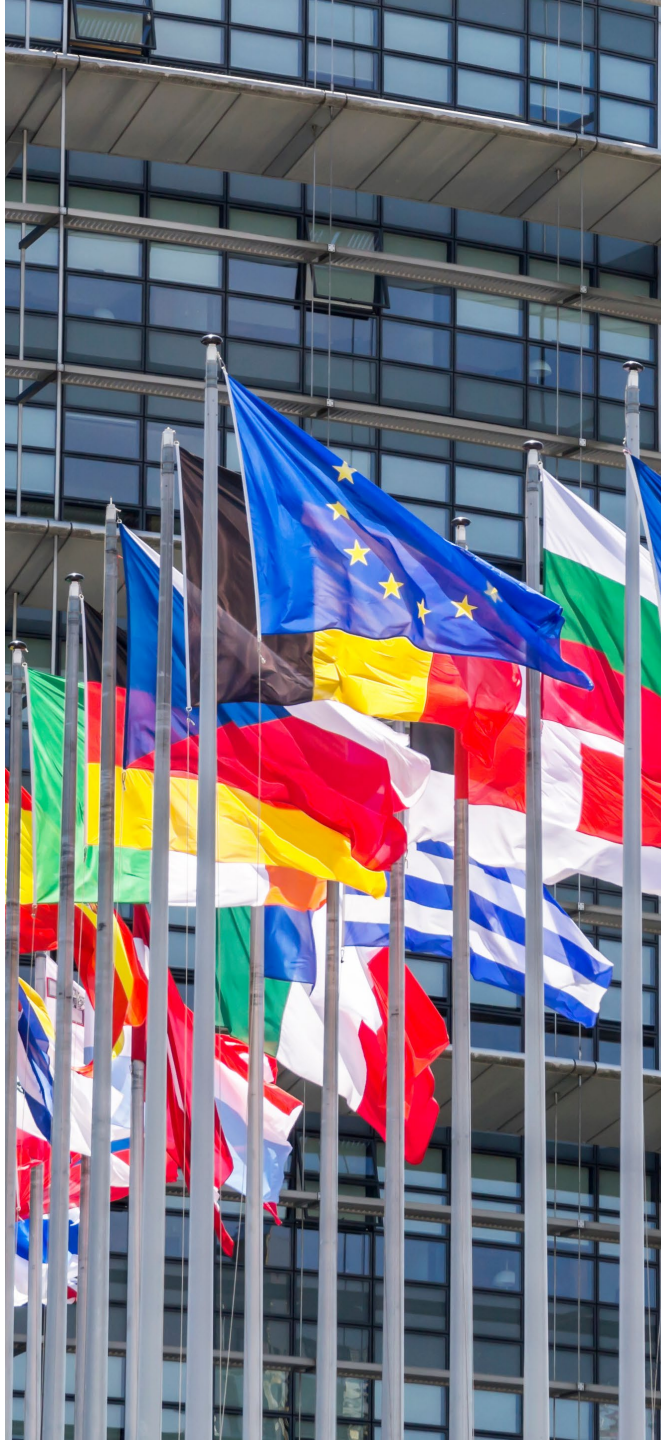
Vanessa Bennett

Senior Medicines and Medical Devices Shortages Specialist, TRS-SAM, EMA

19 November 2025

Background

- Political Guidelines for the next European Commission 2024–2029
  - 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."
  - Committed to a Commission proposal within the first 100 days of the new Commission
- 23 Member States called for an EU Critical Medicines Act
- Related EU initiatives, e.g.:
  - Structured dialogue on security of medicines supply and associated Staff Working Document
  - Reform of the EU pharmaceutical legislation
  - Communication on addressing medicine shortages in the EU
  - Critical Medicines Alliance



Relevant information on the ongoing negotiations (1/2)

European Commission

- Proposal for a Critical Medicines Act — Public Health — European Commission adopted on 11 March 2025
- Staff Working Document
- EC Fact Sheet: Factsheet — Critical Medicines Act: Improving the availability and securing supply of critical medicines in the EU - Public Health
- Other information: Critical medicines Act — Public Health — European Commission

Council

- Discussions ongoing in the Council Working Party
- General approach anticipated under Danish Presidency

Relevant information on the ongoing negotiations (2/2)

Parliament

- General overview: Carriages preview | Legislative Train Schedule
- European Parliament's Rapporteur Tomislav Sokol (EPP, SANT) presented his draft report on the Critical Medicines Act to the Committee on Public Health (July 2025), followed by more than one thousand amendments to the draft report tabled and published in October 2025.
- ENVI, ITRE and IMCO adopted opinions in November 2025. A vote in SANT committee is expected at the beginning of December 2025.

