Medicines for Europe response to the Strategy for European Life Sciences

Medicines for Europe, representing manufacturers of generic, biosimilar and value-added medicines across Europe, welcomes the European Commission's intention to publish a Strategic plan for European Life Sciences.
The off-patent medicines sector has played a leading role in ensuring Europe's industrial competitiveness in life sciences. Medicines for Europe members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Furthermore, the EU has been a global leader in biosimilar medicines with the concept[1] originating in Europe along with R&D, biotechnological and biomanufacturing know-how.
The off-patent sector is also an essential driver of pharmaceutical innovation, as it is built around the current IP and patent systems. Off-patent medicines competition stimulates innovation into the next generation of innovative medicines.
However, without sound policies which are adapted to the specificities of the off-patent sector, the EU cannot capitalise on the strong existing knowledge and technological basis. This can lead to high-value technologies not reaching the market, but also to the security and strategic autonomy of the EU being undermined.
Nurturing and expanding existing R&D, production and technological capabilities are of strategic importance in ensuring preparedness for the next crisis, particularly in the current political and economic climates.
The risks associated with the off-patent medicines sector are distinct from those in the on-patent sector, but they are equally consequential, therefore it is essential to ensure predictability and to de-risk investments in order to capitalise on the existing strengths of this industrial sector.
Therefore, we encourage the EU to set out an ambitious Strategic Plan for Life Sciences, which can leverage the off-patent medicines sector and off-patent led innovation.
This should include the following elements:

1. Ensuring the definition of innovation encompasses off-patent innovation

It is essential to take into account social, environmental and economic benefits of innovation, as set out in the Innovation Principle paper. Off-patent driven innovation can significantly contribute to achieving these benefits and should be supported.
As highlighted in the Draghi report, State Aid and IPCEI for strategic sectors should be leveraged to ensure competitiveness and the definition of innovation should be expanded to include manufacturing processes and investments that support green and digital transitions, as well as security of supply.
More specifically, the definition of "first-of-a-kind" facilities should be updated to reflect the role of innovative manufacturing in bolstering supply autonomy and security. These facilities would incorporate advancements such as automation, continuous manufacturing, and improved environmental performance, while aligning with

[1] A biosimilar medicine is a biological medicine; it is an interchangeable version of an already approved originator biological medicine (reference medicine); the reference medicine and biosimilar medicine(s) can be used interchangeably without a patient experiencing any changes in the clinical effect[1]

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

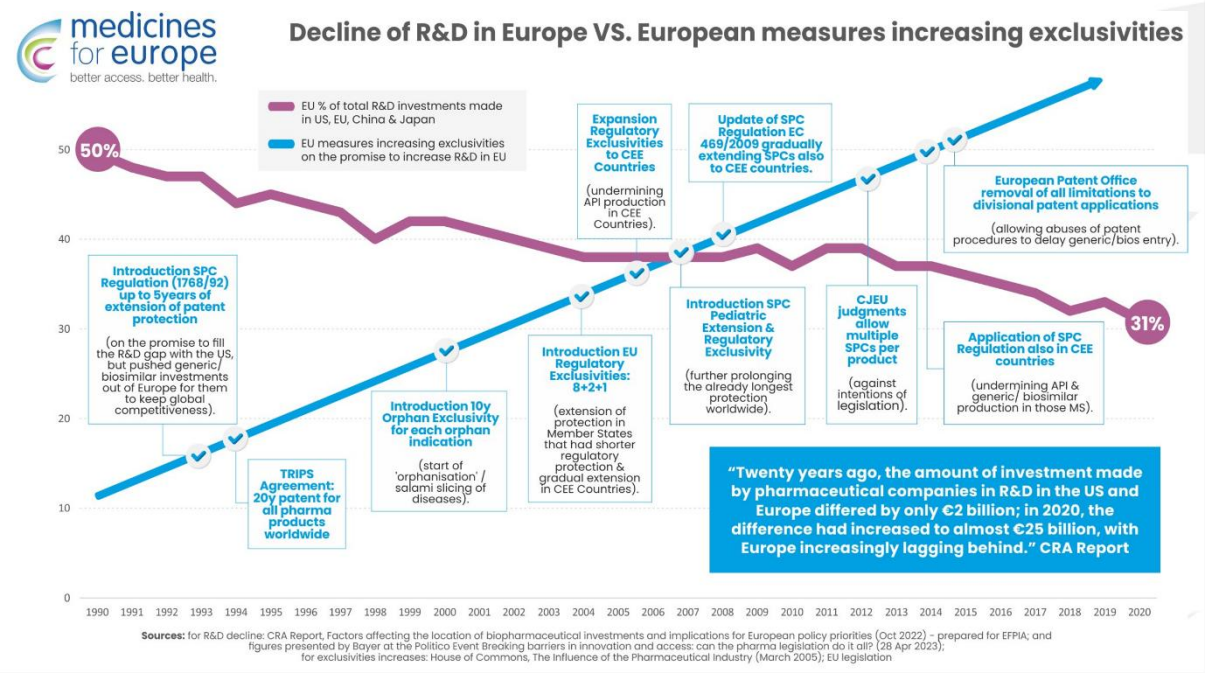
strict EU environmental and chemical regulations. There should also be a "last production site in Europe" criterion to ensure that the EU has the technological platform capability to produce critical medicines and APIs. By enabling the reintroduction of compliant production processes into Europe, these investments would enhance supply chain resilience and sustainability. Such measures would not only address current vulnerabilities in the pharmaceutical supply chain but also ensure adherence to EU environmental standards and support the region's green and digital transitions.

