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Competition of regulatory ecosystems in approving medicines:

Policy implications in the case of Europe

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Abstract

The competition between business ecosystems is relevant not only for strategic management but also for health policy and regulators. Regulation is one key factor in ecosystem competition, and government and regulatory bodies implement new pharmaceutical legislations, policies, and guidelines contributing to business environments capable of attracting startups, biotech firms, and pharmaceutical industry investments in innovative medicines and technologies. Implications for patients and societal welfare require a thorough analysis of strategies aimed at enhancing the European Union's competitive advantage in attracting pharmaceutical companies to prioritize the submission of their innovative medicines. This analysis is essential for ensuring that patients have timely access to new treatments, that society benefits from advancements in healthcare and may foster the competitive advantage of the European regulator's ecosystem. In this research note, we present data from 65 interviews with pharmaceutical industry professionals, offering direct insights into regulatory ecosystem competition and global health policy. It underscores the necessity for effective strategies that enhance the competitive advantage of the European regulatory system.

Highlights:

- Competition between regulatory ecosystems

- EU Pharmaceutical Legislation revision
- Policies recommendation to promote innovation and regulatory competition
- Initiatives aimed at encouraging pharmaceutical companies to prioritize submissions in Europe.

Keywords: Competition,, regulatory policy, regulatory ecosystems, regulatory bodies, pharmaceutical legislation, pharmaceutical regulation, regulatory system, FDA, EMA, national regulatory authority, pharmaceutical industry, startups, biotech firms, innovation, innovative medicines, medicines, health policy, strategic management, competitive advantage and incentives.

Teaser: We unpack how competition among regulatory ecosystems shapes health policy and regulation, influencing the pharmaceutical landscape and innovation. This article explores strategies for the European Union to attract innovative pharmaceutical investments and strengthen its position in the global market.

Introduction

The pharmaceutical business is today a well-established and a successful industry due to the high demand for medicines, rapid population growth, increase living standards, insurance and the welfare state covering the cost of treatments.

Innovation in the pharmaceutical sector is dynamic and changing rapidly the way that pharmaceutical companies are discovering innovative medicines.¹ The bigger policy debate, however, revolves around the competition between regulatory ecosystems that tend to influence innovation, strategy and business models. This debate is at the heart of policy makers,^{2; 3; 4} who require access to current data supporting complex and multinational decision processes. Changes in the policy and regulatory environment can significantly impact the pharmaceutical ecosystem.^{1; 5}

The European Commission (EC) published the draft proposal for the revision of the pharmaceutical legislation on 26th April 2023⁶ with the aim to introduce some legislative proposals that can change the European pharmaceutical ecosystem to improve the access to innovative medicines, increase availability and affordability of medicines, avoid shortages, guarantee security of supply, create a competitive regulatory framework, enhance environmental sustainability and combat antibiotic resistance. The big policy debate in The European Union is how to improve some of these proposals without undermining innovation⁵ and our study contributes insights from industry experts into how this can be achieved. Regulators aim to safeguard public and animal health by carefully evaluating and supervising medicines entering the market.⁷

Different regulators and governments have implemented various policies and incentives in recent years to increase the number of new pharmaceutical industries, promote drug development and encourage companies to prioritise their markets for submitting innovative medicines. Moreover, Regulators have recognised the importance of engaging and listening to key stakeholders, including patients, healthcare professionals, families, the pharmaceutical industry, governments, politicians, payers, investors, academia, other regulators and more.⁸ By engaging stakeholders, capitalising on capabilities, and fostering innovation, regulators can

play a pivotal role in driving the development and approval of innovative medicines.⁸ It is vital for regulators to have a comprehensive understanding of the services provided by other international regulators in order to create a competitive advantage that attracts companies to submit their products to them first. To sustain this competitive advantage, regulators need to capitalize on their capabilities and resources.⁹ This includes expediting approvals, providing high-quality scientific advice, maintaining well-trained staff, and fostering ongoing innovation in science and technology that will attract pharmaceutical companies to submit their innovative medicines in their markets.⁹ Some regulators excel at attracting valuable and scarce resources, such as renowned scientists in specific areas of expertise, which the industry seeks for early advice or establishing digital innovation in their process and platforms that could accelerated approvals on medicines. In summary, a regulator's strategy must be carefully crafted to meet the needs of stakeholders and maintain a competitive edge.

