A Competitive Strategy for the Pharmaceutical Sector in the European Union

This overview summarizes the most important findings and conclusions of Mario Draghi's report on "The future of European competitiveness" for the pharma sector in the European Union

Van Doorne

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The future of European competitiveness

On 9 September 2024, Mario Draghi published his report 'The future of European competitiveness'. The report contains a comprehensive analysis of the challenges faced by the industry and companies in the EU. The objective of the report is to contribute to the Commission's work on a new plan for Europe's sustainable prosperity and competitiveness.

In chapter 9, the report focusses on the competitiveness of the European pharma sector. The EU pharma sector accounts for 5% of the value added to the EU economy from all manufacturing and employs around 937,000 people. Although the EU leverages a historic footprint in the pharma sector, the EU pharma sector falls behind compared to the US and China.

This overview summarizes:

- The **root causes** of the emerging competitiveness gap;
- Recent **EU reforms and proposals**; and
- The **objective and proposals identified by the report** to address the emerging competitiveness gap.

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Four root causes of the EU's competitiveness gap in the pharma sector

Lesser and fragmented public R&D investments in the EU

- US public R&D spending in health reached around EUR 44 billion (~0,18% of GDP) in 2022, compared to EUR 11.2 billion (~0,07% of GDP) EU public R&D spending in health.
- China's governmental R&D funding for pharmaceuticals rose in 2017 to 0,02% of GDP, compared to 0,05% of GDP in the EU in 2017.
- EU funding is fragmented per member state and EU programmes.

Lesser private R&D investments in the EU

- Over the past two decades, the share of global pharmaceutical R&D investments by companies of the EU remained at 20%, while the US stood at 40% and China rose from nil to 6%.
- In 2021-2022, biotech companies in the US received USD 62.1 billion, compared to USD 11.2 in the EU.
- Lack of critical mass in EU innovation hubs, compared to US and China.

A slow and complex EU regulatory framework

- Median approval time for medicines in the EU (430 days) is much longer than US (334 days). Also, the EMA offers less structured scientific advice than the FDA.
- Subsequent to EMA approval, 27 different national procedures exist for pricing and reimbursement follow in the EU.
- HTA procedures often require additional data and are time-consuming, in contrast with the US.

The complex emergence of a European Health Data Space

- Ineffective secondary use of data in the EU by different rules in member states on the processing of health data for health/social care, public health and scientific purposes.
- The proposed EHDS regulation aims to create a unified European framework for secondary health data use, building on the GDPR and national laws.

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EU reforms, actions and proposals to boost innovation and reform the pharmaceutical regulatory landscape

Clinical Trials Regulation

The CTR introduced the CTIS platform to **streamline clinical trial applications**. Also, the ACT EU initiative and COMBINE project aim to enhance clinical research integration and address challenges in trials involving combined therapies and diagnostics.

1+ Million Genomes (1+MG) and Beyond 1 Million Genomes (B1MG)

The 1+ Million Genomes (1+MG) and Beyond 1 Million Genomes (B1MG) initiatives aim to **enhance research and personalized healthcare** by establishing a European Genomic Data Infrastructure by 2026, allowing secure, cross-border access to genomic data while keeping it locally stored across 25 European countries.

Leveraging Real-World Evidence for Pricing and Reimbursement

Real-world evidence will **streamline the process of patient recruitment and data collection** for pricing and reimbursement, improving decision-making. By example DARWIN EU® offers timely real-world data, completing 16 studies by 2023 on medicine safety and effectiveness.

EU legislation for medicinal products

On 26 April 2023, the EU Commission proposed new legislation to **modernize rules for new medicinal products** by introducing regulatory sandboxes, electronic submissions, and e-leaflets, while simplifying clinical trial regulations for GMO-based medicines to enhance R&D in advanced therapies.

HTA Regulation

From 2025, the EU Health Technology Assessment (HTA) Regulation is expected to **streamline national pricing and reimbursement processes**, by pooling clinical assessments. Implementing acts are to be adopted by December 2024 which will further specify key data requirements for the Joint Clinical Assessment of medicinal products.

