



Pharmaceutical Strategy for Europe

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A pharmaceutical strategy for Europe -Why?

Inadequate patient access to and affordability of new medicines, shortages of approved medicines and health system sustainability at risk

Possible limitations of the regulatory framework to enable need-driven innovation in light of technological and scientific developments

EU's competitive position as innovator may be challenged and growing dependency on non-EU countries





Mission letter

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

2016: innovation & access to innovative products for unmet needs and the financial sustainability of health systems

2019: EPSCO conclusions on access to pharmaceuticals through a lifecycle approach

2017: resolution on possible EU options for improving access to medicines

2018: resolution on AMR

2020: own initiative report (ENVI) on shortages

Pillars of the strategy

Ensuring
access and
availability
addressing
shortages

Ensure
affordability of
medicines for
patients and
health systems
sustainability

Enabling
sustainable
innovation

Succeeding on
the global level

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



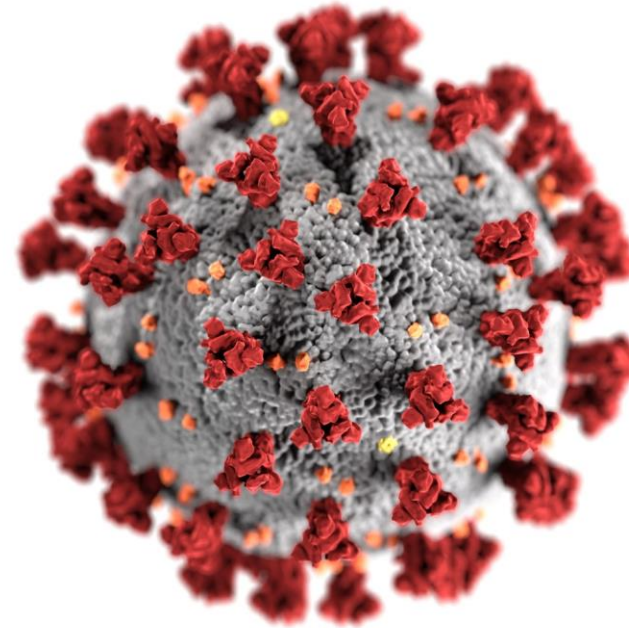
Reducing medicines
shortages and
securing strategic
autonomy