This research aims to uncover strategies for the European ecosystem to regain its competitive edge in attracting pharmaceutical companies to submit their innovative medicines in the European Union ahead of other regions. According to the current literature,¹⁰ the prevailing trend indicates that most pharmaceutical companies currently opt to submit their innovative medicines in the US before considering Europe.

Approval time and access to medicines

The US regulatory ecosystem has been dynamic in fostering innovative regulatory pathways and providing support to the pharmaceutical industry during drug development (see table 1). In contrast, European Regulatory Authorities have been less proactive in adopting innovative regulatory strategies and pathways, with some exceptions such as the biosimilar regulatory pathway established in the European Union earlier (see table 1) than in the US.

The orphan drug ecosystem shaped by legislations in the US and in the European Union, has significantly impacted the development of orphan drugs. Before the implementation of the orphan drug act in the US in 1983, there were only 10 medicines approved by the FDA^{13;14} that could be classified as an orphan drug.

Similarly, in the European Union, there were only 8 medicines^{13;14} identified as orphan drugs before the implementation of the orphan drug legislation in 2000. However, the regulatory landscape has evolved, with the FDA now approving over 1259 orphan drugs¹¹ and the EC over 244¹². These legislations offer incentives such as additional regulatory and scientific support, grants, free scientific advice, marketing exclusivity, tax credits, fee reductions, fostering confidence in pharmaceutical investment in high-risk projects for a reduced number of patients worldwide.^{13;14} Any changes to this ecosystem may undermine further orphan drug development.^{13;14}

Enhancing regulatory ecosystems is crucial for fostering the development of life-saving innovative medicines in the modern era.⁷ This can be achieved by establishing robust policies that promote innovation in the pharmaceutical sector, attracting public and private research initiatives, fostering talent acquisition, strengthening intellectual property protection, reducing taxes, providing incentives, and improving network infrastructure.⁷ These measures contribute to an improved environment for innovation and ultimately benefit society by advancing the development of ground-breaking medicines.¹⁵ Delays in the approval of innovative medicines within the European Union mean that patients in areas of unmet medical need, particularly in oncology and rare diseases, may not have the same chances of survival as those in other regions.

Approval timelines of new medicines across regulatory agencies

Based on the literature¹⁶ and CIRS report¹⁰ on new medicines approvals in six major authorities 2013-2023, the European Union had the highest median approval timelines of new medicines (453 days), while Japan (322 days) and US (333 days) had the shortest median approval timelines (Graph 1). The European Union has maintained a constant median approval timeline of new medicines over the years (433 days), while the US experienced an increase in approval timelines in the last two years (+88 days compared to 2021). The submission strategy and rollout timelines in different countries and regions are influenced by parameters such as approval timelines, expedited pathways, regulatory support during drug development, reimbursement requirements, company strategy, and worksharing procedures. According to the literature, pharmaceutical companies tend to select the FDA for their first global submission.^{10;16}

Access to Medicines

Access to medicines follows regulatory approval, with insurances, HTA (Health technology assessment) bodies, and payors discussing reimbursement based on clinical evidence. Among G20 countries, the US typically launches new medicines into the market first, while patient access inequalities and reimbursement assessment times vary across the European Union, ranging from an average of 133 days in Germany to over 899 days in Romania.¹⁷ Delays in medicine access varies from a range of factors, including commercial decisions, national market access obstacles, clinical evidence, and pricing policies.¹⁸

