



Università degli Studi di Milano
Jean Monnet Centre of Excellence

“The impact of European Union Research and Innovation
Policy upon Services of General Interest”

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European pharmaceutical research and development Could a public infrastructure overcome market failures?

Presentation of the study prepared at request of the Panel for the Future of Science and Technology (STOA)

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THE STUDY MESSAGE AT GLANCE

- **The misalignment of priorities between the public health agenda and the pharmaceutical companies' R&D is a structural issue** that cannot be effectively and efficiently corrected by government subsidies to the industry
- **The EU has large but fragmented capacities for pharmaceutical research: a critical mass is needed** to deal with future threats to health in fields underinvested by the industry
- **A new European player with a public mission in pharmaceutical R&D and innovation is needed**
- **The EU is lagging behind others.** The US has strongly reinforced their health federal agencies in terms of budget and scope
- **A European Infrastructure for Medicines can become the top player in the world.** The EU can take advantage of the highly successful **model of large-scale research infrastructure**, which has proven to be an original solution to the fragmentation of R&D in several fields, from physics (e.g. CERN) to space (e.g. ESA) and biology (e.g. EMBL)

CONTENT OVERVIEW

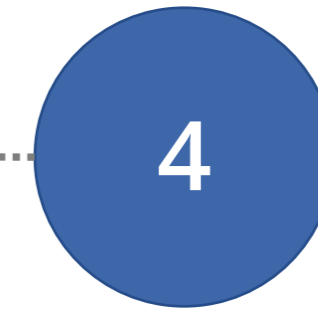
Study objectives

Data & methods

Results

Policy options

Conclusions



1. OBJECTIVES OF THE STUDY

- The business model of the pharmaceutical sector: innovations and **market failures**
- The need of a **large-scale European R&D and innovation infrastructure for medicines**
- **Policy options for a structural change**

2. DATA & METHODS



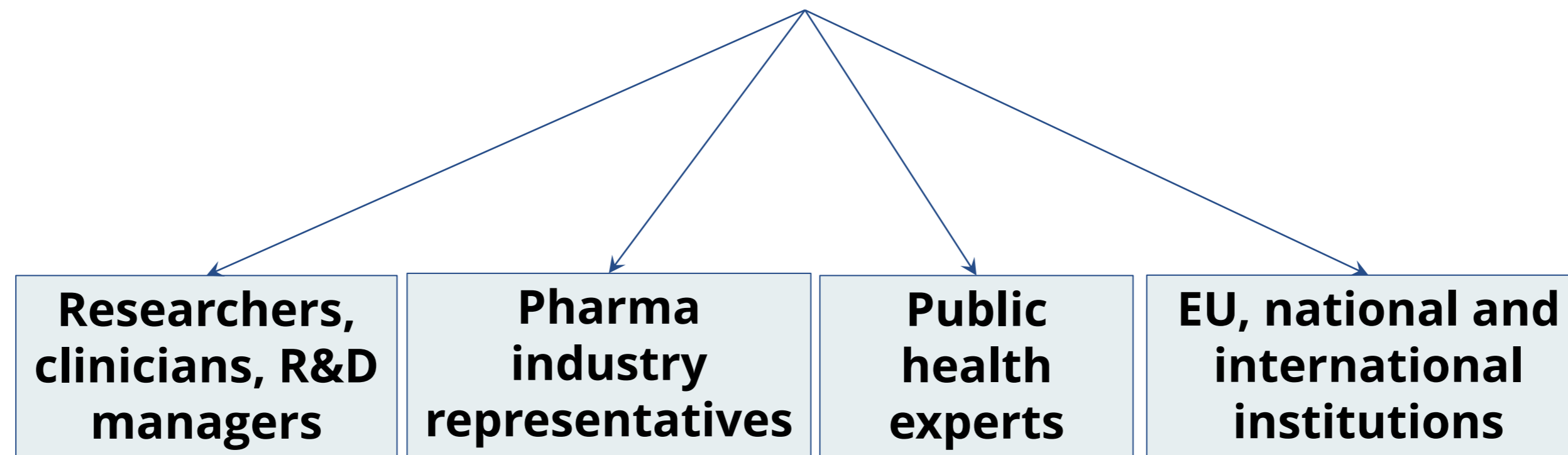
Literature review

- 128 academic papers
- 75 reports
- 26 books
- statistical sources



Interviews to expert stakeholders

- **56 participants from 48 different organisations**



Report drafting

- Evidence triangulation
- Critical reviewers
- Policy options design
- Interactions with Scientific Foresight Unit (STOA)