#EUPharmaStrategy

Aspects highlighted by COVID-19

**Crisis
management and
preparedness**

**Dependency
on APIs**

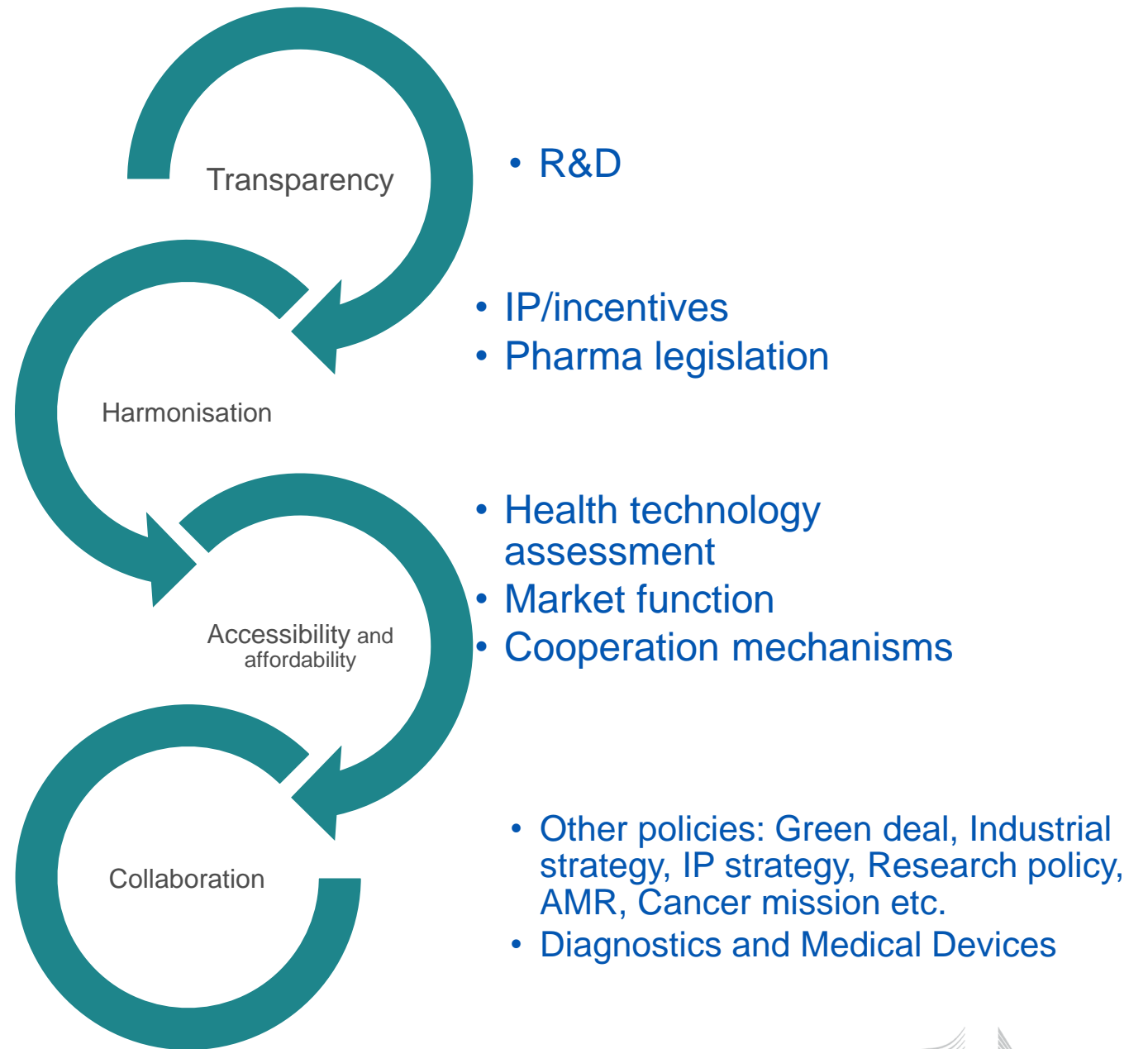


Shortages

**International
aspects**

Innovation

Holistic approach
(across policies, across DGs,
at national and EU level)



Public consultation

Feedback to the ROADMAP: Key points

Industry

- Need for funding for R&D in early stages of drug development
- Stable regulatory environment, flexibility where needed
- Use of RWD and RWE in clinical development and regulation
- Role of a European Health Data Space and pan-European clinical trial networks
- Off-patent sector: emphasis on competition, procurement criteria, IP

Healthcare stakeholders

- Increase availability of medicines especially for unmet needs
- Promote the use of digital tools (e.g. ePI, smart prescriptions, digital medical records)
- Measures to monitor/prevent shortages
- An EU approach to repurposing of medicines
- Environmental concerns

Public authorities

- Measures to monitor/prevent shortages and diversify supply
- Measures to support affordability, access to medicines and financial sustainability of health systems
- Address medical devices incl. in vitro

Civil Society Organisations

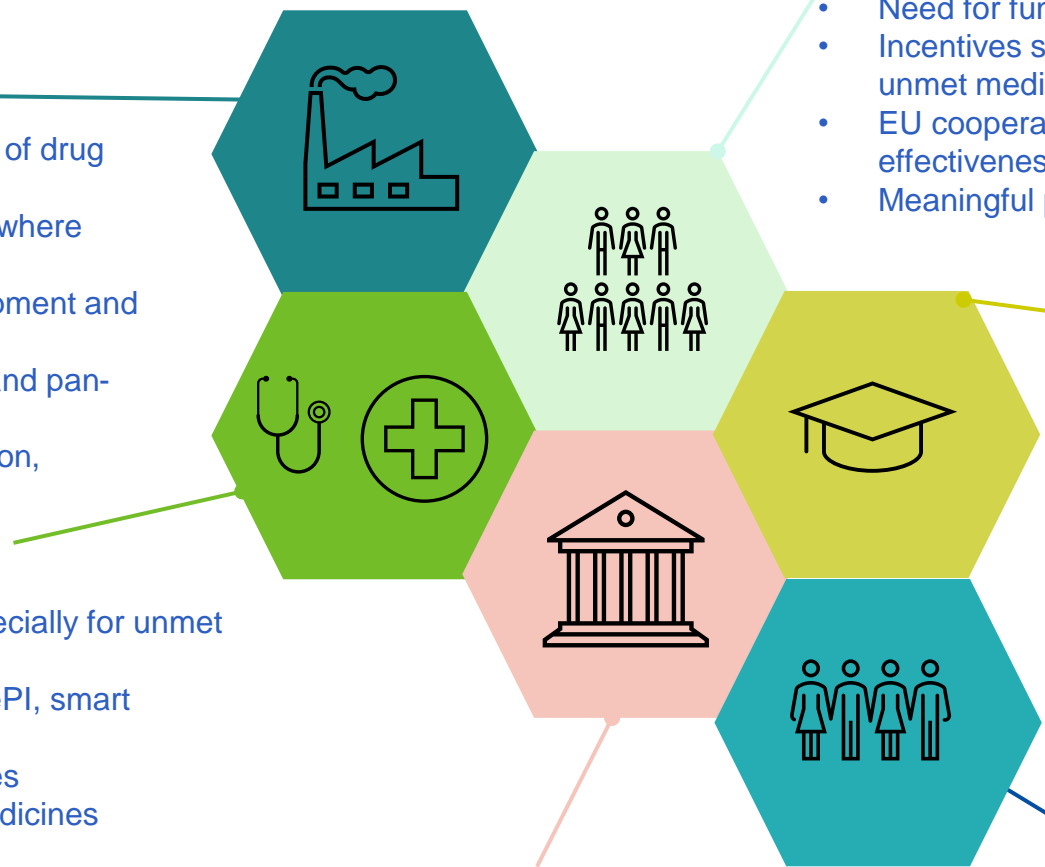
- Need for funding and R&D
- Incentives should improve availability of treatments to address unmet medical need
- EU cooperation on affordability, assessment of value, cost effectiveness, P&R, procurement
- Meaningful patient involvement in setting research priorities

