Anti-D actions at EC/EMA – connection to CMA

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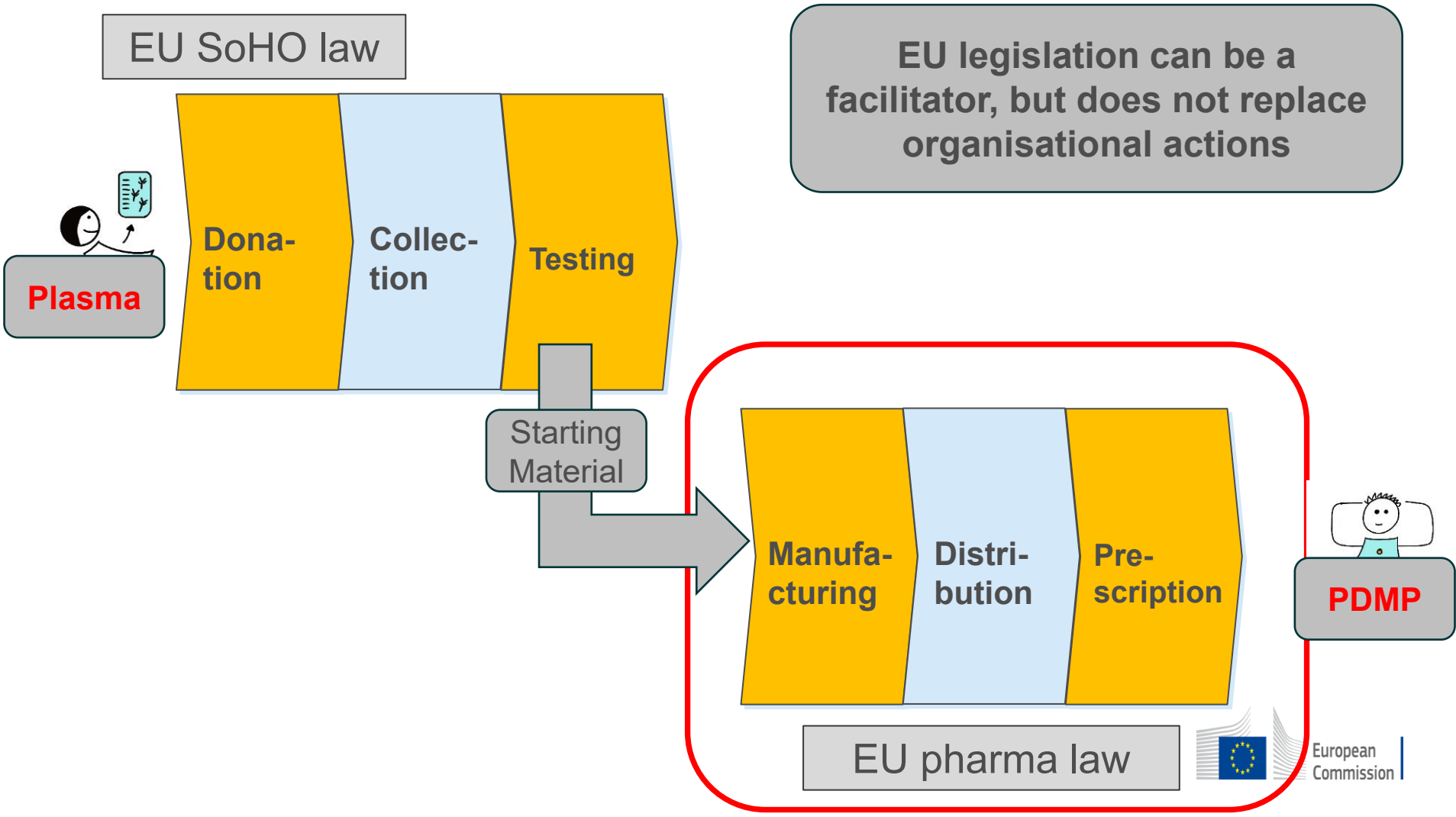
European Commission

