EPF's reaction to the European Parliament's position on the revision of the EU pharmaceutical legislation

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The European Patients' Forum (EPF) welcomes the **European Parliament's adoption of the reports on the Directive and the Regulation**, formalising the Parliament's official position on the revision of the EU pharmaceutical legislation.

The revision represents a **unique opportunity to prioritise patients' needs** by increasing their involvement throughout the medicine lifecycle and improving their access to safe, effective, and high-quality medicines.

This landmark agreement brings us closer to achieving a more patient-centred EU pharmaceutical regulatory framework. We look forward to working with the Council of the EU to embed the Parliament's improvements and include additional amendments to ensure that the revision truly meets patients' needs.

We commend the progress made in **improving patient involvement in the regulatory process,** which is critical to achieving high-quality regulatory outcomes. For example, the introduction of mechanisms for patients to report shortages at national level promises to improve data collection and understanding of the societal impacts of shortages. The formal inclusion of patients in the scientific working groups established by the Committee for Human Medicinal Products will ensure that their perspective on benefits and risks of medicines is duly taken into account. In view of EMA's restructuring, we support the inclusion of an ad hoc working group on paediatrics, although more details on its role and functioning are needed.

We also welcome the **improvements to the patient leaflet**, particularly the inclusion of a key information section and the consultation with patient groups before moving to an electronic-only leaflet. However, it remains unclear how Member States will enforce patients' formal right to continue to receive a paper leaflet. Ensuring access to a paper leaflet is essential to avoid creating new inequalities for patients without internet access or with limited digital literacy.

More can be done to ensure that **medicines are tailored to patients' needs**. The inclusion of the patients' perspective and lived experience when defining and assessing whether a product fulfils an unmet medical need is crucial. Patients' priorities often differ from those of the general public and other health stakeholders. The more systematic inclusion of patient experience data in the marketing authorisation dossier can provide invaluable information about the impacts of a product on outcomes that matter to patients.

Finally, the revision should **strive to enhance access to medicines and address the unacceptable inequalities that remain within and between EU member states**. We hope that the proposed mechanisms to incentivise innovation and improve access in the Parliament's position will translate into tangible benefits for all patients across Europe. We call on the Council to **continue to prioritise the discussion on access** as part of the negotiations of this legislation. We reiterate our call for a balanced approach which encourages R&D of products that provide real added value while ensuring patients' access, wherever they are in the EU.

As the legislative process moves forward, EPF will continue to work closely with the EU institutions to ensure that the new rules benefit those they affect first and foremost: the patients.

ABOUT EPF

EPF is an umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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