Reunião Anual do Colégio de Especialidade de Assuntos Regulamentares
Ordem dos Farmacêuticos - 13 Maio 2021

Pharmaceutical Strategy for Europe

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Mission letter Csser Kyriakides

- *Help ensure Europe has the **supply of affordable medicines** to meet its needs and **support the European Pharmaceutical industry** to ensure that it remains an **innovator and world leader**.*

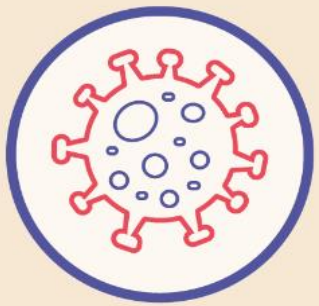
- *I want you to work on the **creation of a European Health Data Space** to **promote health-data exchange and support research** on **new preventive strategies**, as well as on **treatments, medicines, medical devices and outcomes**. As part of this, you should ensure **citizens** have **control** over their own **personal data**.*

A holistic approach covering the full lifecycle of medicines

- Research & Development
- Innovation
- Clinical Trials
- Digital & data
- Advanced therapies
- IP/incentives
- Pharma legislation
- Health technology assessment
- …

- Market function
- Procurement
- Manufacturing
- Generics, biosimilars, APIs
- Supply chains
- Environment
- Competition policy
- Trade
- …

PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from COVID-19, towards a crisis-resistant system

Ensuring accessibility and affordability of medicines

Supporting sustainable innovation, emerging science and digitalisation

Reducing medicines shortages and securing strategic autonomy

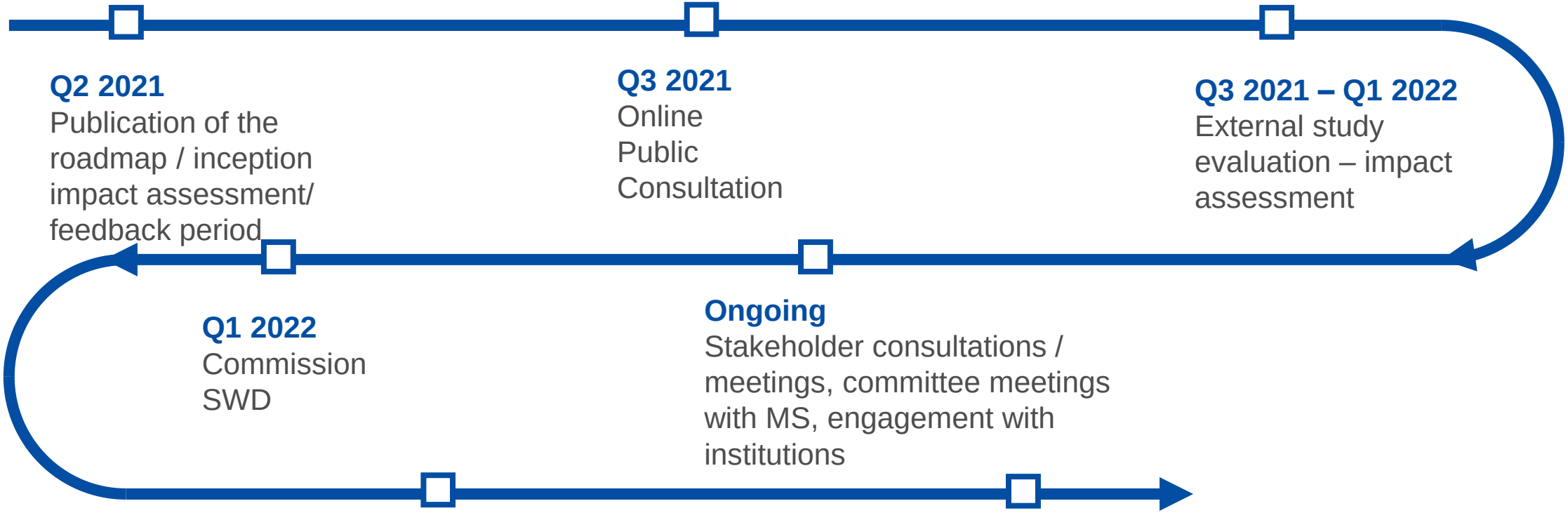
#EUPharmaStrategy

European Commission

Main legislative agenda

- Revision of the basic pharmaceutical acts: Dir. 2001/83/EC & Reg. (EC) No 726/2004 – 2022
  - Incl. revision of the variations framework - 2023
- Revision of the orphan and paediatric legislation – 2022
- Health Technology Assessment proposal - ongoing
- Creation of a Health Emergency Response Authority (HERA) – 2021
- Implementation of the clinical trials framework - 2021
- Intellectual Property Action Plan – 2022
- Proposal for a European Health Data Space – 2021

Revision of basic pharmaceutical acts indicative timeline



European Commission

Innovation and Digitalisation I

- Propose to revise the pharmaceutical legislation, to adapt to cutting-edge products, scientific developments (e.g. genomics or personalised medicine) and technological transformation (e.g. data analytics and digital tools) and provide tailored incentives for innovation – 2022.

- Enhance dialogue among regulatory and other relevant authorities in the area of medicines and medical devices to increase cooperation on evidence generation within their respective fields – 2021.

- Develop and implement electronic product information (ePI) for all EU medicines with involvement of Member States and industry, evaluate and revise relevant provisions in the legislation – 2022.

Innovation and Digitalisation II

- Legislative proposal on a European Health Data Space, enabling better healthcare, health research, innovation and evidence-based decisions – 2021.

- Establish by 2025 interoperable data access infrastructure for the European Health Data Space in order to facilitate secure cross-border analysis of health data; tested in 2021 with a pilot project involving EMA and national authorities – 2021 – 2025.

Strengthening the Network

• The Pharmaceutical Strategy and the European Health Data Space cannot be implemented without the commitment from Member States. This requires supporting NCAs dealing with primary and secondary use of health data, but also investments in data quality and digital infrastructure.

• The Multiannual Financial Framework, including EU4Health and other funding instruments, together with the Recovery and Resilience Facility, offer valuable opportunities for MSs' digital transformation, incl. on infrastructure and training needs.

Collaboration in the implementation phase

Channelled through existing structures:

- **Pharmaceutical Committee** will be the main forum for discussion with Member States
  - Possibility to use ***ad-hoc working groups,*** currently there are three: market launch, pharmaceuticals in the environment and supply chain.
  - Possibility for ***joint sessions*** with other committees on cross-cutting issues
    - pricing and reimbursement, health technology assessment, clinical trials etc.)
  - Extendable to ***stakeholders***
- **Safe and Timely Access to Medicines for Patients** expert group (STAMP) for more technical discussions
- Meetings of Directors responsible for pharmaceutical policy
- Ad-hoc events (e.g. conferences, workshops)

Thank you

European Commission
Public Health information:
http://ec.europa.eu/health/index_en.htm

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https://ec.europa.eu/health/human-use/strategy_en

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