EMA Extended mandate

Industry vision towards implementation

Multi-stakeholder Workshop on EMA's extended mandate 1st April

efpia
European Federation of Pharmaceutical Industries and Associations

medicines for europe
better access. better health.

AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

EuropaBio®
The European Association for Bioindustries

Vaccines Europe
An industry for healthy lives

What is the added value/ your expectations on the new legislation?

New legislation on EMA extended mandate will create the framework to:

- Increase and improve the
  - **ability and agility to respond to shortages and health crisis** via improved data-sharing among regulators and industry
  - **efficiency and predictability** during public health emergencies and major events, accelerating the decision-making process while avoiding duplication of efforts and unjustified *burdens on stakeholders*. (Recital 20)
  - **coordination and collaboration with MAHs**
  - **data quality and data-sharing for an appropriate data mining** from regulators (SPOC – iSPOC lessons learned)
  - **increase availability and facilitate reallocation of medicines where needed** (electronic leaflet, Regulatory flexibility)
- **An EU Coordinated and funded project to harmonised implementation of European Shortages Monitoring platform** (ESMP) harmonised/timely manner across all Member States

What are the main challenges in implementation?

Challenges

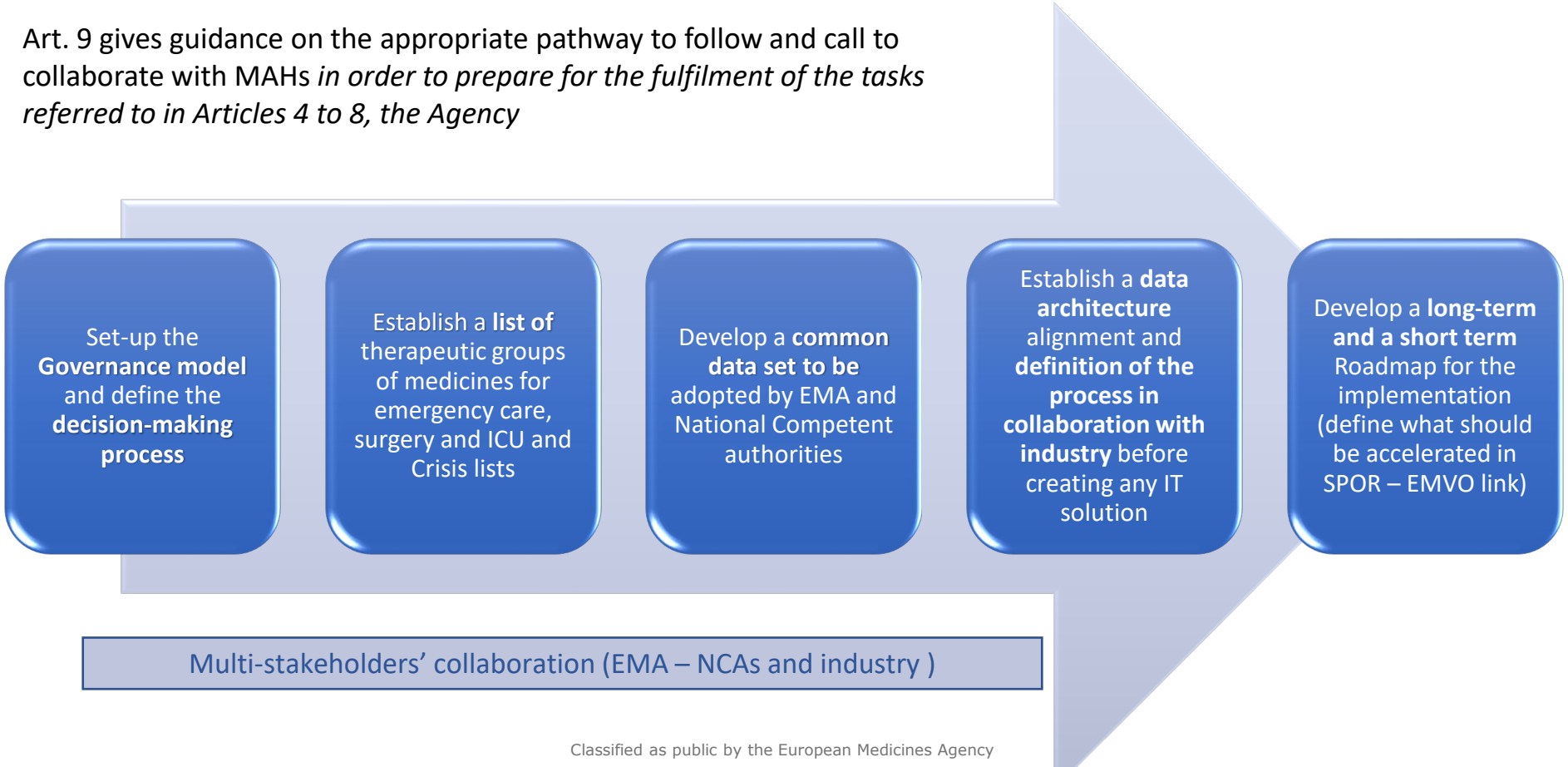
- **Fragmented implementation between EU and National reporting systems** and duplication of submissions of same data
- Develop an **IT solution** that is not based on the **business process** it should serve
- Achieve **interoperability**

Recommendations

- Clear **Governance and decision-making process** to assign responsibility for implementation at EU and national level
- Roadmaps for implementation with realistic deadlines for each building block
- **Interoperability by design** (with SPOR and EMVS -Rx) and develop the platform along the **related business process**
- Map available data source (SPOR) and align with industry on **Data architecture** and **process definition** before creating any IT solution
- Contract the strategic-design and implementation to IT provider
- National reporting into one common data-base where data will be accessible to both EMA and NCAs - centralised data maintenance (update)
- Define the business process, rules for data-access and engagement in remediation: clear design of how the system will be used before the start to maximize the benefits

What should the priorities be for implementation?

Art. 9 gives guidance on the appropriate pathway to follow and call to collaborate with MAHs *in order to prepare for the fulfilment of the tasks referred to in Articles 4 to 8, the Agency*



How stakeholders should be involved?

- Regular dialogue between the Executive Steering Group on Shortages and Safety of Medicinal Products and trade associations for the preparation of the critical medicines lists to be annually updated and the 'major event critical medicines list' (art 8) while complying with Competition law; **Critical Medicines list Group** to be established

- Industry to collaborate in designing **how to extract the maximum benefit from the future available information at EU level** so to prevent, address and remediate shortages;

- **ESMP steering group** to be established under the governance of the MSSG to lead on the strategic design and implementation plan. Industry to be part of the group from now to 2025.

- **Collaboration with industry** to rapidly align regulator-industry on corrective measures; **EMA Mitigation Department to coordinate and** work with parties (NCAs and industry representatives in mitigation actions (as established in some NCAs)