Reaction to EU Pharmaceutical legislation: Timely and equitable access for patients will be delayed by the reform

Brussels, 26 April 2023

Medicines for Europe is committed to **more equitable and timely access** to medicines for all EU patients and has delivered massive access gains through the supply of generic, biosimilar and value added medicines.

We deeply regret **the watering down of the legislation's measures to stop well documented patent gamesmanship and evergreening and the extension of regulatory protections beyond 11 years which will delay access to life saving therapies and cost healthcare systems billions of euros**. This must be corrected by re-introducing measures against these abuses and unjustified extensions in the legislation.

We also stand by our engagement to increase the security of medicines supply in Europe. We will strive for more rapid digitalisation in the legislation to predict, prevent and mitigate medicine shortages and for the creation of a Medicines Security Act to stimulate more investment in manufacturing.

We are supportive of a One Health approach to pharmaceutical policy that combines access to medicines and the environment. However, we draw the line against any attempt to reduce safety, quality or efficacy requirements which must continue to be the underlying public health purpose of the medicines regulatory system.

Commenting on the launch of the pharmaceutical legislation revision, Medicines for Europe President Elisabeth Stampa (Medichem) said *"The long-awaited revision of the EU pharma legislation is here. The central role of the off-patent medicines industry for the patient is clearly reflected in the objectives of the draft legislation, mirroring our commitment to make medicines available when and where they are needed. We will help the EU deliver on better access to medicines with day-1 competition. We have had years of good cooperation with the European Commission, through the pandemic and the war in Ukraine, and this legislation must reflect the hard-learned realities of the medicine's framework. We are still lacking an industrial strategy to strengthen the European off-patent sector and improve open strategic autonomy in health. Therefore, I am looking forward to working with the European Parliament and Member States to make equitable access, availability, and security of supply for all a reality in Europe."*

Resource hub

The files related to the revision of the EU pharmaceutical legislation are available at https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

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Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.