3. RESULTS

MARKET AND POLICY FAILURES IN A NUTSHELL

1. Disconnection between corporate R&D and health priorities

- **Risky areas** for industry
- **High priorities** for public health
- Governments **subsidies** to corporate R&D: not efficient and effective

2. Mismatch between open science and patents

- Universities and not-for-profit R&D: **open science**
- Pharmaceutical industry: **legal monopoly** for 20 years and more

3. High returns for financial investors in the pharma industry

- **Direct and indirect subsidies** to R&D of new medicines: probably 50% of cost
- **Return on capital** higher than in most industries

3. RESULTS

MARKET AND POLICY FAILURES IN A NUTSHELL

4. Oligopolistic market power

- **Limited competition** and **high prices** of new medicines
- **Affordability** problems for patients and **sustainability** of health care systems

5. Inadequate optimisation studies

- No incentive to perform post-authorisation **comparative clinical trials**
- Unsystematic studies by regulators

6. Information asymmetries

- Pharma companies do not share information on the **R&D, production, distribution cost of medicines**
- Few **independent benefit-cost studies**

4. POLICY OPTIONS

ASSESSMENT OF THE PROPOSALS BY THE EC

- The EC proposal of **European Health Emergency Preparedness and Response Authority HERA**: progress compared to the pre-COVID-19 situation
- Market failures, however, are not adequately addressed by **HERA** (and by the reinforced role of EMA and ECDC)
- HERA apparently will not have the responsibility, resources, and capacities to directly implement its own **pharmaceutical R&D projects**
- HERA would need to mostly rely on the **current pharma players**
- As such, HERA will not have the **critical mass** for a **structural change**

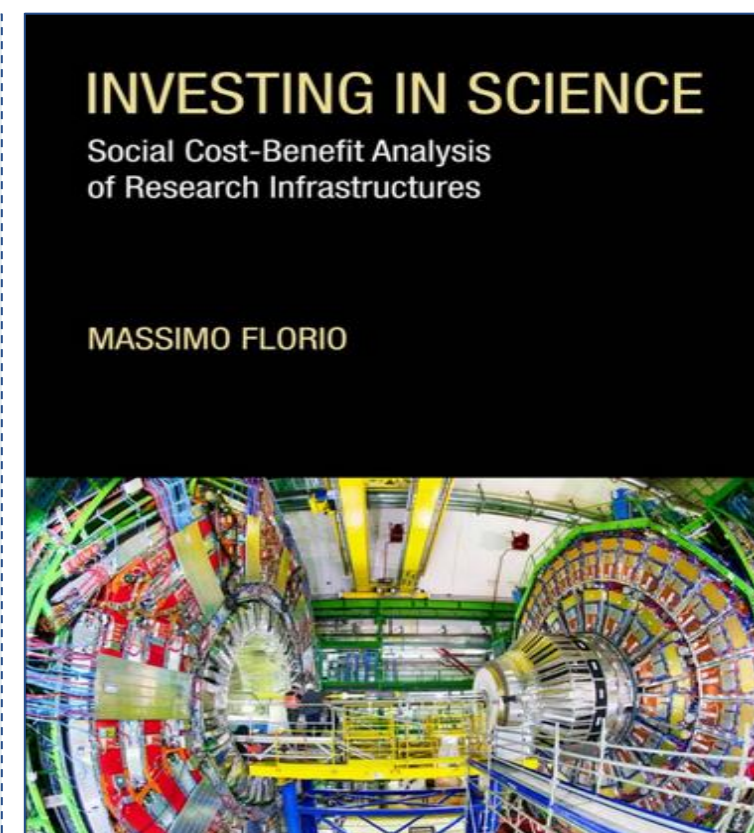


4. POLICY OPTIONS

WHY A EUROPEAN MEDICINES INFRASTRUCTURE?

