EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

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EUCOPE POSITION PAPER IN RESPONSE TO THE PUBLIC CONSULTATION ON THE PHARMACEUTICAL STRATEGY FOR EUROPE –TIMELY PATIENT ACCESS TO AFFORDABLE MEDICINE

Executive Summary

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) is the voice of small to medium-sized innovative companies active in the field of pharmaceuticals, biotechnologies and medical technologies at the European level.

Since the Public Consultation on the Pharmaceutical Strategy is structured in a way that does not allow to elaborate on several aspects of great of relevance to EUCOPE members, we seize this opportunity to contextualise our position with regard to some fundamental aspects that we hope to see reflected into the Pharmaceutical Strategy.

This paper complements our contribution to the Pharmaceutical Strategy Consultation and highlights the key points we call upon the **European Commission and the Member States to** tackle to create a forward-looking and patient-centric pharmaceutical ecosystem in Europe.

1. **Ensure a coherent and balanced approach that delivers on all the objectives of the Pharmaceutical Strategy by:**
   - Promoting the European pharmaceutical sector competitiveness and investing in tomorrow's innovative solutions;
   - Maintaining a strong incentive ecosystem to foster research in areas of high unmet needs, as well as supporting delivery of continued innovation where treatments exist;
   - Ensuring the integrity of the regulatory framework by reinforcing the fundamental principle of patient safety.

2. **Adopt a value chain approach, encompassing not only European manufacturing but also innovation leadership by:**
   - Encouraging measures to strengthen existing manufacturing capabilities in Europe but also investing in infrastructures fostering innovation leadership and pushing for becoming an attractive innovation hub;
   - Promoting international regulatory convergence and reducing trade barriers;
   - Striving for adaptable yet clearer and faster regulatory pathways to harness the potential of new technologies;
   - Reducing administrative burdens and overregulation;
   - Promoting harmonisation of Intellectual Property (IP) and tech transfer policy.

3. **Build on the existing EU initiatives rather than creating new ones in accordance to the principles of better regulation and, at the same time, reduce red tape and create a more**

attractive environment for homegrown and foreign biopharmaceutical companies by:

- Reaching an agreement on the EU Health Technology Assessment (HTA), provided that it takes into account the specificity of innovative therapies such as Orphan Medicinal Products (OMPs) and Advanced Therapy Medicinal Products (ATMP);
- Ensuring progress with regard to industry involvement in the European Reference Networks (ERNs);
- Working towards making cross-border healthcare a reality;
- Maintain the efficiency and speed of response shown during the pandemic.

4. **Consider health as a long-term investment with high returns for patients and society as a whole by:**
   - Assessing the cost of medicines in the context of overall healthcare expenditures and in conjunction with wider national budgetary policies;
   - Avoiding that recovery measures in response to the COVID-19 crisis affect long-term investment in health innovation.

1. Ensure a coherent and balanced approach that delivers on all the objectives of the Pharmaceutical Strategy

As we stated in our response to the Pharmaceutical Strategy Roadmap, we believe that there is a disconnect between the identified issues and the actions proposed in the Strategy, with a lack of concrete proposals to **promote European pharmaceutical sector competitiveness and investment in innovative solutions**.

EUCOPE's members, a wide range of **small to medium-sized companies** active in pharmaceuticals, biotechnologies and medical technologies, **play a key role in the European pharmaceutical environment**. Some of them have unique profiles due to their highly specialised product portfolio, no or limited revenues to date, significant and continuously risky R&D investments, including in OMPs and ATMPs. **Targeted incentives need to be maintained to** sustain lengthy investments and planning cycles required to foster research **in areas of high unmet needs, such as rare diseases and antimicrobial resistance (AMR)**, as well as to support the delivery of continued innovation where treatments exist. The EU's objective of ensuring greater access, availability and affordability should go along with enabling innovation through a strong incentive ecosystem.

Patient safety is one of the key underlying principles of the European legislation on the authorisation of medicines. The integrity of the regulatory framework must be upheld with no exception. **European citizens deserve medicines which are proven to be safe, effective and of high quality.** Any decision on the usage of unauthorised medicines must be left to the medical professionals (notwithstanding any provisions of public health emergencies) and the concerned patient. The EU must reinforce its system to track

emerging data on risks for patients' safety regardless of the authorisation regime of the medicines and allow for speedy reactions at European level to provide for high safety standards throughout the European Union.

2. Adopt a value chain approach, encompassing not only European manufacturing but also innovation leadership

When it comes to the Strategy's objective of reducing dependence on manufacturing from non-EU countries for essential medicines the EU should **strengthen its existing production capabilities**. The EU should also work with its Member States to **encourage advanced manufacturing capabilities** and other incentives such as favourable tax reforms to effect gradual change for targeted products. In line with the Directive on Public Procurement 2014/24/EU, European manufacturing capabilities should be encouraged by means of a broad range of criteria, including security of supply, value created, social and environmental performances, but also appropriate and competitive requirements instead of overregulation.

The Strategy's Roadmap acknowledges how COVID-19 "showcases that European responses to new and emerging health crises do not happen in a vacuum but rather have an important international dimension." In view of this, the EU should consider building resilient and diversified European supply chains by working more closely with like-minded countries, including through **regulatory convergence and reducing trade barriers** to ensure diversity of supply sources.

The aspect of manufacturing sovereignty should be part of a holistic approach to the pharmaceutical value chain, encompassing today's public health needs looking towards tomorrow's healthcare solutions. In this respect, the EU should also further build its **''innovation hub"** by investing in infrastructures such as pan European **disease registries, e-health system, and biobanks and factoring in public-private partnerships to do so**.