First, take a step back – dual framework



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 June 2025
European Medicines Agency
EMA/135603/2025

Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products to address anti-D immunoglobulin supply chain vulnerabilities

1. Introduction

Human anti-D immunoglobulin (anti-D Ig) medicinal products are currently the only available prophylactic medicine in Europe used for the prevention of Rhesus D (RhD) immunisation in pregnant women. RhD immunisation may occur during pregnancy of a RhD-negative woman with a RhD positive foetus where antibodies directed against red cell surface antigens may be developed. These allo-

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Key vulnerabilities

- Limited number of immunized donors and decline in pool of existing donors (hyperimmunization may be necessary)
- Challenges related to collection, manufacturing and pooling of small plasma batches
- Global supply capacity constraints with a limited number of MAH and centers collecting plasma for manufacturing anit-D IgG
- High dependency on countries outside EU/EEA for plasma supply to manufacture anti-D IgG and finish plasma derived anti-D MP

➔ Requiring **long-term multi-factorial** policy measures

Efforts to come from all actors around and across the donor-recipient supply chain

EC/EDQM plasma symposium 2019

- **European Commission** (donor protection and vigilance, awareness building on need for collection, support strategic independence, optimize legal framework, …)
- **EDQM** (Council of Europe) (data reporting, awareness building evidence based guidance, networking and conference on optimal use)
- Member States/National Competent **Authorities** (national targets for collection, monitor/report, contingency plans, donor vigilance)
- **Blood Establishments** (increase collection, donor safety, good practice exchange)
- **Manufacturers** (Collaboration on optimal use, data and knowledge sharing (SARE, best practice, decision support)
- **Associations/Societies** of patients, donors and professionals (awareness building, optimal use, good practice)

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Need for comprehensive end-to-end actions, operational, not just legal (SUPPLY action EU4H)

- Improve organisational efficiency (public sector)

Dona-tion | **Collec-tion** | **Testing**

- Public awareness building
- Donor recruitment and retention
- …

- Coherence requirements
- Allocation (e.g., toll/contract manufacturing)
- …

- On/off-label use,
- Central approval system
- Prioritisation schemes
- …

Manu-facture | **Distri-bute** | **Pre-scribe**

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MSSG recommendations – for Member States

- Develop Action Plans:
  - Assessing clinical need
  - Optimize pre-natal screening to avoid unnecessary use
  - Anti-D collection programmes
  - Consider existing good practices
  - Consider plasma ownership and contract manufacturing
  - Facilitate cross-sector cooperation
- Ensure high-quality (high titre) plasma while ensuring donor protection
- Safeguard fractionation/manufacturing capacity (for/in the EU)
- Fund development of alternatives to anti-D and new solutions for supply vulnerabilities
- Prioritization of use – Union-level prioritization plan (MSSG)
- Inform SPOC of critical shortages
- Awareness building for plasma (anti-D) collection and utilisation

MSSG recommendations – for European Commission

- Support MS for effective plasma collection - considering **strategic projects** in Critical Medicines Act
- Cooperation between stakeholders and NCA, ensuring cross-sector coherence
- Support MS to optimize use and to have action plans for collection and for pooling/manufacturing (across Member States) - consider **joint procurement** Critical Medicines Act
- Support funding for development of anti-D alternative and innovative solutions for supply vulnerabilities