Research infrastructures are facilities that provide resources and services for the research communities to conduct research and foster innovation in their fields. **Technology Infrastructures** [...] develop, test and upscale technology to advance from validation in a laboratory up to higher technology readiness levels prior to competitive market entry. They can have public, semi-public or private status (European Commission 2021)*

The **research infrastructure paradigm** points to a new avenue in the governance of knowledge-based organizations beyond science, based on collective intelligence and intrinsic motivation, with implications also for mission-oriented innovation policies (Florio 2019)*



*EC, Horizon Europe, Work Programme 2020–2021, 2021. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-3-research-infrastructures_horizon-2021-2022_en.pdf

*Florio, M., Investing in Science: Social Cost-Benefit Analysis of Research Infrastructures, MIT Press, 2019.

4. POLICY OPTIONS

EUROPEAN MEDICINES INFRASTRUCTURE

An organisation pursuing a public health overarching mission, conducting research and innovation, and delivering pharmaceutical and related biomedical innovations through dedicated facilities, resources, and services available to the scientific community, enjoying long-term budgetary autonomy

1

GOAL

Fulfilling European citizens' interest by developing and offering safe, effective, innovative, affordable **medicines in areas affected by market failures**

2

STRATEGY

Comprehensive, forward-looking, **long-term portfolio strategy** and dedicated leadership and governance supported by the consensus of scientific health communities and health authorities

3

INTELLECTUAL PROPERTY

Owning the results on the undertaken R&D projects, and managing intellectual property rights **exclusively in the public interest**

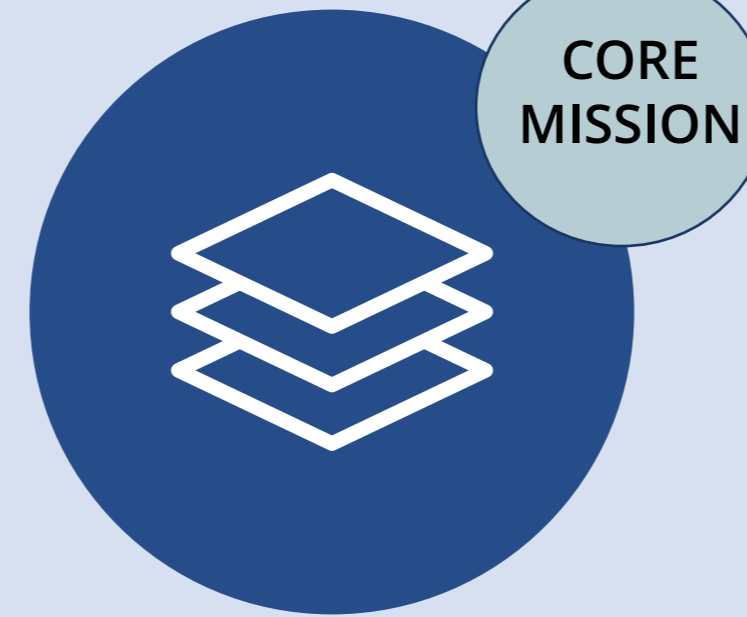
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PARTNERSHIPS

Open to collaborations, in partnership with third-party research centres at national or European level and with pharmaceutical companies based on **transparent contractual arrangements**

4. POLICY OPTIONS

MISSIONS FOR A EUROPEAN MEDICINES INFRASTRUCTURE



CORE MISSION

To build a portfolio of innovative pharmaceutical R&D projects

Focus on clinical areas:

- Under-invested by the industry and subject to market failures
- where there are affordability and equity concerns
- where there are shortages



