EUCOPE
European Confederation of
Pharmaceutical Entrepreneurs AISBL

14 September 2022

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By e-mail

MEETING REQUEST - REVISION OF THE GENERAL PHARMACEUTICAL LEGISLATION AND ORPHAN MEDICINAL PRODUCTS REGULATION

Dear Commission President Von der Leyen,
Dear Commissioner Šefčovič,
Dear Commissioner Kyriakides,
Dear Commissioner Breton,

EUCOPE commends the European Commission's ambition to streamline and future-proof the EU legislative and regulatory systems and its efforts to improve patient access. However, we are deeply concerned by some of the options explored by the Commission, which **risk undermining the competitiveness and attractiveness of the EU** and the direction of research to treat those patient in need. Our main concerns regard the topics of launch conditionality and defining "unmet medical need/ highest unmet medical need", in short (H)UMN in the context of the General Pharmaceutical Legislation (Regulation 726/2004 and Directive 2001/83/EC) and Orphan Medicinal Products Regulation (Regulation 141/2000). The proposed policy options are **particularly punitive for small and mid-sized companies** to whom EUCOPE gives a voice.

We would appreciate the opportunity to meet and expand on our concerns raised to the Cabinet of Commissioner Kyriakides in May 2022 and explore possible solutions.

Regrettably, the Commission's **policy options regarding launch conditionality** fail to recognize the realities of the small and mid-sized pharmaceutical industry and access challenges. This revision will inform the direction of research, innovation and patient welfare for decades to come, and we are deeply concerned by its current direction.

First, it is essential to reiterate that **industry is not the only actor involved in launch and access decisions** in the EU Member States. The reimbursement authorities are very much involved and in fact are the ultimate decision-maker in these discussions. **Industry does not have full control** over the timing of access and placing obligations on industry alone, is **not proportionate** with our decision-making ability. The approach of launch conditionality is inherently flawed because **it provides no guarantees for national health authorities to arrive at a pricing and reimbursement decision within 2 years of marketing authorisation** of an innovative medicine. National authorities could artificially delay their decisions to or beyond the proposed 2 years, to apply additional downward pricing pressure on developers or to accelerate generic competition. Fundamentally, this would **contradict the Commission's desired aim of accelerating access and would gradually decrease Europe's level of attractiveness for companies**.

Second, the Commission's proposal does not consider the **unique characteristics of novel therapies, such as ATMPs, and of diseases which require different approaches, such as rare diseases**. The infrastructure requirements or expertise and specialist centres needed to deliver certain innovative therapies, such as gene therapies, do not exist in all Member States. Specific infrastructure or expertise might be needed for diagnostics or treatment which can require patients to move to other Member States

where centres of excellence exist. Additionally, people with rare diseases may not be present in all Member States.

This policy option **does not recognise the practical and real limitations of our small and mid-sized companies** to launch a medicine in all 27 Member States in a fixed timeframe. If a company has a fixed manufacturing capacity or is present in only a handful of countries, a requirement to launch in all Member States, including where it has no presence, has significant commercial implications and interferes with the EU principle of freedom to operate. Providing additional incentives to encourage launch will not overcome this challenge and fails to recognize the real barriers. At the same time, undermining the regulatory data protection will have long-term competitiveness implications. **Thus, this policy option would not achieve the desired change, while simultaneously actively undermining innovation**.

Last, we are concerned that a restrictive interpretation of (H)UMN will shape the long-term direction of R&D and which risks overlooking patient groups. The combination of rapidly advancing science and a long-time lag in developing novel therapies will make it difficult for policies around (H)UMN to respond appropriately to drive research where it is needed without creating inefficiencies. A discussion of 'cure' in any understanding of (H)UMN would be detrimental and fails to reflect the realities of medical innovation. The approach currently being explored by the Commission risks bringing about unintended consequences, while not fully addressing the challenges of underserved areas..

EUCOPE and its members are committed to building an innovative European healthcare and pharmaceutical environment that rewards innovation, promotes access, and balances system sustainability. **We would appreciate the opportunity to meet and build on our conversation from May 2022 with Commissioner Kyriakides' Cabinet** and discuss how the ongoing revisions could best balance different interests and achieve the Commission's goals of encouraging innovation and promoting access.

Yours sincerely,

Dr Alexander Natz
Secretary-General, EUCOPE

Annex 1: EUCOPE White Paper on Incentive Conditionality and Obligations