DIA EUROPE 2021

Pharmaceutical Strategy for Europe

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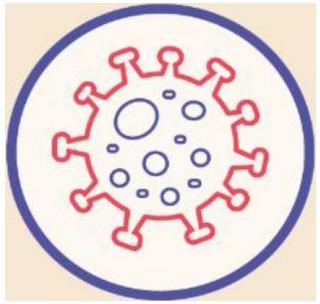
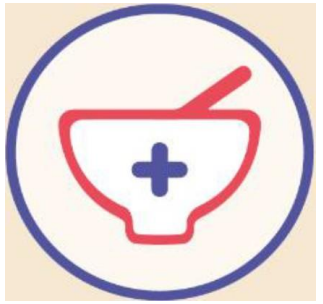
PHARMACEUTICAL STRATEGY FOR EUROPE



Learning fram 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

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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
- Revision of the orphan and paediatric legislation – 2022
- HTA 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

Access to medicines

- Initiate a pilot together with the EMA and Member States, with the engagement of future marketing authorisation holders, to understand the root causes of deferred market launches – 2021.

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

- Initiative for regulatory pilots in a ‘sandbox’ environment provided by the EMA and the Commission to test the adaptability of the pharmaceuticals framework for new cutting-edge product developments – 2022.

Thank you

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

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European Commission