



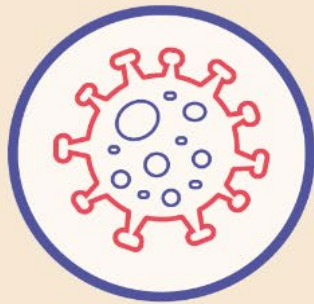
# Pharmaceutical Strategy for Europe

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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

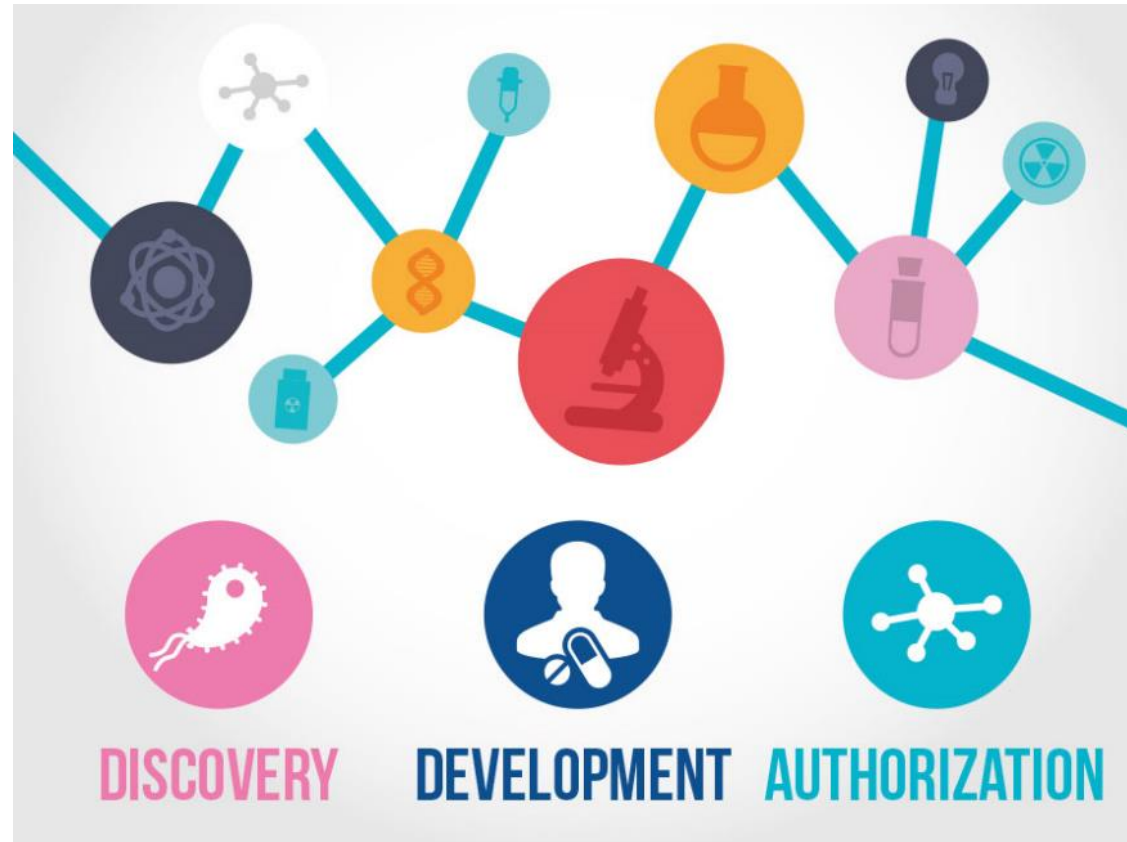


Reducing medicines  
shortages and  
securing strategic  
autonomy

#EUPharmaStrategy

# 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
- ...

# Flagships of the pharmaceutical strategy

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

## Unmet needs

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

## 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)

# Flagships of the pharmaceutical strategy

## Ensuring availability and addressing shortages

### Secure the supply

- Revise the legislation to **enhance security of supply and address shortages** (2022)
- Launch a structured dialogue to **identify vulnerabilities** in the global supply chain (2021)
- Ensure **increased transparency of the industry** on the supply chains (2021)