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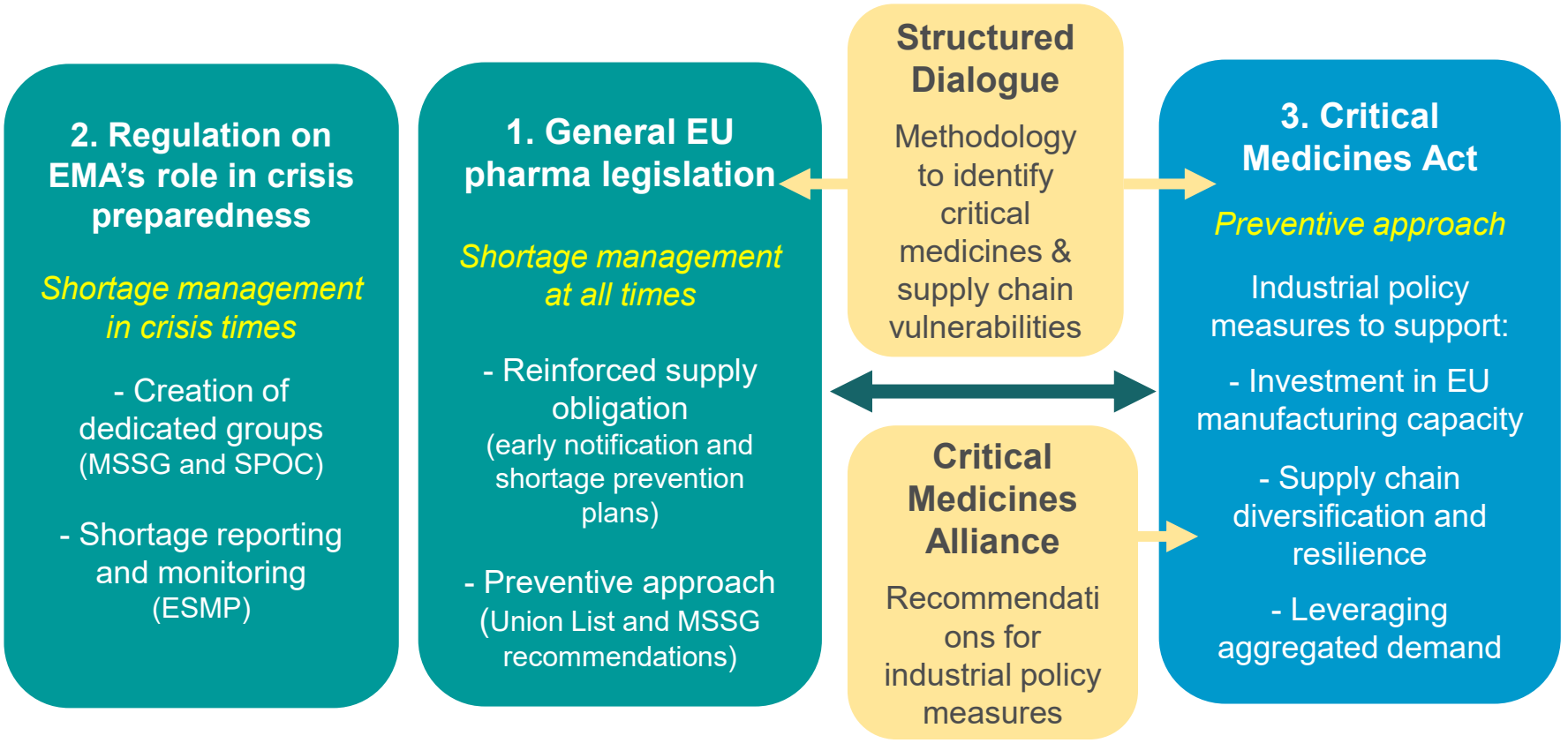
MSSG recommendations – for plasma industry and research organisations

- Ensure appropriate/sufficient fractionation/manufacturing capacity
- Invest in development to alternatives for anti-D and in innovative solutions for supply vulernatbilities
- Collaborate with MS and COM for effective plasma collection and use. Provide relevant data

Comprehensive approach to ensure availability of critical medicines



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Getting the target right…

1. Union List of critical medicines

1. Ensuring medicines considered to be most **critical for health systems** are available at all times.

2. Critical medicines may be subject to coordinated Union level actions to **improve security of supply** following vulnerability analysis.

