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EU & global access to medicines: *Where to from here?*

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Interest declaration

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Outline

A. Why focus on global health influence of EU *internal* pharmaceutical regulation

B. Pharmaceutical Strategy for Europe

C. Revision & adoption of the EU Pharmaceutical Legislation

D. Proposal for an EU Regulation on Critical Medicines (‘Critical Medicines Act’)

E. Zoom out to other initiatives

EU powers

Safe internal medicines supply > *Development cooperation, aid, R&D*

EU law

Drug development

Market regulation

Joint purchasing

Safety monitoring

Developing countries

Tuberculosis infections

EU 1-5 people **per 10,000**

Africa 12-64 people **per 10,000**

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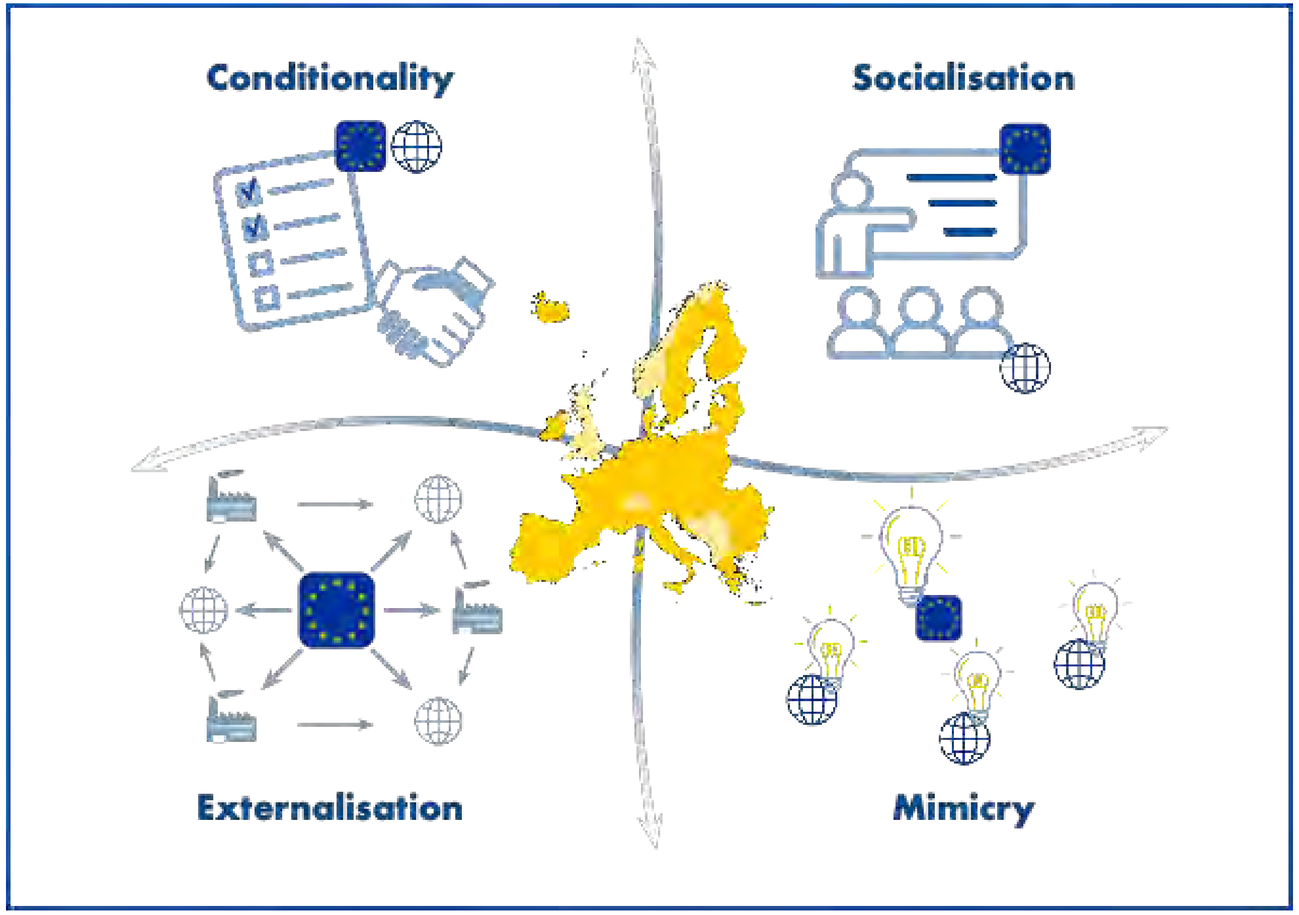
How EU law produces extraterritorial effects
Four mechanisms