A strong intellectual property (IP) ecosystem (Patent protection; RDP; Marketing Exclusivity and Supplementary Protection) is crucial for fostering innovation, and the European Union has established robust IP protection rights, including patents, regulatory data and market protection, marketing exclusivity, and incentives for R&D in orphan and paediatric medicines. Any changes to IP protection in the European Union could undermine the pharmaceutical innovation ecosystem.¹⁸

The pharmaceutical industry faces various pressures, including new discoveries, changes in policies & legislations, rising R&D costs, digitalization, geopolitical factors, and demands for innovation. Additionally, the return on investment from the pharmaceutical industry decreased in 2022.^{19;20;21} Therefore, it is crucial to continue supporting the industry by establishing a pharmaceutical ecosystem with the right policies, legislations, incentives and funding opportunities.^{19;21; 21}

Research Question

To explore the research question (**How can the European Union regain competitive advantage in approving innovative medicines?**) we conducted an exploratory qualitative study to collect insights concerning the main reasons for pharmaceutical companies not selecting the European Union as the first country of submission to launch their medicines.^{22;23;24} In this context, semistructured qualitative research interviews²³ based on thirteen open questions (see appendix II) were drafted to encourage the interviewees to share insights, ideas and articulate solutions. When possible, the interviews were conducted in their mother tongue (English, French, Spanish and Portuguese) to facilitate the communication and

increase interaction with the experts in their native language. Before starting any interviews or data collection as part of this research, ethics approval was obtained via the City University Research Ethics Committee.

Data Collection

A total of 65 pharmaceutical industry professionals were invited to participate in interviews between 14 December 2022 and 01 March 2023. A total of 47 experts from 19 different nationalities were interviewed, representing 72.30% of those contacted. The gender balance was nearly equal (25 female, 24 male), but there was an overrepresentation of European interviewees (80.85%) due to non-European experts feeling less knowledgeable about the European regulatory system. The majority of experts were Spanish (19.15%), British (12.77%), German (10.64%), and French (10.64%). Additionally, most these experts were not living in their country of birth but in countries where many pharmaceutical companies are established, such as Switzerland (21.28%), the UK (23.40%), the USA (19.15%), and Germany (8.51%)

The experts interviewed had a very senior positions and many years of experience in the pharmaceutical sector (10-45 years) as described in Table 2. It was also noted that the majority of the senior roles (Senior Vice President and Vice President) in the pharmaceutical industry are established in US (8/13 – 61.54%). Further details on demographics can be found in Table 2.

Data Analysis

All data transcribed during the interviews was coded using NVivo, a data management system allowing analysis of qualitative data.²⁵ Detailed content analysis and aggregation of codes allowed us to generate meaningful results from the data collected, including organising, visualizing, and reporting the main findings.²⁵ Descriptive statistics were used to analyse all interviews.

The appendix I contains the detailed and coded responses, along with descriptive Graphs (2-12), reflecting the experts' opinions on various aspects of the thirteen open questions as described in appendix II. These include the identification of barriers in the European regulatory system (Graph 2), such as price and reimbursement, regulatory complexity, lengthy approval timelines and lower

revenues. Measures to decrease regulatory barriers and areas for improvement (Graphs 3 and 4) include suggestions to simplify regulatory requirements, decrease reimbursement requirements and ensure a well-resourced network. Furthermore, necessary measures for the European ecosystem to regain its competitive advantage (Graph 5) were identified, with simplification of the regulatory system, establishment of a new international worksharing procedure, and reduced approval timelines highlighted as key actions.. Reflections on worksharing initiatives and reliance (Graphs 6 – Open project, 7a – Advantages and 7b Disadvantages of Project Orbis & ACCESS Consortium, and 8 – Reliance) were discussed. While most interviewees did not have experience with the Open Project established by the EMA in December 2000 during the COVID pandemic, they acknowledged that both Project Orbis and the ACCESS Consortium were valuable initiatives with which many had experience.