COMPLEMENTARY MISSION

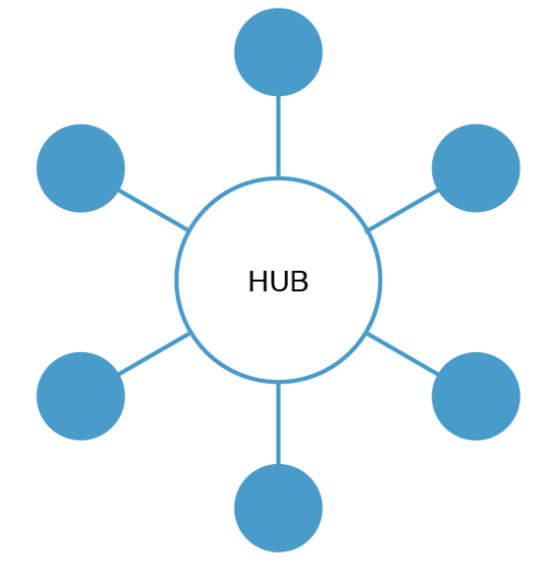
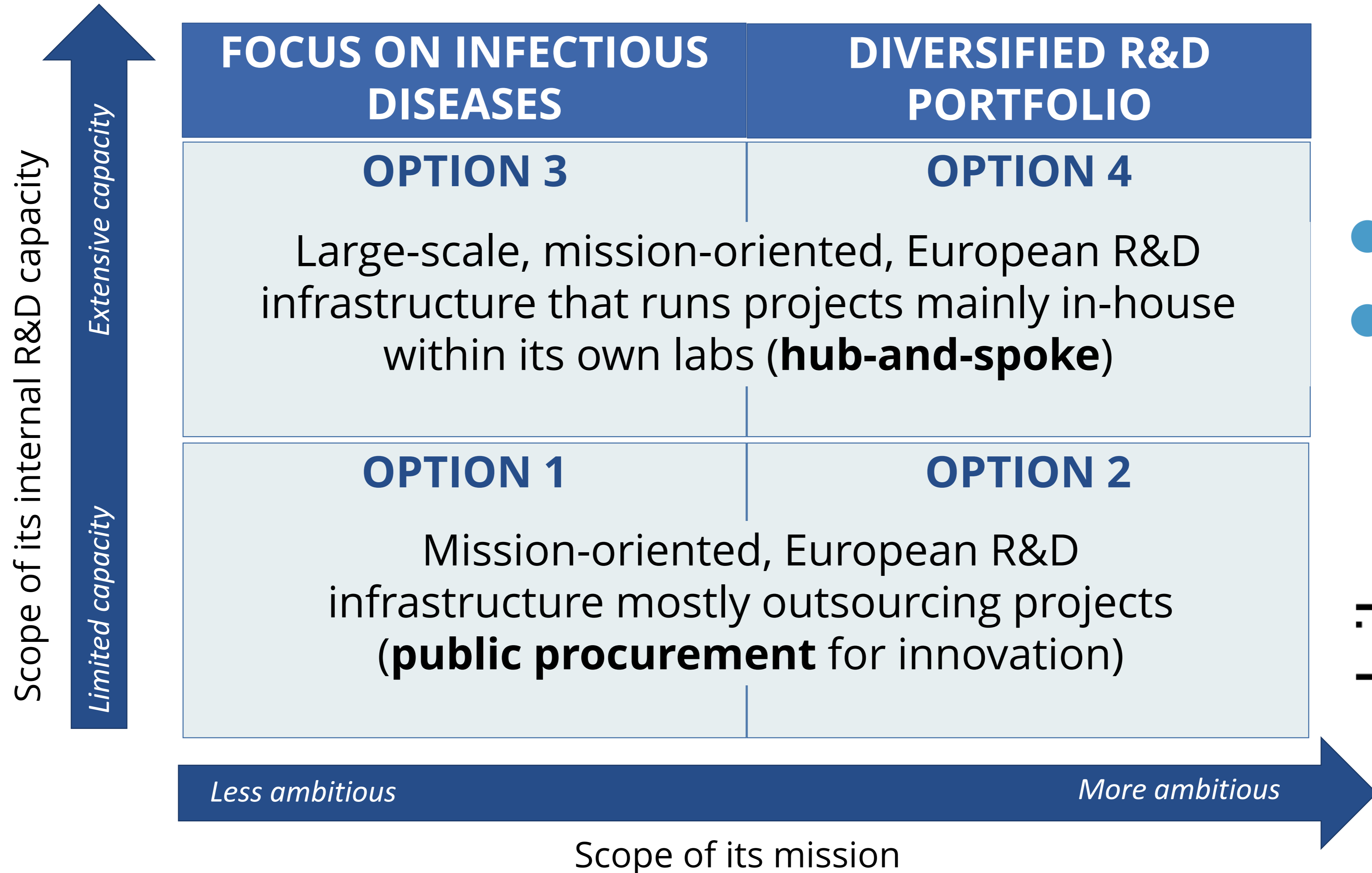
Treatment optimisation studies