Interplay between the proposed pharmaceutical legislation and the proposed Critical Medicines Act

Regulation (EU) 2022/123 on EMA's role in crisis preparedness and response

Shortage management in preparation for and during crisis times

- Establishment of dedicated groups (MSSG and SPOC WP)
- Establishment of ESMP
- Supply and demand monitoring, Shortage management and mitigation for medicines on crisis specific lists

Proposed pharmaceutical legislation

Shortage management at all times and security of supply of critical medicines on Union list

- Early notification and shortage mitigation plans to support coordinated, EU level management of critical shortages, with targeted MSSG recommendations
- Establishment of Union List of critical medicines, identification of vulnerabilities in their supply chains and MSSG recommendations to support strengthening security of supply of those medicines

Structured dialogue

Methodology to identify critical medicines & consideration of the need for both regulatory and industrial policy measures to address supply chain vulnerabilities

Critical Medicines Alliance

Strategic Report informed drafting of Critical Medicines Act

Critical Medicines Act

Primarily industrial policy measures to support:

- Investment in EU manufacturing capacity
- Supply chain diversification and resilience
- Leveraging aggregated demand
- Covers critical medicines on the Union list, with and without vulnerabilities, but also for some provisions, 'medicines of common interest' in cases of market failure

Complementarity of the legislation intends to avoid duplication and minimise burden on all actors

MSSG: Medicines Shortages Steering Group; SPOC WP: Single point of contact WP; ESMP: European Shortages Monitoring Platform

Union list of critical medicines and vulnerability assessment

- Most measures apply to all **critical medicines on the Union list**, with some exceptions which require the **identification of supply chain vulnerabilities**:
  - 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 or MSSG recommendation issued
- Other measures relate to **medicines of common interest**

Critical Medicines Coordination Group

- Establishment of a Critical Medicines Coordination Group
- Composed of EC and Member States' representatives, EMA as observer
  - Member State members are responsible for ensuring national coordination
- Will work closely with EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), with joint meetings, where necessary
- Main tasks:
  - Facilitate coordination in the implementation of the Regulation and provide advise to EC
  - Facilitate coordination on strategic orientation of financial support for Strategic Projects
  - Enable exchanges, cooperation and coordination on public procurement policies
  - Facilitate discussion on collaborative procurement needs
  - Provide advice to MSSG on the order of priority for the vulnerability evaluation of critical medicines
  - Periodically discuss strategic partnerships and consistency and synergies between national, EU and international actions or cooperation

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 (1/3)

- 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 and 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

Strategic projects (2/3)

