EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

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BUILDING A COMPETITIVE PHARMACEUTICAL ECOSYSTEM FOR SMALL AND MID-SIZED INNOVATIVE COMPANIES

Dear President of the European Commission Ursula von der Leyen,
Dear President of the European Council Charles Michel,
Dear President of the European Parliament Roberta Metsola,

Over the past five years, the global healthcare landscape has undergone major shifts due to the COVID-19 pandemic and international crises. New policies and structures have been rapidly established and implemented at EU and national levels. The pharmaceutical industry has been a reliable partner for the EU and the Member States to overcome these challenges and is committed to ensuring healthcare systems are more resilient. As the EU plans for the next decades, we must ensure that the European healthcare and pharmaceutical landscape is equipped to address current and future challenges and leverage available opportunities.

EUCOPE represents over 2,600 small and medium-sized pharmaceutical companies who research and develop the next generation of pharmaceutical innovation and therapeutic solutions across the 27 Member States. At the start of the new institutional cycle, we would like to share our perspective on the outlook of the pharmaceutical sector and competitiveness of the EU.

With the appropriate policy landscape, the EU can remain a region for novel therapies and technologies to flourish, delivering necessary treatments for patients. EUCOPE calls on the EU Institutions and Member States to cooperate in building a competitive and attractive pharmaceutical ecosystem. We especially emphasise the role of small and mid-sized innovative companies in Europe, many of whom actively drive the development of technologies, such as advanced therapy medicinal products (ATMPs) and orphan medicinal products (OMPs).

It is crucial to underline critical aspects of the ongoing Revision of the EU's General Pharmaceutical Legislation. It presents us the opportunity to enhance the EU's competitiveness globally. Future proofing this legislative framework requires renewed support to attract investments in the development and manufacturing of innovative medicines for patients in Europe. Policies need to keep abreast of pharmaceutical innovation, preserving the robust foundations that have been proven elements leading to success.

For this purpose, it is pivotal that the new legislative framework will:

- Maintain a strong and predictable incentive and intellectual property protection framework for all medicines, and especially for OMPs and ATMPs, which require targeted and riskier investments.
- Increase R&D in underserved areas through support mechanisms for basic research and fostering public-private partnerships between academics, researchers and industry, as well as the direct involvement of patients.
- Adopt a holistic approach to access policies, that take into consideration the specificities of different medicinal products, such as OMPs, ATMPs and AMR products, and the peculiarities of small and mid-sized companies.
- Modernise the regulatory framework, to anticipate and adapt to future methodologies and technologies, maintaining a positive risk-benefit approach while reducing the time to authorise innovative medicines.
- Tackle the root cause of medicine shortages, alleviating concerns of citizens and healthcare systems day-to-day, while also providing robust preparedness strategies to pre-empt any future crises.

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A host of healthcare policy files will determine the future EU competitiveness and attractiveness for innovative pharmaceutical companies, and therefore must be thought of holistically. Reforms in these areas must be thought of in the context of the entire healthcare ecosystem to truly benefit all stakeholders – for patients, payers, regulators, policymakers and developers alike. Different legislations and initiatives impact our ecosystem, including the implementation of the EU Health Technology Assessment (HTA) Regulation, European Health Data Space (EHDS) Regulation, and the Communication to Boost Biotechnology and Biomanufacturing in the EU, as well as much needed initiatives such as the European Rare Diseases Research Alliance (ERDERA) and the EU4Health Joint Action on integration of European Reference Networks into national healthcare system (JARDIN). In the area of rare diseases, the EU needs a comprehensive Rare Disease Action Plan or Rare Disease Framework to ensure a comprehensive and coordinated approach on rare diseases across various policy fields.

To remain globally competitive, the EU's pharmaceutical industry needs a robust, predictable and strong investment and industrial ecosystem. Thinking beyond strictly pharmaceutical-related legislation, EU industrial policy further shape the business environment that our members operate in, thus in turn directly impacting the pharmaceutical ecosystem. We are encouraged by the intention of the report on the future of European competitiveness, developed by Mario Draghi, and the inclusion of the pharmaceutical industry in its reflections. The combination of these elements should work cohesively towards ensuring that the EU remains a leader at global level.

Small and mid-sized companies are key drivers of pharmaceutical innovation in the EU. They deserve an ecosystem within which they can prosper and compete on a global scale, benefiting not only patients but also the whole health community and European society at large. As their voice in Brussels, EUCOPE is willing to work together with EU Institutions, Member States, patients and any other relevant stakeholder to build the framework that will put the EU at the forefront of pharmaceutical innovation.

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