DIA EUROPE 2021

Pharmaceutical Strategy for Europe

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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
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

Q2 2021
Publication of the roadmap / inception impact assessment/feedback period

Q3 2021
Online Public Consultation

Q3 2021 – Q1 2022
External study evaluation – impact assessment

Q1 2022
Commission SWD

Q2-Q3 2022
Drafting of legal initiative

Ongoing
Stakeholder consultations / meetings, committee meetings with MS, engagement with institutions

Q4 2022
Adoption of Commission proposal
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

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

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