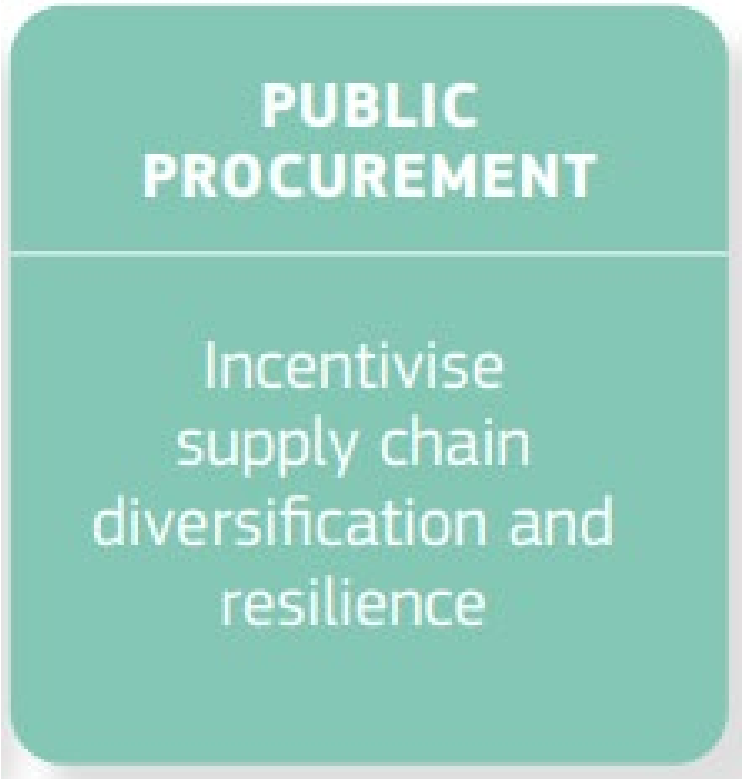
- Projects that create or increase **EU manufacturing capacity** for critical medicines, their active substances or key inputs; **modernise existing manufacturing sites or contribute to roll out of enabling technology** for critical medicines, their active substances or key inputs
- **Aim**: Ensure **prioritised EU supply** if financial support received
- **Benefits**:
  - **Decentralised approach for recognition at national level**
  - **Fast-track administrative procedures** (permit granting, coordinated or joint environmental assessment), in light of public interest
  - **Administrative, regulatory and scientific support** (at national level, including prioritised GMP inspections, and EMA scientific advice on innovative manufacturing processes)
  - **Facilitated financial support,** including through the STEP Seal

Strategic projects (2/3)

- **Financial incentives:**
  - **EU level: Funding opportunities under MFF (2021–2027)** strategic projects may be supported under e.g. EU4Health, Horizon Europe, Digital Europe Programme if requirements are met
  - **Legal Financial Digital Statement** of the proposal provides €80million for the period 2026–2027, under EU4Health
  - The proposal amends Regulation 2024/795 establishing **STEP** to support industry and boost investment in critical technologies (facilitates awarding of STEP sovereignty seal and access to shared management funds e.g. Cohesion funds)
- **Coordination** of financial support provided at national and EU level will be ensured by the Critical Medicines Coordination Group

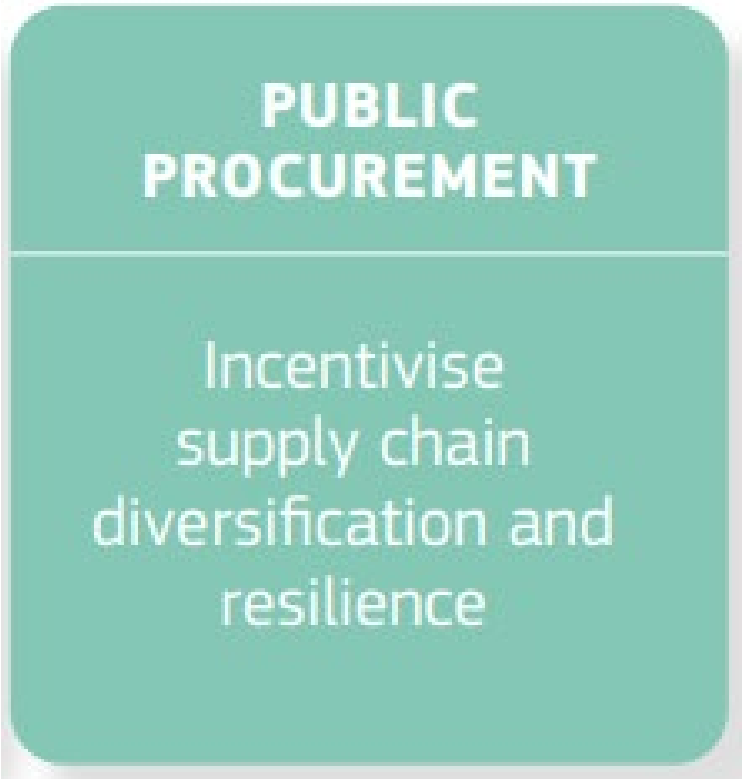
Public procurement (1/2)