2. Bolstering competitiveness of the industry, especially in the off-patent sector

Stimulating competitiveness in the pharmaceutical sector generally implies (1) stimulating R&D investments in Europe, (2) ensuring timely competition, and (3) strengthening the EU manufacturing base.

(1) In the context of stimulating R&D investments in Europe, the Draghi Report stresses the increasing gap in companies' R&D investments in Europe compared to US or China, identifying the reasons for this in the lack of innovation hubs, and the need for better taxation incentives, stressing that "*EU funding should be refocused on the development of a limited number of world-class innovation hubs in life sciences for advanced therapy medicinal products*" (p.35, Part A) and that "*[m]ore uniform taxation policies benefit R&D activities in the US. Tax systems significantly influence biopharmaceutical companies' decisions regarding the location of their headquarters and R&D centres.*" (p.193, Part B)

This confirms the actual delink between investments in R&D in Europe and intellectual property (IP) protection in Europe, which is often wrongly described as the driver for EU R&D. Indeed, the graph below describes the significant increase of IP/regulatory protections in Europe over the past 30 years in the face of a constant decrease of EU companies' R&D investments in Europe vis-a-vis US and China. This confirms what the Commission has clarified on several occasions, which is that incentives to invest in R&D in Europe depend on factors unrelated to IP.



(2) On the contrary, stimulating timely competition strengthens the competitiveness of the industry and effectively stimulates innovation. The Draghi Report stresses that the "*evidence is overwhelming that competition stimulates productivity, investment and innovation*" (p.17 & 13, Part A). It also stresses the need for "*revamping competition policy and reducing administrative and regulatory burdens*" and "*avoid the pitfalls of the past – such as defending incumbent companies or picking winners*" (p.63, Part A). But the Draghi Report goes even further by urging more powers to European Competition authorities stressing that security and resilience considerations "*should get more weight in competition evaluations, since they have become increasingly important in today's world*" and that these should be used as "*an additional public interest criterion*" (p.300, Part B), therefore denoting the importance of increasing not only competition in the pharmaceutical sector, but also pharmaceutical manufacturing in Europe to strengthen industry competitiveness.

(3) Strengthening competitiveness of the industry and manufacturing in Europe is also an objective of the Supplementary Protection Certificate (SPC) Manufacturing Waiver (Regulation (EU) 2019/933), one of the key legislations intended to support biosimilar and generic manufacturing in Europe. It has the objective to remove the competitive disadvantage that European developers have vis-a-vis non-EU producers of biosimilar and generic medicines. Indeed, Europe has the longest IP protection worldwide and therefore European manufacturers have been forced to delocalise production of medicines in order to remain competitive with other regions (US, Asia, etc.).

To remedy such unintended effect of the Supplementary Protection Certificate (SPC), the SPC Manufacturing Waiver allows production of biosimilar and generic medicines during the SPC protection in Europe, with the ultimate objective to allow immediate launch of these products in EU and worldwide after IP expiry. However, due to the several conditionalities introduced in the legislation in 2019, the Regulation foresees a regular 5-year review in order to assess if such conditionalities effectively allow the achievement of the stated objectives, ie. to stimulate manufacturing of biosimilar and generic medicines. According to The 'Review of the SPC Manufacturing Waiver: a 2024 Industry Report' by Medicines for Europe (https://www.medicinesforeurope.com/wp-content/uploads/2024/06/Updated-2024-Industry-Report-on-SPC-Manufacturing-Waiver-Medicines-for-Europe-REV-CLEAN.docx.pdf), the current form of the regulation imposes disproportionate regulatory burdens and legal uncertainties, particularly for more complex products (eg. biosimilars), which makes the legislation unusable for companies, which continue suffering from a competitive disadvantage vis-à-vis non-EU developers. We urge the Commission to quickly review the Regulation as mandated by the law and amend and clarify the aspects that frustrate the competitiveness of the EU manufacturing industry.

3. EU market dynamics which foster healthy competition

Healthy market competition acts as an enabler to innovation. Monitoring competition levels and developing pro-competitive policies should be an intrinsic part of the plan.

The development of off-patent medicines, be it generic, biosimilar or value added medicines, remains a high-risk, capital-intensive activity. Whereas opportunities for access to finance exist, a sound business case is needed to attract the necessary investments which enable companies to develop and commercialise new therapeutic alternatives.