COMPLEMENTARY MISSION

Improving generics and ingredients safety and security of supplies

4. POLICY OPTIONS



4. POLICY OPTIONS

EXPECTED OUTCOMES AND BUDGET OVER 30 YEARS

FOCUS ON INFECTIOUS DISEASES	DIVERSIFIED R&D PORTFOLIO
<p>OPTION 3</p> <ul style="list-style-type: none">• New antibiotics, vaccines, other medicines <p>Budget: EUR 6.5 billion per year* (size similar to ESA for 2021)</p>	<p>OPTION 4</p> <ul style="list-style-type: none">• Wider range of biomedical innovations
<p>OPTION 1</p> <ul style="list-style-type: none">• New antibiotics, vaccines, other medicines <p>Budget: EUR 3.5 billion per year* (size similar to the NIH Intramural Research Program)</p>	<p>OPTION 2</p> <ul style="list-style-type: none">• Wider range of biomedical innovations



*Given the yearly budgets, taking into account overheads and capital cost, and taking as a benchmark the R&D cost per drug of about EUR 1 billion

5. CONCLUSIONS

- The industry is a key player for pharmaceutical **R&D and innovation**
- However, overwhelming evidence of a **structural disconnection of priorities** between corporate strategies and public health priorities
- **Market failures: high financial returns** for private investors because of public subsidies, legal and de facto monopoly power
- **Policy failures:** inefficient subsidies and regulations unable to shift the industry business model, leading to **affordability and sustainability** concerns

5. CONCLUSIONS

- **Public research is privatized:**

Patents on the last mile of R&D do not adequately protect public investments

NEWS EXPLAINER | 30 November 2021

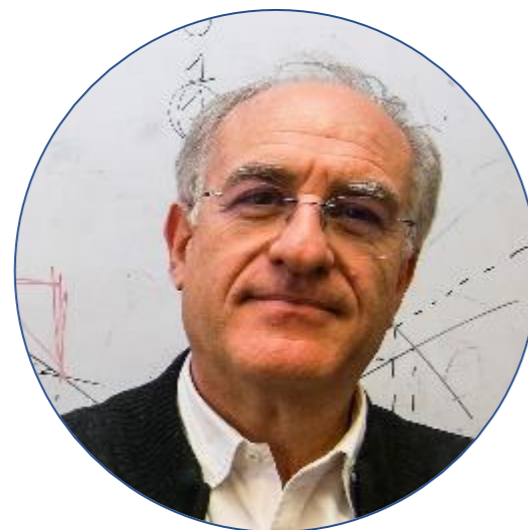
nature
International journal of science

What the Moderna–NIH COVID vaccine patent fight means for research

- High consensus of interviewed experts agree on concept of a **European pharmaceutical R&D infrastructure**: a new approach to public-private partnership
- **Four policy options: focus on infectious diseases vs wider portfolio, hub-and-spoke model vs public procurement for innovation model**
- Potentially Europe can host the most important **global player for pharmaceutical innovation** over 30 years of investment

Q&A

THANKYOU



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