EPF reaction to the draft reports on the revision of EU pharmaceutical legislation

October 2023

The European Patients' Forum (EPF) welcomes the publication of the draft negotiating positions, bringing the legislative process one step closer to the adoption of the revision of the EU pharmaceutical legislation. The patient community has been waiting a long time for this crucial revision, which will have an impact on their access to safe, effective and high-quality medicines, as well as on their involvement in the lifecycle of medicines.

From the drafting of the European Public Assessment Report to the management of shortages and security of supply, significant progress has been made in streamlining patient involvement throughout the regulatory process. We strongly support the inclusion of patient representatives in EMA working parties, including in the new 'ad hoc paediatric working group'. We call for this increased involvement of patients to be accompanied by reasonable compensation from the EU budget for the time and effort spent. We also welcome the inclusion of quality-of-life criteria and the involvement of patients in the definition of "unmet medical need", whose primary objective should be to stimulate research and development of medicines that bring real and significant added therapeutic value to patients.

We further welcome the improvements to the patient leaflet, with the inclusion of a key information section. However, it is not entirely clear how patients will continue to have access to a paper leaflet when they need it. The electronic leaflet must not create additional inequalities between patients, particularly for those who do not have access to the internet or who have low digital skills.

We also call on the European Parliament to support measures that will help address the current inequalities in patients' access to medicines across the EU. We are concerned about the lack of balance between incentivising innovation and ensuring that patients have access to the medicines they need. We regret that the proposed approach to incentives does not sufficiently focus on ensuring the actual placing of a medicine on the market and that longer periods of regulatory data protection will further undermine the sustainability of healthcare systems without boosting relevant innovation that reaches patients. We appreciate however the recognition of the importance of "push" and "pull" incentives to drive the development of new antimicrobials, taking into account the specificities of these products and the need for better stewardship to fight against antimicrobial resistance effectively.

Lastly, EPF warns against new proposals that would jeopardise patient safety for the sake of speed by oversimplifying the regulatory process. While adaptive pathways can save lives when they allow patients to access a particularly promising medicine early, patient safety and strict regulatory oversight should always remain a priority.

EPF will continue working with the European Parliament to ensure a patient-centred revision of the EU pharmaceutical legislation.

UPDATE ON THE PROCESS AND NEXT STEPS

On 4 and 5 October, the European Parliament's Rapporteurs for the Directive and Regulation, which revise and replace the EU's existing general pharmaceutical legislation, published the two draft negotiating positions. Both

draft reports will be debated in the Committee on the Environment, Public Health and Food Safety and the deadline for amendments is mid-November.

ABOUT EPF

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