

Reaction to EU Pharmaceutical legislation: Timely and equitable access for patients and security of supply essential for reform

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Medicines for Europe is committed to **more equitable and timely access** to medicines for all EU patients and our industry has delivered massive access gains through the supply of generic, biosimilar and value added medicines. During the Covid-19 pandemic, we mobilised our entire industry to supply essential and critical medicines and will continue to invest in Europe's security of supply. We will engage strongly in the legislative process to strengthen these key public health objectives for Europe.

We strongly support the proposal's intention to stop the well documented patent gamesmanship and evergreening and the adaptation of incentives to necessary equity of access across the EU. We will work with the co-legislators to ensure that all the relevant legal articles fully deliver on those much-needed reforms notably for the intended legal certainty. Moreover, there should not be an accumulation of regulatory incentives that would extend the regulatory data protection period beyond the existing system (8 years) which is already the longest in the world. Regarding AMR, the Commission proposal for a reserve fund is the correct alternative to transferable vouchers and most efficient policy to protect against future risks.

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 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 intentions 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 and timely 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

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.