Pharmaceutical Strategy for Europe

Directorate General for Health and Food Safety

Pharmaceutical Strategy for Europe

- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs

European Commission

Flagships of the pharmaceutical strategy

Ensure access and affordability of medicines for patients and health systems sustainability

Enabling sustainable innovation

Ensuring availability and addressing shortages

Succeeding on the global level

European Commission

Flagships of the pharmaceutical strategy

Ensure access and affordability of medicines for patients and health systems sustainability

Unmet needs

- Collaboration on unmet needs **evidence generation** , **HTA** (2021)
- Boost **novel antibiotics** - 2021
- Restrict and optimise the **use** of antimicrobial medicines (2021)
- Support medicines for **children and rare diseases** (2022)

Accessibility

- Revise the **system of incentives and obligations** in legislation to support innovation, access and the affordability of medicines (2022)
- Improve access to **generic and biosimilar medicines** (2022)

Affordability

- Address in legislation the **market effects** impacting on affordability (2022)
- Develop **mutual learning and best-practice exchange** on pricing, payment and procurement policies (2021-2024)

Flagships of the pharmaceutical strategy

Enabling sustainable innovation

Fertile environment

- Optimise the **supplementary protection certificates system** (2022)
- Legislative proposal on **European Health Data Space** (2021)
- **Interoperable data access infrastructure** to facilitate secure cross-border analysis of health data (2021-2025)
- Support **public-private and public-public partnerships** (2021)

Innovation and digital transformation

- Adapt legislation to **cutting-edge products, scientific developments** and transformations (2022)
- **Enhance dialogue** among regulatory and other relevant authorities (2021)
- Take forward the use of **HPC and AI** (2021-2022)
- Establish the secure federated access to 10 million **genomes** (2025)

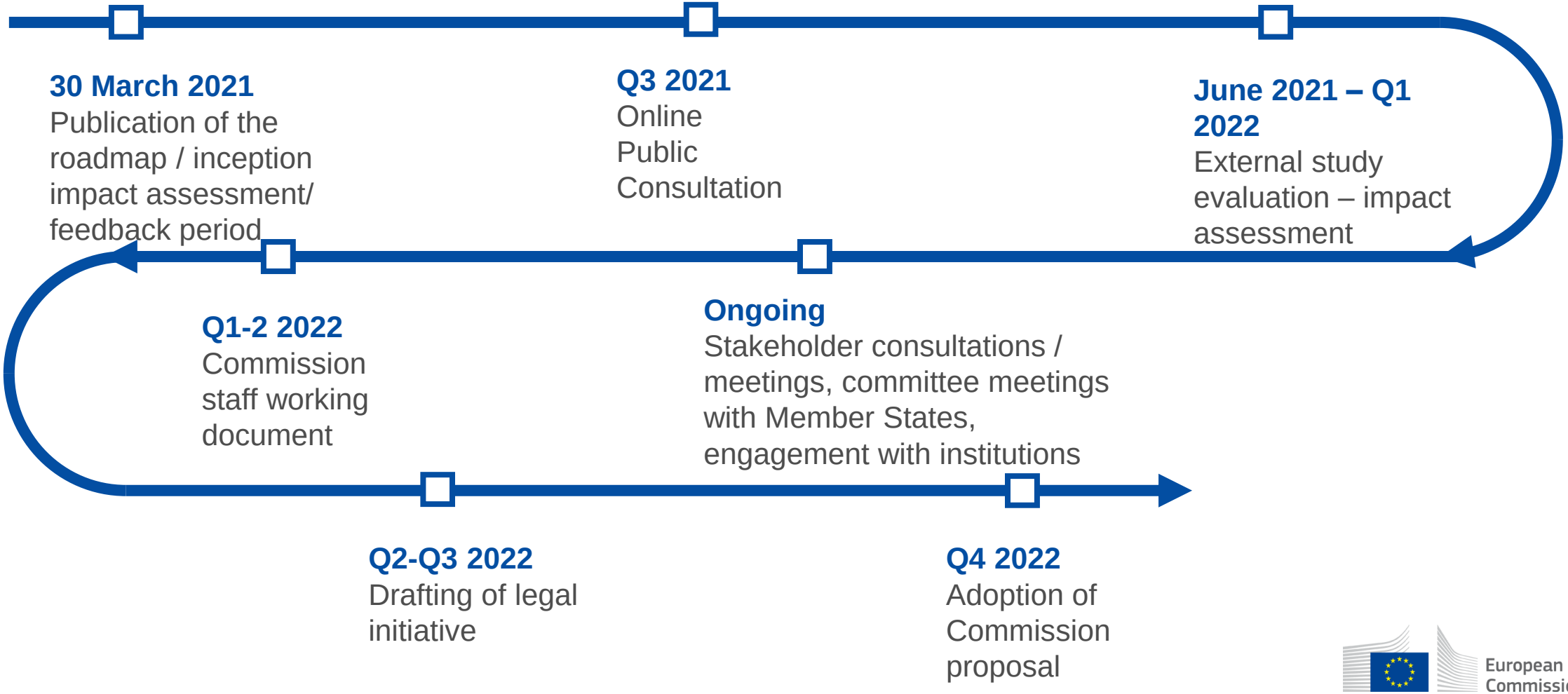
Flexible regulatory system

- **Simplification and streamlining** of approval procedures and flexibility for timely adaptation (2022)
- **Optimise the lifecycle management of medicines** more efficient and adapted to digitalisation (2021-2023)

