

Off-patent medicines ready to drive pharma policy reform for equitable access, availability and security of medicines supply

Malta, 15 June 2023

The EU has initiated a major overhaul of EU pharma legislation ranging from regulation to intellectual property and supply chains. The off-patent medicines industry is fully engaged to ensure that reforms transform healthcare delivery and access for patients. Generic and biosimilar medicines help the majority of patients with major chronic diseases such as cancer, cardiovascular disease, diabetes, autoimmune conditions and others. Value added medicines promise affordable, patient-centred innovation which can address unmet medical needs and the crisis in hospitals with personnel shortages and greater demand for healthcare.

Medicines for Europe sees the revision of EU pharmaceutical legislation as an opportunity to accelerate patient access to safe, effective, and affordable medicines and to improve Europe's security of supply.

For this to succeed, Medicines for Europe calls for a particular focus on:

- **Optimising use:** timely competition and uptake measures that encourage greater access to off-patent medicines.
- **Flexibility:** A regulatory system that facilitates timely access for patients and embraces digital tools like electronic patient information leaflets.
- **Prevention:** An emphasis on preventing shortages, through guidance on procurement policies and EU finding policies that safeguard well established, inexpensive but essential medicines, with a dedicated Medicines Security Act.

Speaking at the **Medicines for Europe** annual conference, association **President Elisabeth Stampa** said *“Medicines for Europe is strongly engaged in the EU pharma policy reform process to ensure that patients have equitable and timely access to secure supplies of medicines in Europe. This will entail comprehensive support of manufacturing and addressing the trends that persistently drive medicines shortages, through a Medicines Security Act. We believe that a joint effort with the European Parliament, Council and Commission with our industry is essential to tackle the challenges faced by health systems in every country in Europe. By working together, we can develop policies that promote sustainable and efficient manufacturing practices, create a framework for value added, affordable innovation, work to eliminate medicines shortages of essential medicines, and vastly improve access to medicines for better health outcomes for European patients.”*

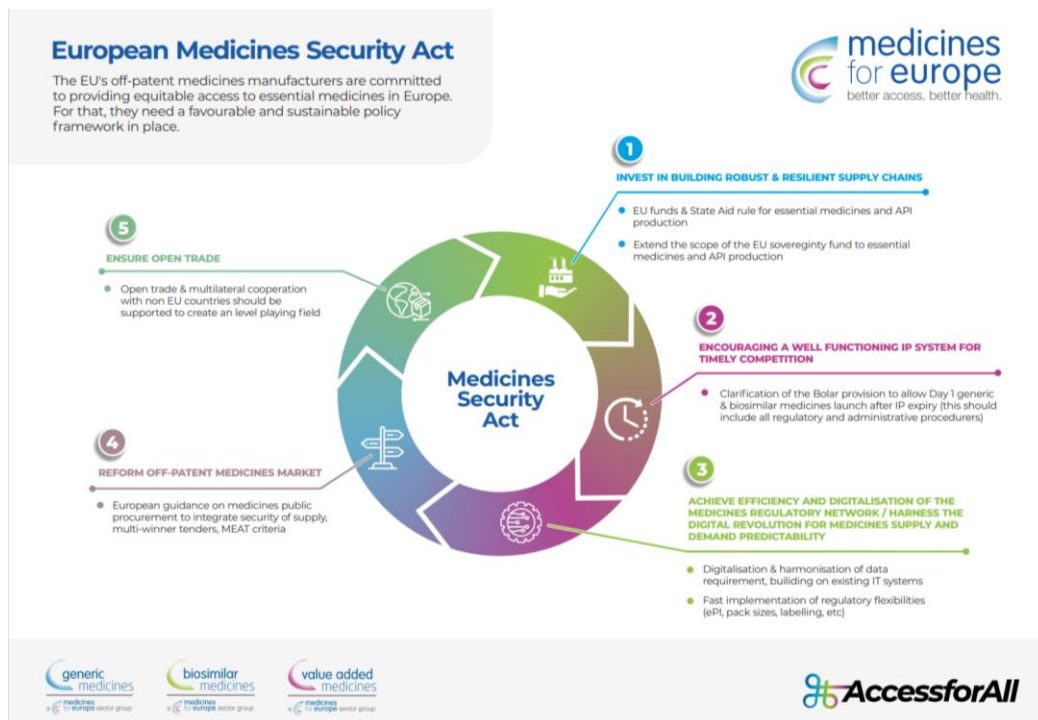
*The **Deputy Prime Minister and Minister for Health of Malta, Chris Fearne** said that he “welcomes the long due reform and the proposed modernisation of the EU Pharmaceutical Regulatory Framework. The current framework is problematic in that it unnecessarily complicates supply chains, is costly to industry, and does not benefit patients. It is essential that we break down current barriers within the internal market to the benefit of all EU*

patients. The new approach within the Commission proposals in which incentives for innovative products are linked to access to patients within all Member States is the right approach and should be the basis of future negotiations. It is likewise important that we take this opportunity to stimulate development of new antibiotics, since the status quo is not an option”.

Resource hub

The full programme of the Medicines for Europe annual conference is available at the following link:
<https://www.medicinesforeurope.com/events/annual23/>

Medicines for Europe’s proposal for a Medicines Security Act can be found [here](#) and the respective infographic below:



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.