



Critical Medicines Act and other relevant EU-level updates

PPRI Network meeting 8 April 2025

François Janssens, Unit D2
DG SANTE, European Commission

Context

MISSION LETTER

Brussels, 17 September 2024

Ursula von der Leyen
President of the European Commission

Olivér Várhelyi

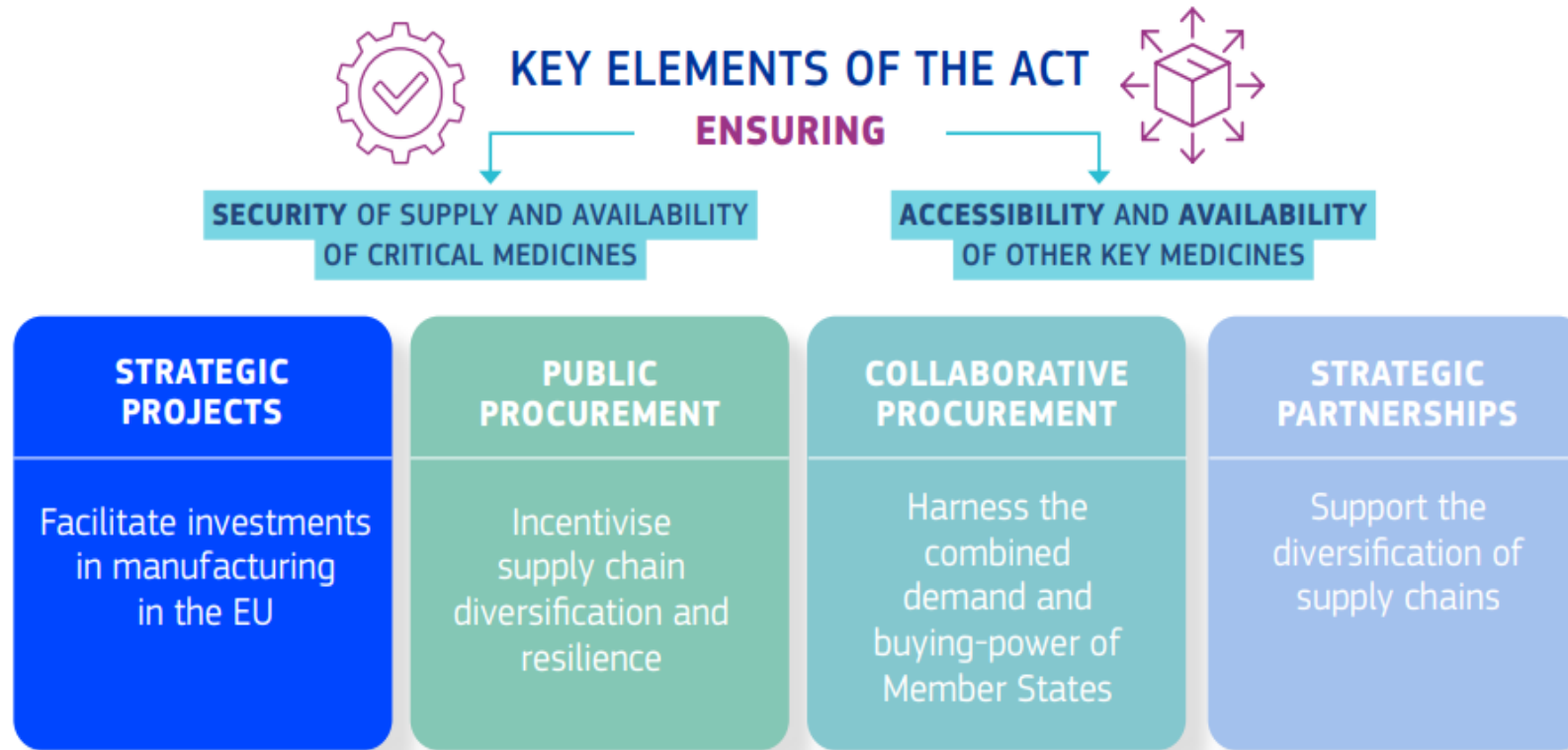


I would like to entrust you with the role of Commissioner for Health and Animal Welfare.

You will focus on **completing the European Health Union**, by further diversifying supply chains, improving access to the most advanced treatments, boosting the competitiveness, resilience and security of health systems and working on strategic inventories.

- You will propose a **Critical Medicines Act** to address the severe shortages of medicines and medical devices and reduce dependencies relating to critical medicines and ingredients, as well as to ensure the supply of affordable medicines.
- Europe needs a strong, competitive, and innovative pharmaceutical sector. You will lead efforts to support the European Parliament and the Council to conclude work on the **pharmaceuticals** reform and follow up on its implementation.
- I would like you to lead the work on a new **European Biotech Act**, focusing on the need for a regulatory environment conducive to innovation in areas of health technology assessment, clinical trials and others.
- You should work to complete the **European Health Data Space**. You will promote the uptake of artificial intelligence, notably through clear and timely guidance on its use in the lifecycle of medicines. You will make proposals to **scale up genome sequencing capacities**.

Critical Medicines Act



- Status: adopted by EC 11 March 2025
- Link: [Critical medicines Act - European Commission](#)

Other relevant EU-level updates

- [European Health Data Space Regulation \(EHDS\) - European Commission](#)
→ entered into force March 2025 (general framework application March 2029)
- [Reform of the EU pharmaceutical legislation - European Commission](#)
→ at the level of the co-legislators
- [Towards a Strategy for European Life Sciences - European Commission](#)
→ EC adoption planned for Q2 2025 (call for evidence open)
- [Actions to boost biotechnology and biomanufacturing in EU](#)
→ EC adoption of Biotech Act foreseen in 2026
- [Public procurement directives – evaluation](#)
→ EC adoption planned for Q4 2026