EU external relations
Eg. Trade & accession agreements

EU internal market
Eg. Regulatory reliance; GCP in clinical trials, GMP



EU internal market
Eg. EUMedicines4All: EMA opinion on medicines intended for non-EU countries only

EU internal market
Eg. Definition of rare diseases (<5/10,000 people)

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Perehudoff SK. From Brussels to the World: The Diffusion of EU Pharmaceutical Legislation towards Developing Economies. *European Journal of Risk Regulation*. 2024:1-7.

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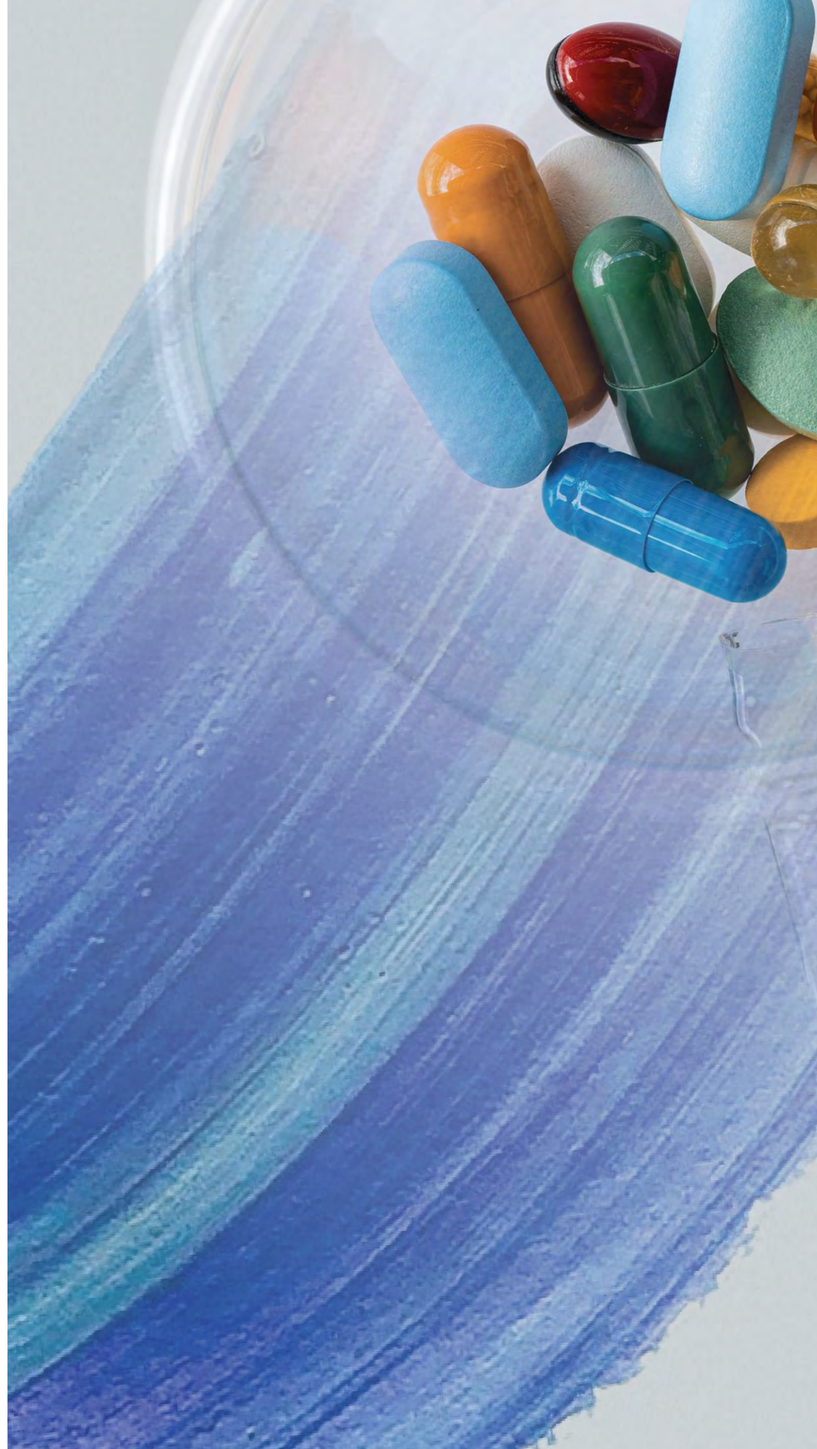
Why is EU pharma regulation relevant for global health?