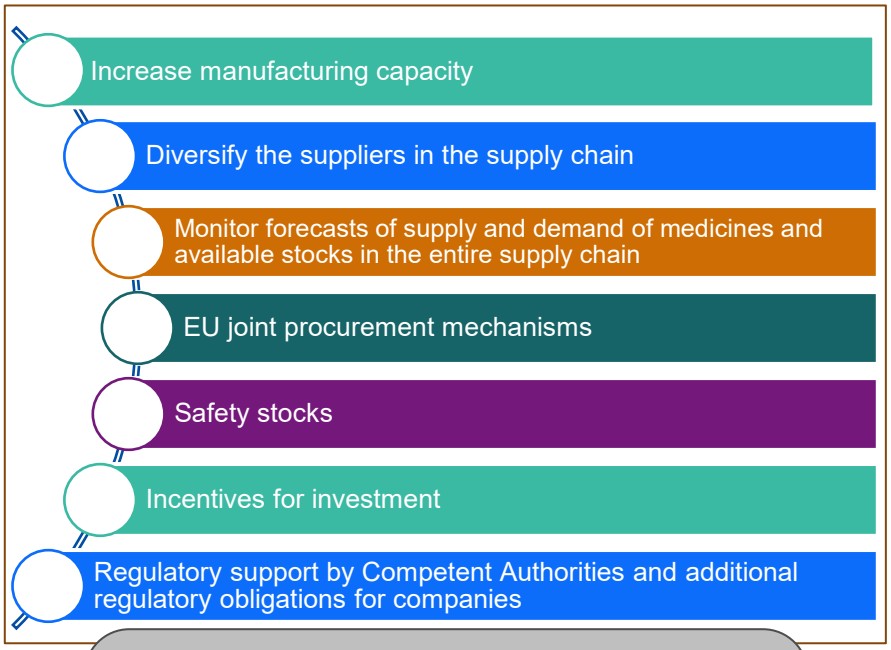
3. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

4. **Recommendations to Industry** on *"diversification of suppliers and inventory management"*

Current list includes, amongst others: normal Ig (IV and SC), Anti-D Ig, tetanus Ig and rabies Ig

[First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU | European Medicines Agency (EMA)]

2. Strengthening supply chains of critical medicinal products



Under leadership of…

- EMA/HMA
- MSSG
- SPOC

[MSSG recommendations to strengthen supply chains of critical medicinal products]

2. EMA's roles in critical shortages of medicines

International cooperation

Global Regulatory Working Group on Drug Shortages

- Meets every quarter and share information about relevant drug supply issues (exchange of information and support each other)
- International cooperation on Drug Shortage Reporting, Signal Detection and Signal Assessment
- International cooperation and alignment on shortage mitigation and prevention strategies

Bilateral exchanges with e.g. FDA, HC, TGA, etc

- Shortages of concern to both regions
- Exchanges of best practices to mitigate and prevent shortages

MSSG Solidarity Mechanism

The VSM is used as a **last resort** to **temporarily alleviate critical shortages in a Member State**.

Allows a MS to **request assistance** from other Member States in obtaining stocks of a medicine **during critical shortages**

>10 VSM procedures concluded, all successfully

Conditions:

1. EMA already notified of the shortage (SPOC WP)
2. No or insufficient therapeutic alternatives available
3. Insufficient quantifies to treat critical indications
4. No or insufficient relief from short-term measures
5. Urgency (e.g., < 1 month supply)

