EUCOPE Feedback DirectivE– EU Pharmaceutical Package

(max. 4000 characters – Current 3971)

EUCOPE acknowledges the objectives of the Pharmaceutical Package, and welcomes maintaining a separate Directive and Regulation for decentralized and central approval process. While we appreciate streamlining and digitisation of regulatory procedures, we are concerned that other proposed provisions will undermine R&D, innovation, EU competitiveness, and be particularly detrimental for small and mid-sized companies. The proposal introduces more risks and unpredictability into the system, while significantly reducing incentives.

**Unmet medical need (UMN)**

The EU should retain a broad common understanding of UMN, governed by EMA and involving patients, industry and other key health stakeholders, and not codify this in legislation. The proposed definition of UMN is strict and unclear. This introduces unpredictability into the system which makes it challenging for companies to invest in the development of new therapies and ultimately jeopardizes broader patient access. The strict criteria risk hampering innovation, and risk overlooking some patient populations over other. A legally binding definition of UMN will have unintended consequences at P&R level, by giving products a ‘stamp’. This definition will not contribute to a future-proof system, since not all patients and diseases are the same and UMN evolve over time. UMN should not form the basis of the modulation of incentives, as it will not address the existing challenges, but risks exacerbating them.

**Regulatory Data Protection (RDP)**

The proposed modulation of RDP will hinder innovation and make the EU less competitive at global level, undermining what was a competitive advantage for the EU. Any reduction in RDP will disproportionately affect companies, especially small and mid-sized. Conditionalities will increase unpredictability and risk reducing investments in the EU, with knock-on effects on innovation for patients. Many small and mid-sized companies have a limited portfolio of therapies, which means that strong and predictable RDP is imperative to their sustainability within the EU, and for investment and research into complex areas.

**Launch conditionality**

EUCOPE’s members are committed to making their therapies available as widely as possible. Sometimes launching in all 27 Member States is unfeasible, particularly for ATMP and OMP developers or smaller companies. A launch conditionality (release and continuously supply), where developers only receive their full exclusivity period for launching in all Member States in 2-3 years is punitive and won’t address the underlying access challenges. The proposal doesn’t appropriately consider the infrastructure requirements, implications on small patient populations, or resource limitations of smaller developers. Developers aren’t the sole decision-makers regarding launch (e.g., P&R decisions or national priorities) which isn’t appropriately reflected in the proposal. To support access, alternative solutions should be pursued, e.g., cross-border healthcare.

**Hospital Exemption (HE)**

EUCOPE welcomes the Commission’s efforts to provide additional clarity and harmonization regarding the implementation of HE across the EU. An important exemption to the centralized procedure, we call on further clarity on its use and when it can be used, especially regarding the definition of non-routine use, bringing important predictability to the system, while continuing to protect patient safety.

**Other areas of concern include:**

* Linking environmental risk assessment (ERA) to obtaining or withdrawing marketing authorization: this entails the risk of delaying approval and patient’s access to new treatments.
* R&D transparency requirements.
* DCPs/MRP: new “Opt-In” provisions for national authorities.

**Other provisions we welcome include:**

* Maintaining the 6-monhth SPC extension as reward for conducting PIP.
* Increased use of digitisation and electronic processes.
* Active substance master file certificate and quality master file certificate.