We call for strategies in line with the latest technological developments leading to the progressive integration of pharmaceuticals and medical technology, technology and personalised medicines. EUCOPE hopes to see a cross-sectoral approach applied to the interplay between healthcare, trade and intellectual properties (IP). **Adaptable yet clearer and faster regulatory pathways,** avoiding any divergent and duplicative requirements, will be key to harness the potential of new technologies, such as ATMPs, nanotechnologies, drug-device combination (DDC) products and medicinal products that are developed and used in combination with companion diagnostics.

To date, the EU provides no legislation that harmonises technology transfer policy across its Member States. Despite the European Commission stated in 2010 that it hoped to better facilitate knowledge transfer between the public and private spheres by establishing clear rules surrounding ownership of (IP) rights[1], no European-wide legislation has followed. **Harmonisation of IP and tech transfer policy could help further commercialise EU-funded research and innovation and generate value locally.**

[1] https://ec.europa.eu/research/innovation-union/pdf/innovation-union-communication_en.pdf

3. Build on the existing EU initiatives rather than creating new ones in accordance with the principles of better regulation and, at the same time, reduce red tape and create a more attractive environment for homegrown and foreign biopharmaceutical companies

A final agreement between the European Commission and Member States on the EU Health Technology Assessment (HTA) would be a concrete step in the right direction. The joint clinical assessment proposed by the EU HTA, if allowing for a sufficient level of flexibility to manage of evidential uncertainty in specific cases such as ATMPs and OMPs, would significantly contribute to foster innovation in Europe. By minimising the red tape and fragmentation (regulatory and financial), the Commission has the potential to make commercialisation and scaling-up in Europe easier and, therefore, more attractive for emerging homegrown and foreign biopharmaceutical companies.[2]

The Commission's new Pharmaceutical Strategy presents also a unique opportunity to explore options to improve already existing initiatives, such as the **European Reference Networks (ERNs)** and cross-border healthcare. Increased industry involvement within the ERNs would allow both the research field and the innovative pharmaceutical industry to learn from each other, and ultimately improve patients' lives. With regard to cross-border healthcare, even if European legislation has been long adopted, the **Commission and Member States still need to work with all parties on its full implementation**. The transfer and treatment of COVID-19 patients from one European country to another has demonstrated that this is possible. This should be the case not only during health emergencies but also in day to daycare for patients. **In accordance with the principles of better regulation**, it is also of paramount importance to avoid a further increase of the regulatory burden on businesses, citizens or public administrations. The European Commission should rather build on existing legislation and existing initiatives by providing clear guidance on their interpretation and application where needed.

4. Consider health as a long-term investment with high returns for patients and society as a whole

While the innovative pharmaceutical industry is determined to cater for all patients, **access is a shared responsibility and it requires an aligned approach**, with Member States playing a crucial role. It is important to recognise the **need for investment in healthcare systems and new technologies** as a precondition for access to available and affordable medicines, as stated in the Mission Letter to Commissioner Kyriakides. The Joint Evaluation of Regulation of the on medicinal products for paediatric

[2] On EU Health Technology Assessment (HTA), EUCOPE supports the initial proposal put forward by the European Commission with few caveats. Although it would be a positive outcome to reach an agreement on the Regulation, there is also the question about any additional clinical data that Member States might request as mandatory to pharmaceutical companies. This would pose further regulatory burden and could delay the whole process, and subsequently delay final patient access too. Instead, theF joint clinical assessment as proposed by the EU HTA, and sufficient level of flexibility to manage evidential uncertainty in specific cases such as ATMPs and OMPs, would significantly contribute to foster innovation in Europe.

use[3] and Regulation on orphan medicinal products[4] outlines the increasing inequalities in access to innovative medicines, but it does not recognise that small to mid-sized companies do not have operations in all European countries. In particular, due to the fragmentation of the European pharmaceutical markets and the difference between healthcare systems, companies need to decide where they can invest and set-up their operations. Access does not stop at reimbursement, and there is a series of commercial, medical and regulatory activities that go together with the launch of a product and requires the set-up of a dedicated entity in a country. This requires a significant investment from companies, especially new and emerging companies that are often pre-commercial or with limited revenues and therefore not yet profitable.

Rewarding and encouraging innovation should not be seen as a cost, but as a long-term investment, with a considerable return for European society as a whole. When examining the value of a medicine, it is essential to look at the savings it is expected to bring to the healthcare systems. Even the World Health Organization has recommended against "cost-plus" (based on input costs) pricing approaches as the foundation of national pricing policies. While we recognise that coordinating the decision making process of different national budget holders is challenging, we believe cost of medicines should not be evaluated in isolation – but instead reviewed in the context of the overall healthcare expenditures. Only then, **affordability can be assessed by keeping an open dialogue between industry and national authorities**. This includes, but is not limited, to the authorities responsible for medicines reimbursement and budgets and who should jointly explore innovative solutions to bring new products to the market.

Actions at EU level should also adopt a holistic approach and long-term vision towards economic and austerity policies. For instance, the new European Commission's Recovery and Resilience taskforce, established to coordinate the implementation of **the recovery plan across the EU in the wake of the coronavirus** crisis, should ensure that the proposed measures within the European Semester and the overall economic governance of *NextGenerationEU* **do not penalise or curb long-term investment in healthcare and pharmaceutical innovation.**

[3] (EC) No 1901/2006
[4] (EC) No 141/2000