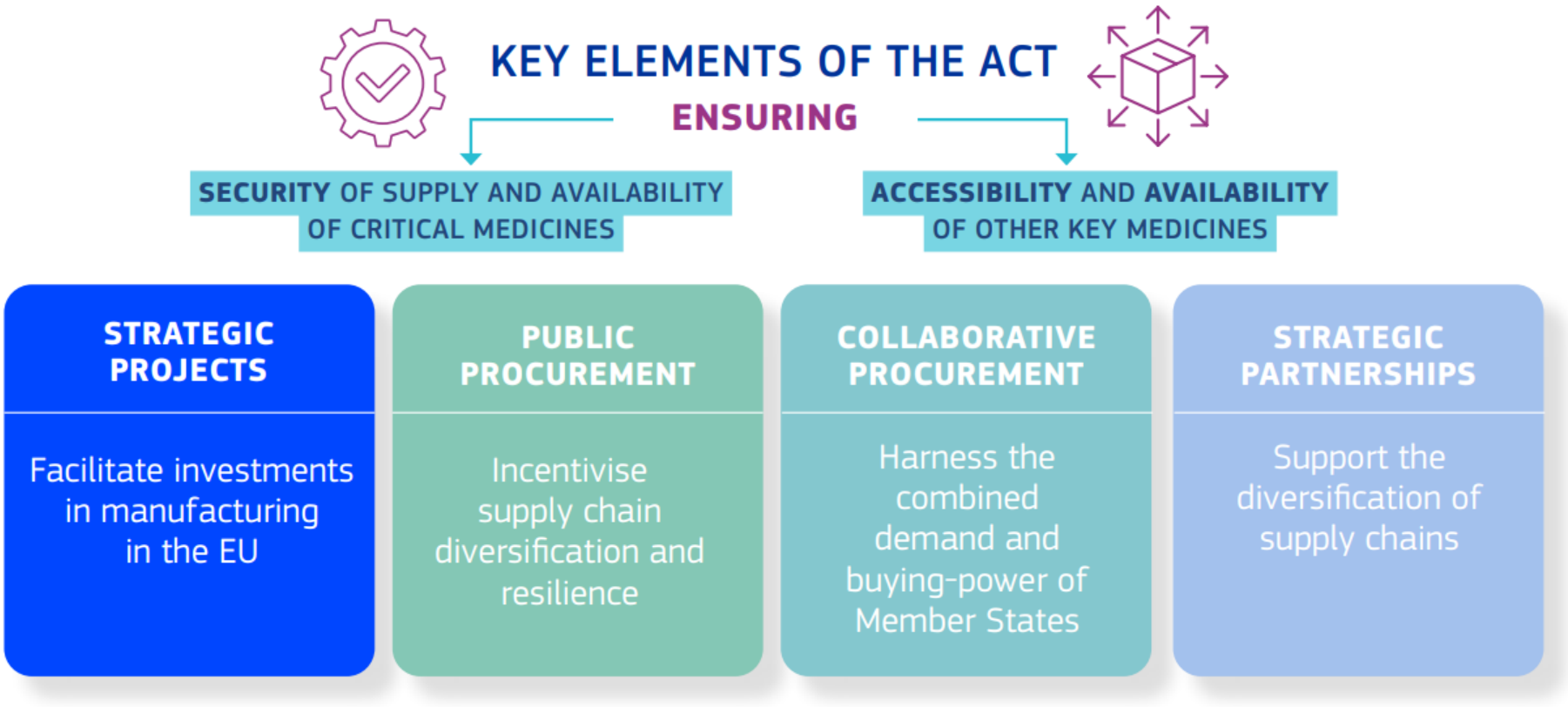
MSSG Solidarity mechanism process (europa.eu)

MSSG Toolkit

- Labelling exemptions
- Extension of shelf life
- Accelerating supply-critical variations
- Liaison with EDQM (CEP acceleration)

MSSG recommendations toolkit (europa.eu)

3. Critical Medicines Act



- COM Proposal in March 2025 – in Trilogue EP/Council/COM
- Entails an industrial policy, and complements Pharma Reform
- EMA, MSSG's and SPOC roles

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Strategic projects

- Projects that create, increase or modernise **EU manufacturing capacity** of critical medicines, their active substances and other key inputs
- Recognition at Member States' level (lean, decentralised approach)
- 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
- Obligation: **Prioritise EU supply** if received financial support
- [14] **State aid Guidance** to assist Member States
- Exchanges and coordination *via* Critical Medicines Group

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

Thank you

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