- Contracting authorities obliged to use flexible procurement requirements other than price award criteria for critical medicines (e.g. award criteria, selection criteria, tender specifications, contract clauses)
    - Possible approaches: stockholding obligations, diversification of suppliers, contract performance clauses on timely delivery, monitoring of supply chains and their transparency to contracting authorities
- Obligation for procurers to favour EU production for specific critical medicines with high dependencies or when justified, possibility to favour EU production for other medicines of common interest

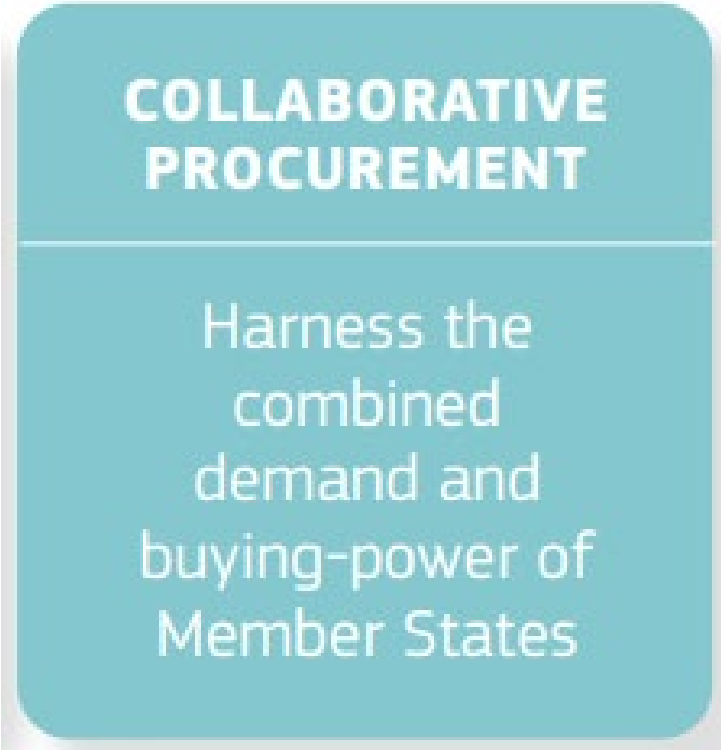


Public procurement (2/2)

- Member States to develop strategy (national programmes)
  - Covering procurement practices (incl. multi-winner approaches) and
  - possibly incorporating supply security requirements in pricing and reimbursement policies (e.g. for medicines not purchased by public procurement)
  - Notified to European Commission who distribute them to CMCG, to inform coordination and CMCG opinions
- Commission guidelines on procurement practices to support implementation of these measures
  - Build on best practices identified in cooperation of national competent authorities on pricing and reimbursement (NCAPR)



