



Media statement

EURORDIS: Compromise amendments on pharmaceutical reforms are a 'meaningful step' forward

19 March 2024, Brussels – The European Parliament's Committee on the Environment, Public Health, and Food Safety (ENVI) voted today on key amendments to reform the EU's pharmaceutical legislation. Achieved through broad consensus across European political groups, these amendments aim to improve the development and availability of treatments for rare diseases within the EU.

The approved amendments maintain the market exclusivity for all orphan medicinal products at nine years as proposed by the European Commission but elevate, and to eleven years for those addressing diseases currently require treatments the most. Additionally, the amendments refine the 'significant benefit' definition and clarify the 'High Unmet Medical Needs' classification.

The PRIME scheme, designed to accelerate the development of medicines for unmet medical needs, can now cover all orphan medicinal products. This expansion is complemented by increased incentives for academic research and mandatory patient involvement in European Medicines Agency (EMA) consultations, most importantly when defining guidelines to identify unmet medical needs.

Furthermore, the amendments advocate for the creation of a comprehensive policy framework for rare diseases, adjustments in regulatory data protection, and streamlined processes for advanced therapies.

Responding to the vote, **Simone Boselli**, Public Affairs Director at EURORDIS-Rare Diseases Europe, said:

"We welcome the ENVI Committee's approval of compromises reached across political lines, which enhance the original proposals by the European Commission. From the start of these legislative reforms, our community has tirelessly called for the proposals to evolve the current framework, given that 94% of rare diseases still lack specific treatments. We believe that the proposals passed today mark an important moment in European policymaking on rare diseases, with a meaningful step taken toward bridging the gap between rapid scientific progress and the slower advancement in patient care.

"We welcome the compromise amendments that ensure patient organisations' voices are heard in regulatory processes and create a robust toolkit to enhance research and improve access to medicinal products across the EU. We are particularly encouraged by amendments requiring mandatory patient consultation, establishing progressive market exclusivity for research-intensive entities, facilitating

central procurement for swifter access to orphan medicinal products, and extending the PRIME scheme.

“Finally, our community will celebrate the amendment calling for the delivery of an EU policy framework for rare diseases. Our community, many Members of the European Parliament, over 20 Member State governments, and the European Economic and Social Committee have all endorsed the call for such a policy framework, in the form of a European Action Plan for Rare Diseases. Recently, the European Commissioner herself affirmed that the Commission is well-equipped to implement a detailed and resourced strategy on rare diseases, mirroring the comprehensive approach adopted in the cancer strategy launched in 2021.

“As we approach the Strasbourg plenary session votes on the pharmaceutical reforms next month, it is imperative that all political groups uphold the compromises already reached. At the same time, we call upon Member States to take note of the progresses made in the European Parliament and build upon them as they continue their reading of the proposed reform.”

About EURORDIS-Rare Diseases Europe

[EURORDIS-Rare Diseases Europe](#) is a unique, non-profit alliance of over 1,000 rare disease organisations from 74 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe. By connecting people, families, and rare disease groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies, and services.

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