### High quality, safe and environmentally sustainable

- Revise manufacturing and supply provisions in the legislation to **ensure environmental sustainability, quality and preparedness** (2022)
- Revise the legislation to strengthen **environmental risk assessment** requirements and conditions of use (2022)

### Crisis response mechanisms

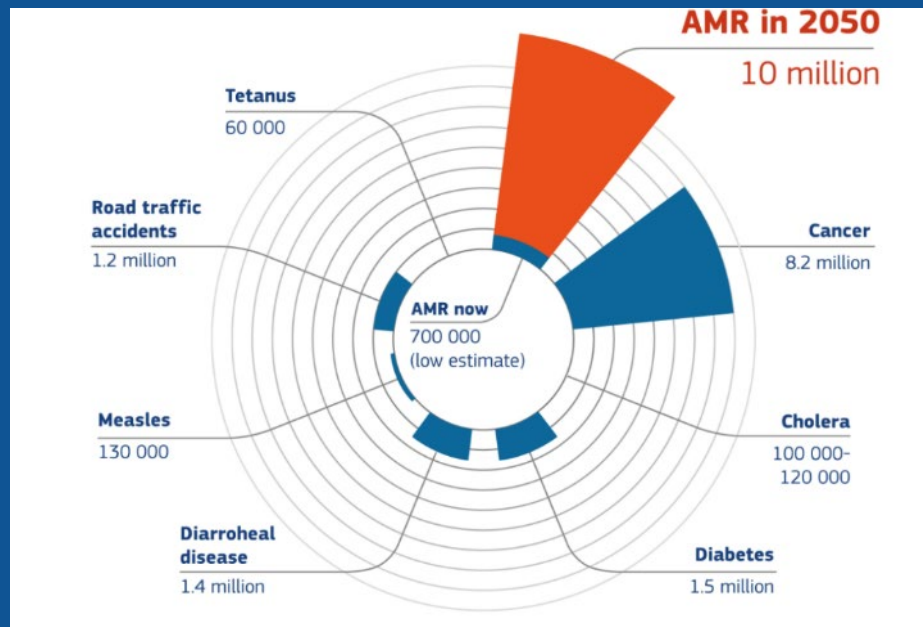
- Proposal for an **EU Health Emergency Response Authority** (2021)

# Flagships of the pharmaceutical strategy

## Succeeding on the global level

Work with the EMA and the network of national regulators, to promote **regulatory convergence** to ensure access to safe, effective high-quality and affordable medicinal products globally (ongoing)

# Deaths attributable to AMR every year worldwide



700.000  
=  
1 person  
every 45 seconds

Source: *The Review on Antimicrobial Resistance*,  
Jim O'Neill, 2016





AMR claims 33,000 lives in the EU  
every year.

Equivalent to 1 Boeing 747 crashes  
each week.