Collaborative procurement



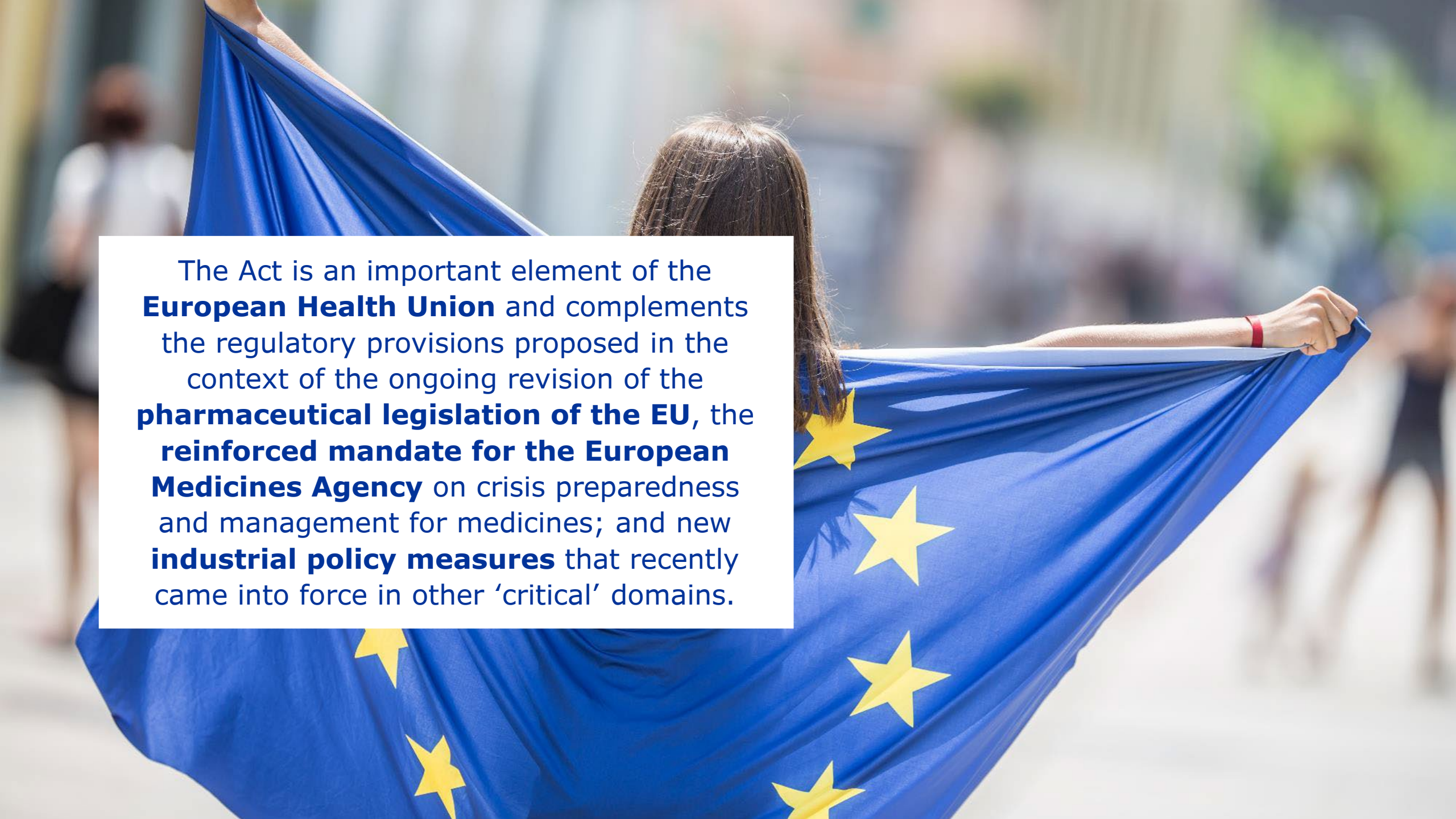
- Objective: to increase economies of scale, bargaining power and equal access to medicines
- Member States request support from the European Commission to use different tools of collaborative procurement, each subject to specific conditions and thresholds, and building on existing mechanisms:
  - **Member States' cross-border procurement** facilitated by the Commission *(available only for other medicines of common interest) [Art 39 Directive 2014/24/EU]*
  - **Commission procurement** on behalf or in the name of Member States [EU recast Financial Regulation sets out the general procedural framework in Article 168(3)]
  - **Joint procurement** by the Commission (lead) and Member States [EU recast Financial Regulation sets out the general procedural framework in Article 168(2)]

Contingency stocks

- **Safeguards** related to national measures on security of supply, in particular **contingency stock requirements**
- Contingency stock: obligations imposed by Member States on supply chain actors to hold buffer stocks of certain medicines to mitigate the risk of supply disruptions (SWD). To be distinguished from ‘stockpiling’ by a (public) health institution/ MS to anticipate and manage a specific crisis
- **Objective**:
  - **Avoid negative impact** of national measures on security of supply on other Member States
  - Member States to respect principles of **proportionality**, **transparency** and **solidarity**
  - **Commission guidelines** to support implementation, taking into account work and discussions in Pharmaceutical Committee
  - **Complementary** to measures foreseen in the **Proposed pharmaceutical legislation**
    - Implementing act to impose EU wide contingency stock requirements for critical medicines
    - MS reporting on measures

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



The Act is an important element of the **European Health Union** and complements the regulatory provisions proposed in the context of the ongoing revision of the **pharmaceutical legislation of the EU**, the **reinforced mandate for the European Medicines Agency** on crisis preparedness and management for medicines; and new **industrial policy measures** that recently came into force in other ‘critical’ domains.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

vanessa.bennett@ema.europa.eu

Follow us