Concerning reliance, the majority agreed that could be used more often to accelerate approvals and optimise resources. The primary suggestions for revising the pharmaceutical system (Graph 9) included reducing regulatory complexity, introducing new incentives, and providing additional support for innovation and research.

Insights into policies & regulations identified, that are hindering further investment in R&D (Graph 10) revealed that regulatory complexity, lack of incentives, access to capital, and the intricacies of the reimbursement system were significant challenges. The majority of the interviewees agreed to keep the present incentives and proposed of the creation of new ones to promote innovation (Graph 11). Additionally, some of the proposals identified to innovate the European regulatory ecosystem (Graph 12) included reducing the regulatory complexity, well-resourced network, increase international collaboration, etc.. Additionally, 72.34% of participants confirmed that the current regulatory framework impacts the company's hiring policy per region, with a trend of senior positions in the US. Most of the industry experts (41/47) admitted their pharmaceutical companies conduct clinical trials in all main regions (US, Europe, Asia, etc.). Approximately 40.43% of the experts admitted that there is already a reduction of clinical trials in Europe (due to the complexity of the regulatory system). The insights of these interviews as described in Graphs 2-12 contribute to

the formulation of the recommendations for policy makers as detailed in the discussion section.

Discussion

Government and regulatory bodies implemented new pharmaceutical legislations, policies, and guidelines, creating a unique ecosystem capable of attracting startups, biotech firms, and pharmaceutical industry investments in innovative medicines and technologies. The regulatory ecosystems from different countries and regions have been working not only in cooperation but also in competition to be the first to approve innovative medicines.^{26;27} Today regulators in the US (FDA), in the European Union (EMA), Japan (PMDA), the UK (MHRA) and China (NMPA) aim to be the first to approve an innovative medicine. It can be highly politically and economically advantageous to be the first country to approve a medicine, as was evidenced by the fast approval of the AstraZeneca COVID 19 Vaccine in the UK, several weeks earlier than other countries. After BREXIT, MHRA put in place an aggressive strategy that allows UK to have medicines at the same time as the European Union, US, Japan, Australia, Switzerland, Singapore and Canada.²⁸ As described in the literature^{27;29} cooperation and competition between regulators ecosystems co-occur as may work together to support innovation and satisfy patient needs.

Despite efforts in regulatory cooperation and harmonisation through ICH & ICMRA (International Coalition of Medicines Regulatory Authorities) forums, individual governments and regulatory agencies have implemented different type of expedited regulatory procedures, simplified regulatory requirements and increased scientific touch points that create value by encouraging the pharmaceutical industry to submit their medicines for approval in their specific countries or regions, aiming to accelerate the approvals of innovative medicines. As an example, during the COVID-19 pandemic, different regulatory ecosystems worked closely and exchanged crucial information, while also prioritizing expedited national approvals of medicines and vaccines in their markets.

The **Draghi report**³⁰ on the future of European competitiveness, authored by former Italian Prime Minister and European Commissioner Mario Draghi and published on 09 September 2024, supports several conclusions from our research. It highlights

critical issues such as the stagnation of growth in the European pharmaceutical market compared to other regions, the complexity of the European regulatory framework, and the slower approval timelines of medicines relative to other regions. The report emphasises the need for enhanced direct engagement with regulators for scientific advice, the adoption of new technologies like AI, and the streamlining of clinical trial approvals. Moreover, it points out that a significant portion of innovation in biological and orphan medicines is driven by US companies, underscoring the necessity to boost innovation within Europe Union. The report acknowledges the pharmaceutical sector's vital role in the European economy, being the fourth largest market globally and a significant source of employment. It also addresses challenges in securing capital in the European Union, highlighting a substantial gap in private equity investment compared to the US, as well as the fragmented nature of public R&D investment across Europe. Similar to our findings, the Draghi report³⁰ identifies Health Technology Assessment as a significant barrier to introducing innovative medicines in the European market. Additionally, it recognizes the importance of regulatory sandboxes to foster innovation in the European Union. Nevertheless, it is important to recognise that Europe has enamours strengths, including a rich diversity of cultures and expertise, a strong educational system with reputable universities, robust healthcare systems, and the capability to coordinate complex regulatory processes across 27 Member States.