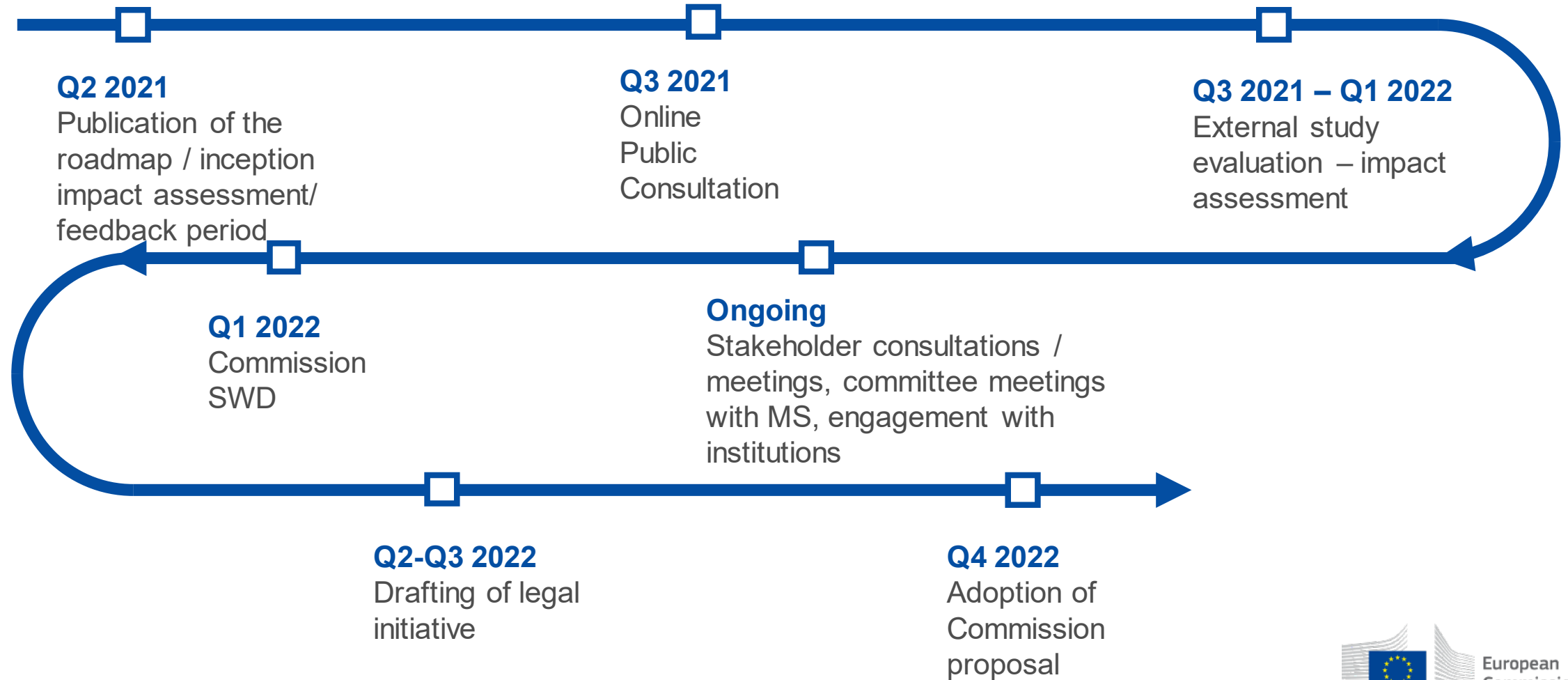


# Flagships of the pharmaceutical strategy

## AMR

- Pilot innovative approaches to EU R&D and public procurement for antimicrobials and their alternatives aiming to provide pull incentives for novel antimicrobials –target date 2021.
- Promote investment and coordinate research, development, manufacturing, deployment and use for novel antibiotics as part of the new EU Health Emergency Response Authority, prior to the start of the authority's operations preparatory action on AMR –2021.
- Consider in the review of the pharmaceutical legislation to introduce measures to restrict and optimise the use of antimicrobial medicines. Explore new types of incentives for innovative antimicrobials –2022
- Propose non-legislative measures and optimise the use of existing regulatory tools to combat antimicrobial resistance, including harmonisation of product information, draft evidence-based guidance on existing and new diagnostics; promote the prudent use of antibiotics and communication to healthcare professionals and patients –2021.

# Revision of basic pharmaceutical acts indicative timeline



Collaboration in the implementation phase:  
How to deliver a quality proposal?



# Thank you



European Commission  
Public Health information:  
[http://ec.europa.eu/health/index\\_en.htm](http://ec.europa.eu/health/index_en.htm)  
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