- EU's large pharmaceutical market that (transnational) pharmaceutical companies want to enter
- EMA's significant regulatory capacity (technical, procedural, …)
- Many new medicines are first evaluated by EMA before being marketed in foreign countries
- EMA publishes product information online
- Generally, EU pays greater attention to the precautionary principle than other global powers
- Increasingly important: EU is a reliable and consistent regulator, lawmaker and global actor



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Part B. Pharmaceutical Strategy for Europe (2020)

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Impetus for Strategy

- Tackle high medicine costs for patients and health systems.
- Support a vital economic sector creating skilled jobs and driving innovation.
- Address unequal access to innovative therapies and medicine shortages.

- Strengthen resilience after COVID-19 exposed supply vulnerabilities.
- Reduce dependence on non-EU suppliers.

- Respond to ageing populations and rising disease burdens.
- Combat antimicrobial resistance and improve environmental sustainability.

Four pillars of Strategy

"It is a **patient-centred strategy** that aims to ensure the quality and safety of medicines, while boosting the sector's **global competitiveness**. " (p2)

‘Flagship initiatives’ in Strategy

Legal measures

- Revision of EU pharmaceutical legislation: incentivise new medicines including antimicrobials & their prudent use; incentivise new medicines for paediatric cancer; address supply shortages
- Adopt Regulation on Health Technology Assessment
- Legislative proposal on the European Health Data Space and on Critical Medicines
- Propose a (new) Health Emergency Response Authority

Policy measures

- **Technical and financial support** public-private partnerships through Innovative Medicines Initiative
- **Coordinate** research, development and manufacturing of antimicrobials;
- **Faciliate cooperation** between relevant MS authorities for medicines pricing, payment and procurement for a lifecycle approach;
- **Launch dialogue** on open strategic autonomy with actors in pharmaceutical supply chain
- Promote regulatory convergence at global level; Promote investment in R&D of new antimicrobials

Part C. Reform of EU pharmaceutical legislation

“EU pharmaceutical legislation can be an enabling and connecting factor for innovation, access, affordability and environmental protection.”

European Commission, 2023

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Lawmaking procedure

- April 2023: European Commission proposes new **Directive** & **Regulation**
  - Replace parts of six existing laws:
    - Pre-marketing authorisation of medicines and pharmacovigilance: Directive 2001/83/EC and Regulation 726/2004
    - Orphan medicinal products (Regulation 141/2000/EC), medicinal products for children (Regulation 1901/2006), and advanced therapeutic medicinal products (Regulation 1394/2007)
    - Harmonised assessment and transparency of trials in the EU (CT Regulation 536/2014)
- April 2024: European Parliament plenary adopted amendments
- June 2025: Council of (Ministers of the) EU adopts a common position
- **NEXT: Council & Parliament negotiate an agreement**

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Perehudoff SK. *European Journal of Risk Regulation*. 2024:1-7.

Key proposals by the Commission & Parliament

- With direct and intentional influence on global health:
    - **Joint subscription-based procurement of antimicrobials**: multi-year contracts with regular payments for continuous supply (Parliament Amendment 148)
        - **Global access plan**: manufacturers must plan to supply non-EU countries in critical need
    - **Expanded Environmental Risk Assessment** including antimicrobial supply chains (also in third countries) (Arts 4(33), 15 (1)(d), 22(4) Dir. Proposal)
- With indirect influence on global health:
    - **New transparency rule** on public R&D funding disclosure by manufacturers (Art. 57(1) Dir. Proposal)
    - **Revised data & market protection** for originator medicines (Art. 40 Reg Proposal)

Perehudoff SK. *European Journal of Risk Regulation*. 2024:1-7.
Perehudoff K. BMJ Global Health. 2025 Apr 29;10(4).