Recommendations

Based on the insights gathered from the interviews, as described in Graphs 2-12, the enhancement of the European Regulatory Ecosystem to attract pharmaceutical companies to prioritise filing their Marketing Authorisation Application (MAA) in the European Union and increase its competitive advantage can be achieved through the following key findings and recommended mitigation strategies as described in Table 3. The primary findings include issues such as lower prices, smaller market size, fragmented pricing and reimbursement systems, regulatory complexity, insufficient expertise and resources, convoluted legislations, limited funding opportunities and incentives, the need to simplify clinical trial approvals, and the importance of enhancing international collaboration. Additionally, The European

Regulatory Ecosystem has a diverse expertise that could be leveraged as a source of competitive advantage.

Conclusions

Pharmaceutical innovation involves inherent uncertainties and risks. Major uncertainties and risks in innovation relate to technology, regulations, and markets, and are typically addressed through mechanisms that aim to simplify.³¹ Regulatory ecosystems play a vital role in the development of new medicines within the pharmaceutical business.³² Early dialogue with regulators and main stakeholders is key for the success of approving innovative medicines.

It is important to highlight that there are positive proposals in the draft pharmaceutical legislation such as streamlining the decision making process by reducing the number of EMA committees and empower EMA to take some decisions, reducing the timelines of standard assessment and decisions, introduction of the concept of “Regulatory Sandbox”, joint scientific advice for drug-devices, introduction of the electronic product information, a new ‘conditional therapeutic indication’ to an existing marketing authorisation, and unlimited marketing authorisation without the need to renew after 5 years. However, there is a need to widen the eligibility of medicines for expedited pathways, better integration of different expedited pathways available in the European Union and establish the possibility of having rolling reviews. New avenues for early dialogue and a more competitive PRIME scheme are key to shaping drug development and to avoiding other regulators taking a prominent lead in influencing the global drug development. Any decrease of IP protection will undermine the competitiveness of the European Market.

The present regulatory and economic incentives proposed are not enough to foster innovation and early submissions in the European Union. The measures proposed to increase access to innovative medicines are not adequate since the root causes for delaying access of innovative medicines are multi-faceted. The measures introduced to enhance the protection of the environment may increase R&D costs. It is crucial that regulators continue to promote additional international collaborations with other

regulators and international organisations and consider establishing more competitive worksharing in cooperation with key regulatory authorities to attract early submissions and launches.

Pharmaceutical companies have limited resources to secure parallel submissions in different countries. Our findings echo existing literature³³ and suggest that the pharmaceutical Industry is likely to significantly shift strategy given policy changes in this regulatory domain and industry. Countries are modernising their regulatory systems (e.g. China) and more countries joining the ACCESS Consortium and Project Orbis, which could undermine the European Union in the first wave of submissions. Our findings suggest that the pharmaceutical industry is recruiting more senior roles in the US since their pharmaceutical market is bigger, translating into more R&D facilities and support for innovation, which could further undermine the European position. Based on the outcome of the interviews, it is urgent to implement new European policies to reform the pharmaceutical ecosystem to attract more research in life science, technology, new medicines, investment in biotech, and foster start-ups and talent in the European Union.

Policy recommendation summary

In summary, the policy recommendations outlined in the Table 4 are proposed to enhance the European regulatory system. These recommendations are based on our analyses of discussions with pharmaceutical experts and relevant literature. They are directly aimed at attracting more pharmaceutical companies to invest in and submit their innovative medicines in the European Union.

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