To achieve this, it is crucial to implement policies that support the market entry, uptake and continued market presence of new technologies and therapeutic options, including generic, biosimilar and value added medicines,

and not just new on-patent medicines. This can ensure that the off-patent market remains a sustainable one and that companies can continue to deliver on the promise of competition.

A sound EU Life Science plan should also include financial measures to support countries in incorporating new technologies delivered through off-patent innovation (e.g. ready to use formulations, digital solutions, new indications, etc.) within their national health systems. These transformative technologies would support the digital transition of EU healthcare systems, as well as support companies investing in the EU, which currently only accounts for a quarter of the total US value added medicines market.

4. Addressing unnecessary regulatory complexity

Streamlining and ensuring predictability in regulatory processes is an essential tool to boost the competitiveness of the EU off-patent medicines industry.

As highlighted in chapter 2 of our position paper on the pharmaceutical legislation there are numerous opportunities to reduce the administrative burden and regulatory complexities faced by EU companies , which would help make them more competitive on a global stage.

These include simplifying and shortening approval and variation processes, ensuring submission predictability, as well as clarifying overlaps between different EU regulations (e.g. the general pharmaceutical legislation and the medical devices regulation).

The transition to ePI would ensure healthcare professionals and patients receive real-time updates about the medicines they use and support the digital transition in healthcare. This would position the EU at the forefront of digital innovation in pharmaceuticals, reinforcing our commitment to modern, patient-centric healthcare solutions.

One element which would make the European generic medicines industry more competitive on a global scale, would be the transition to a single global development approach, which would reduce the current need to duplicate bioequivalence trials. Particularly in smaller populations, such as paediatrics or orphan diseases, this constitutes a significant barrier for companies to develop and commercialise their products.

In the biosimilar medicines space, streamlining clinical trial requirements (so-called comparable efficacy studies CES), is a key pillar to ensuring continued competition in a broader range of the next generation of biological medicines which are losing exclusivity. This will ensure the continued leadership of the EU in the field of biosimilar medicines.

With the implementation of the EHDS Regulation drawing closer, EU developers will have unprecedented access to real-world data which can be used to generate real world evidence. A key consideration in the implementation of this regulation should also be ensuring that the processes which are set-up to access the data are not unnecessarily burdensome from either financial, time or general resource points of view, as that would counter the initial intention of the regulation. Secondly, this key advantage cannot be leveraged without furthering the acceptability of this RWE as a new source of evidence for both regulatory and HTA processes.

One pathway which can be used to ensure predictability, especially as the EU is going through a time of transition, is the possibility for early dialogues with all relevant parties. These can be used both for biosimilar medicines, to ensure early engagement on requirements for emerging areas such as cell and gene therapies, as well as for value added medicines, including repurposed therapies, to ensure alignment between regulatory and HTA requirements. Setting up these processes and employing them can be a resource intensive activity, therefore adequate funding should also be secured.

Finally, the EU should maintain its leadership and continue to push for harmonisation and alignment at an international level, as this would have an exponential effect in boosting the competitiveness of the European life science sector.

5. Creating a supportive investment ecosystem

The green and digital transitions cannot be successfully conducted without creating a supportive investment ecosystem which ensures the ability for companies to produce and invest in Europe.

The EU Life Science Plan should recognise and nurture Europe's skilled workforce, know-how, experience and global leadership on biosimilar medicines, including by ensuring access to any relevant funding instrument. EU investments in biosimilar R&D and manufacturing have consistently expanded over the last 20 years and the EU should fully leverage this European excellence, particularly as the next wave of biological medicines losing protection involves a new set of technologies and technological platforms which the current EU ecosystem would need to expand to meet future EU and global demand.

Funding should be directed towards supporting companies in their green and digital transitions, to ensure that the life science sector maintains and further develops its existing strong EU presence.

Through the Critical Medicines Act, the EU should create an ecosystem that promotes healthy competition, rewards sustainable and secure supply chains, and ensures Open Strategic Autonomy. The Act needs to address the structural challenges that disincentivise medicine and API production in Europe, by encouraging investment in manufacturing and more diversity in supply chains. This will enable the EU to be ready with a core set of essential medicines during any crisis—whether health-related, in times of war, or in the face of protectionist measures from non-EU countries.

The off-patent medicines sector is an essential component of the EU Life Science strategy thanks to its active stimulation of the innovation lifecycle. In addition, to capitalise on Europe's leadership in off-patent medicines and ensure strategic autonomy, the EU must implement a robust Strategic Plan for Life Sciences that recognises and supports off-patent led innovation. This can be done by fostering a competitive environment, streamlining regulatory processes, and creating a supportive investment ecosystem, so that the EU can leverage its existing R&D and manufacturing strengths, drive green and digital transitions, and secure its position as a global leader in life sciences.