Researchers, academia and learned societies

- Cooperation with industry at early stages of R&D
- Promote upskilling & education
- Emphasize patients needs at the centre of drug development

EU citizens & others

- Measures needed on availability of medicines and tackle high prices
- Measures to monitor/prevent shortages and diversify supply
- Competitiveness and environmental concerns



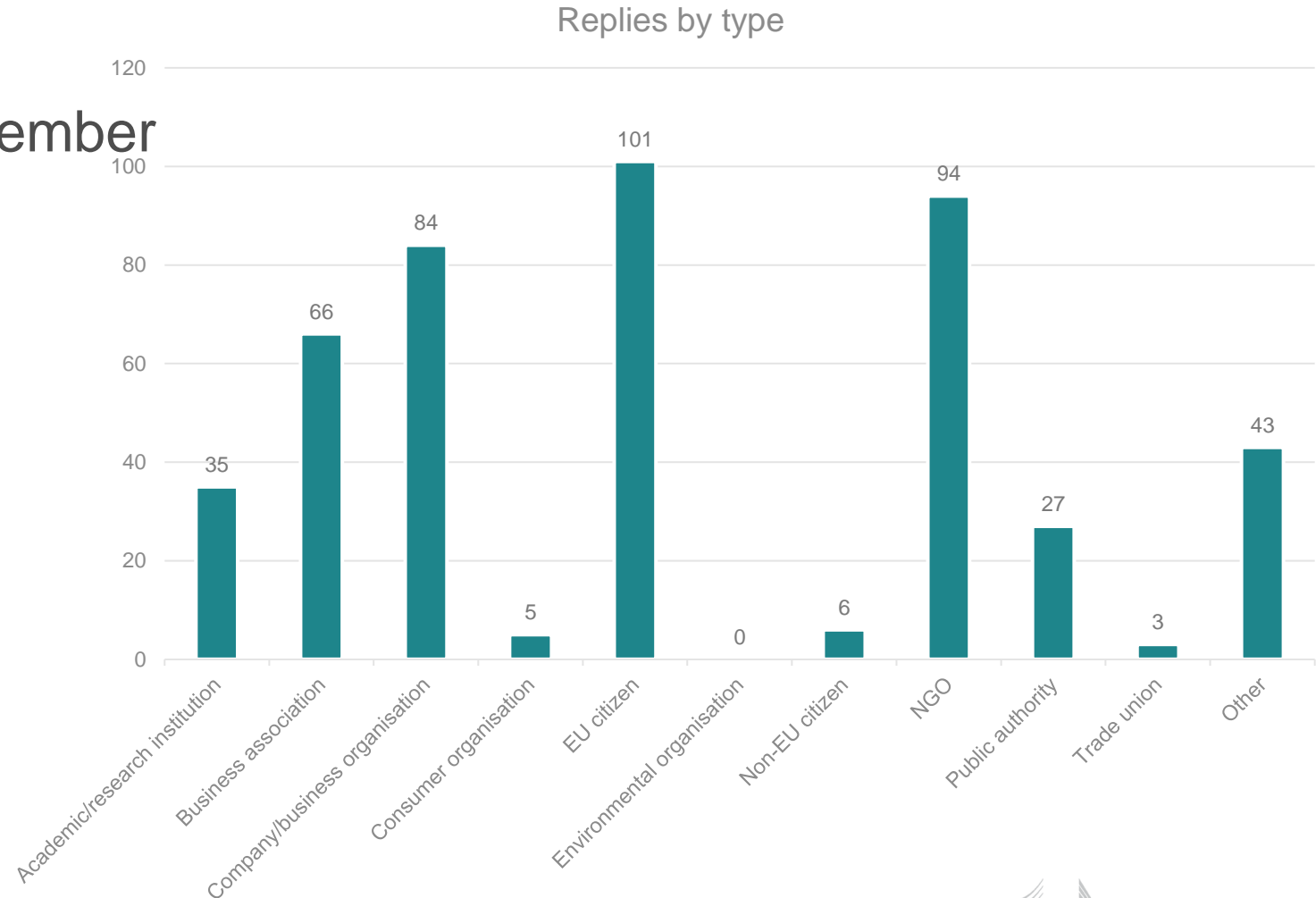
July workshop

Key points

- General support for the roadmap
- Different views as regards what is “unmet need”, reasons for non-availability of medicines, the role of incentives
- Call for regulatory flexibility, adaptation of legislation to digital
- Call for measures on EU dependency on 3rd countries, shortages
- Call for exchange of best practices on procurement /P&R