EHDS Regulation

In spring 2024, the European Parliament and the Council reached agreement on the Commission proposal for a European Health Data Space regulation (the EHDS Regulation) The EHDS Regulation aims to create a **unified European framework for secondary health data use**, building on the GDPR and national laws. Improving access for secondary use is also a precondition for the further development of AI in the context of health data.

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Nine proposals to expand the EU capacity to conduct R&D investments in the pharma sector

1. Maximise EHDS

- The **accessing and sharing of electronic health records** should be supported and the **capacity and resources of national health data access** bodies should be boosted, in order to ensure optimal implementation of the EHDS.
- Further **standardisation of existing health data** to a common data model and leveraging such data for regulatory, policy and clinical decision-making, also by using the Darwin EU® network to generate evidence for innovation in medicine development.
- Further **strengthening of the infrastructure for whole-genome sequencing**, including to enhance data sharing across borders under the EHDS, to build on the European 1+ Million Genomes (1+MG) initiative and complementing Beyond 1 Million Genomes (B1MG).

2. Multi-country trials

- Introduce rules to address **challenges for studies which combine medicines with medical devices and the application of AI**.
- Introduce **reinforced coordination mechanisms** between national ethics committees and a binding EU-level decision-making committee for the authorisation of multinational clinical trials.
- Introduce and incentivize **model templates in the use for trials**.

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3. Access to markets

- **Streamline guidance** to industry on unmet medical needs, the design of clinical trials and the use of real-world evidence across national medicine agencies, national bodies for HTAs as well as pricing and reimbursement authorities.
- Cross-country coordination problems in pricing and reimbursement should be resolved, for instance, by adhering more closely to the pricing principles in the EURIPID collaboration.
- Use **award criteria in public tenders** such as security of supply and production in the EU/EEA or in countries with which the EU has concluded an agreement on government procurement to foster EU competitiveness in the area of pharmaceuticals.

4. AI in lifecycle of medicine

- **Clear and timely guidance** is necessary on the use of AI in the lifecycle of medicine.
- The guidance should **maximise the possibilities** offered by the EHDS Regulation and AI Act.
- The guidance should cover **analysis of raw clinical data** transmitted to the EMA and **data collected for pharmacvigilance purposes**.
- The aim is to **open up the secondary use of health care** data for research purposes.

5. HTA Regulation

- The Health Technology Assessment Regulation (HTA Regulation) should be **implemented rapidly**, especially the joint clinical assessment.
- This creates a potential to **improve efficiency in the uptake of pharmaceuticals** by health systems following their marketing authorization.
- Considerable **resources should be made available** for implementation, in particular to national HTA bodies and the Commission for sufficient expert staff.

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6. Increased business predictability

- Business predictability should be improved by **continuous evidence-based dialogue** with stakeholders. A standard model capturing the key impacts of EU regulatory action in terms of innovation and patient access should be developed, publicized and updated on a continuous basis.

7. Public R&D investments

- EU funding should be focussed on the development of a limited number of **world-class innovation hubs** for ATMPs.
- Disease registries established under **European Reference Networks should be expanded**, consolidated and integrated. Strengthening the usability of patient data collected under ERN's could boost EU-based R&D for orphan medicines.

8. Private R&D investments

- Private R&D investments should be mobilised, and a supporting environment should be bolstered. In particular the **budget of the European Investment Fund should be increased**, especially in relation to investments in the pharma sector. Moreover, higher risk and more scale up investments could be financed through the **InvestEU programme**.

9. International strategic partnerships

- **Strategic international partnerships should be developed** to boost EU's international trade position in pharmaceuticals.
- Supply chains diversification and the development of new productions sites in strategic regions outside the EU, the strengthening of existing supply sources, and the development of strategic partnerships with international partners as well as the optimisation of trade agreements, could **encompass international co-operation**.

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