Key amendments adopted by Council (June 2025)

- Period of **data exclusivity**: 8 years
- Period of **market exclusivity**: + 1 year + 2 years when certain criteria are met
- **Transferrable exclusivity voucher**:
  - Only used in 5th year of data exclusivity period; and
  - Only if MA holder shows annual gross EU sales of medicine do not exceed 490 million Eur in the preceding 4 years
- NEW! **Obligation to supply** (article 56a, Directive): allows Member States to oblige MA holder to make the product available in sufficient quantities
- Clarifies **scope of 'Bolar exemption'** and expands to include submissions for procurement tenders → Earlier market entry of generics and biosimilars

Part D. Proposal for a Critical Medicines Act

Policy evolution

- February 2025: (advisory) Critical Medicines Alliance publishes Strategic Report

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- March 2025: European Commission proposes new **Regulation**
- June 2025: Council of (Ministers of the) EU start discussion of proposed Regulation
- Next steps: European Parliament will also discuss Regulation

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Key proposals – Strategic Report of the Critical Medicines Alliance

One strategy: Find alternative suppliers in third countries

- **Expand the 'Voluntary Solidarity Mechanism'** (intended for exchange of critical medicines supplies between Member States) to reach out to non-EU countries with Member States in need.
    - Last resort and short-term solution
- Create 'dedicated, structured, transparent, and security **repository for exchanging information**' on Member States' experiences with international partners
- **Pursue partnerships with key non-EU countries**: established trade partner countries, large producer and spare capacity countries, neighbouring and strategically positioned countries, and capacity-development countries.

https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf

Objectives of proposed Regulation

- Strengthen security of supply through:
  - Investments in manufacturing critical medicines
  - Diversify supply chains to lower risks of supply disruptions
  - Collaborative procurement (pooling demand of Member States)
  - Strategic partnerships with ‘like-minded non-EU countries’ for diversifying supply

- How? Financial incentives, procurement rules, joint procurement, partnerships
- Missing / to be worked out:
  - Guidelines for **EU solidarity with the wider world**
  - **Conditionalities for EU investments** in manufacturing infrastructure (in the EU)

EU responsibilities in the world

Article 168(1) TFEU

Ensure a high level of **health protection** through all Union policies and activities

Article 3(5) TEU

Respect for **human dignity and rights** in the EU's relations with the wider world

Article 21(1) TEU

Advance **solidarity** in the wider world, through relations with third countries

Respect for UN Charter and international law (→ UN human rights treaties)

Zoom out to other relevant EU initiatives

European Health Union

Aim: Improves EU-level protection, prevention, preparedness and response against human health hazards (in crisis and in normal times).

Key actions:

- **Crisis preparedness**: Integrated surveillance system; capacity for risk assessment; joint procurement of medical countermeasures
- **Reform of EU pharmaceutical legislation**;
- **Europe's Beating Cancer Plan**: Prevention, early detection, diagnosis & treatment, quality of life
- **A comprehensive approach to mental health**: Prevention, treatment & care, reintegration into society

Global Gateway

EU's external infrastructure development plan, including health and pharma systems in 'developing countries'

Aspects of the Global Gateway's focus on pharmaceuticals:

- **Strengthening regulatory frameworks & regulatory cooperation** to meet international standards for safe and effective medicines;
- **Building local production capacity** to support countries making their own vaccines and reduce reliance on global supply chains;
- **Facilitate access** to health technologies including diagnostics and equipment through technology transfer, among other ways;
- **Public-private partnerships**: leverage the expertise of the European private sector, research institutions and healthcare innovators;
- **Sustainable financin**g:

Global Gateway: Recent examples

EU + Team Europe (including Germany) partner to strengthen local manufacturing by upgrading regulatory environment, supporting biotech start-up ecosystem to de-risk R&D (e.g. lab space, business support, mentorship), advanced education to build local talent pool, strengthening quality assurance

Criticism of BioNTainers to Rwanda

Guyana, Barbados, Lithuania/EU (2025): Cooperation agreement to bring Caribbean regulators to WHO maturity level 3

Let’s discuss!

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