EPF response to the European Commission's call for feedback on the revision of the EU Pharmaceutical Legislation

The European Patients' Forum (EPF) welcomes the long-awaited revision of the EU pharmaceutical legislation. This is a unique opportunity to make the EU regulatory framework for the authorisation of medicines **more patient-centred**, aiming for fair access to medicines.

Although the Commission's proposal contains some positive steps forward, more can be done to ensure that the legislation meets the needs of those who will use the approved medicines: the patients.

Firstly, the legislative overhaul must lead to the **development of medicines that target patients' needs**. In this context, EPF is calling for a common EU-wide definition of **"added therapeutic value",** developed in partnership with patients. This is a concept that is currently insufficiently defined throughout the lifecycle of new medicines. Similarly, the **definition of "unmet medical need"** included in the proposal fails to foster patient-centred innovation and ignores factors that are important to patients, such as impacts on quality of life. Patients must be involved at all stages of the development of this definition.

Secondly, the review should also **create a fairer system of access to medicines.** There needs to be a **fair balance** between incentivising R&D of products that provide a real added value and ensuring access to new therapies. As the current system has shown its limitations, we support **modulated incentives** that encourage faster launch of new medicines across all EU member states, while supporting faster access to generics and biosimilars. Member States must also play their role in ensuring the availability and access to medicines, in line with existing legislation.

In the area of **antimicrobial resistance**, we are concerned about the limited evidence on the effectiveness and the potential costs for healthcare systems of the transferrable exclusivity vouchers proposed by the Commission. The regulatory framework should create the conditions for faster approval of new antimicrobials and promote incentives that de-link sales revenues from sales volumes.

While EPF supports the focus on **shortages** in the revision, we regret the lack of patient involvement in the management of shortages, for example in reporting shortages or drafting lists of shortages and critical medicines. Their involvement in the development of policy solutions is key, not only to improve data collection and understanding of the societal impact of shortages, but also to ensure that policy responses meet patients' needs.

Thirdly, the revision of pharmaceutical legislation must lead to **a patient-centred regulatory process**. While we welcome the inclusion of patients in the CHMP, we call for the involvement of patients in the scientific working groups that will be set up by the CHMP. We also need to ensure that the expertise of the scientific committees that are set to disappear under the new proposal will be preserved. We are concerned by the disappearance of the PDCO. Without a dedicated committee, it is unclear how patients' and member states' expertise will be maintained and whether EMA will have the leverage and resources to push for specific studies in the most underserved populations, such as neonates.

In terms of adapting to scientific progress, there is a need for a **flexible and adaptable regulatory framework** that supports innovation and remains fit for purpose, but any new regulatory approaches to emerging technologies must be guided by the principle of patient safety.

Finally, the revision should not create new inequalities between patients. **Paper leaflets should remain available**, alongside electronic formats, for all patients who do not have access to the Internet or have limited digital literacy.

Engaging in meaningful dialogue with the patient community will be essential to ensure that the revision meets the needs of patients. EPF is committed to being a strong and constructive partner in the legislative process and to continuing its reflections with the legislators and key stakeholders.