Online Public Consultation (basic data)

- Deadline closed on 15 September
- 464 replies
- 21% SMEs
- Analysis by early October



Actions and next steps

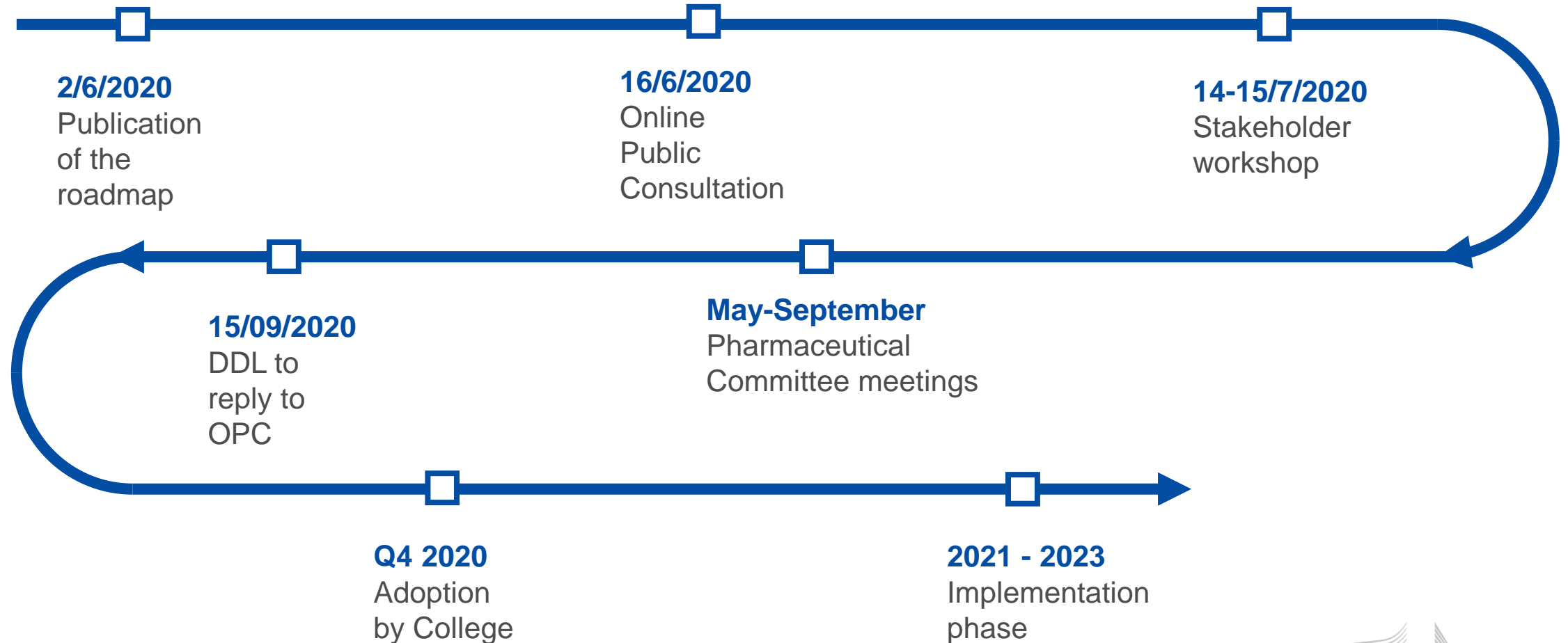
Objectives for possible action

- Sound and efficient regulatory system
- Enable innovation and digital transformation
- Prioritise unmet medical needs
- Ensure accessibility of medicines for patients
- Secure supply of medicines, avoid shortages
- Ensure affordability and health systems' financial sustainability
- Impactful EU and excellence at global level

What's next

- Communication on Pharmaceutical Strategy for Europe
- Action plan
 - Legislative and non-legislative measures
 - Short term, medium term and long term
- Pharmaceutical Strategy and Action plan are first steps in a longer process

Key dates



Thank you



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



@EU_Health

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

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Feedback mechanism: source: [ICF Analysis of contributions to the Roadmap](#)