Main legislative agenda

- HTA proposal – adoption of Council position 2021
- Creation of a Health Emergency Response Authority (HERA) – 2021
- Implementation of the clinical trials framework - 2021
- Proposal for a European Health Data Space – 2021
- Revision of the basic pharmaceutical acts: Dir. 2001/83/EC & Reg. (EC) No 726/2004 – 2022
  - Incl. revision of the variations framework
- Revision of the orphan and paediatric legislation – 2022
- Intellectual Property Action Plan – 2022

Revision of basic pharmaceutical acts indicative timeline



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Implementation: meetings and workshops

- Thematic workshops March to June 2021 (active participation of regulators, HTA authorities, pricing and reimbursement bodies)
- PT Presidency AAA conference April
- Extended Pharmaceutical Committee meeting May
- SI Presidency - Joint meeting of Directors for Pharmaceutical Policy and pharmaceutical committee 8-9 July

Key messages relevant to HTA

- The concept of **unmet medical need** can be a vehicle for prioritising innovation and access in certain treatments. A common definition or principle based approach (regulators, HTA and P&R) will not be easy.

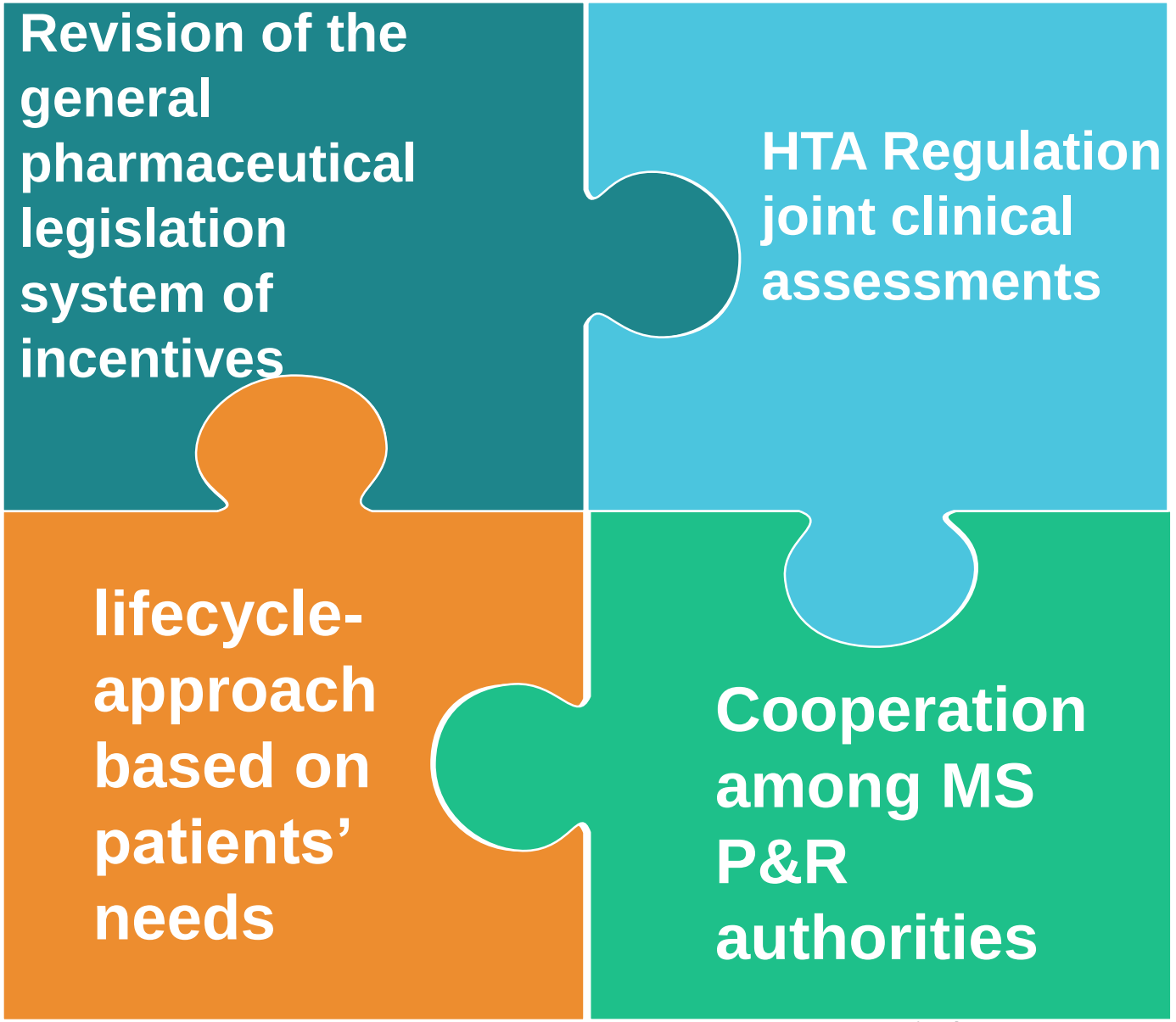
- **Promote innovation with real added value** to patients, including through repurposing of medicines.

- A coordinated **very early alignment of research** with **patients' needs, health technology assessment and reimbursement possibilities** (health systems' willingness to pay) would avoid duplication of work and would send a message to companies where to focus their efforts.

How to deliver

QUESTION:

With the HTA Regulation close to adoption, what policy developments are necessary in terms of pharmaceutical incentives and in cooperation among MS P&R authorities so that the new EU HTA mechanism can reach its full potential?



Thank you

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