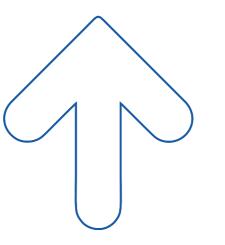


#Levelling up the European Health Union

EU health policy has advanced in strides due to the Covid-19 pandemic. Access, affordability, availability should be more than buzzwords and the EU should capitalise on the solidarity, the efficiency, and the collaboration between industry and the EU to improve populationlevel health outcomes and minimise health inequalities across the whole EU.





BEHIND

Reform EU pharmaceutical laws for equitable access by fostering timely competition and sustainable uptake of generic, biosimilar and value added medicines

NETWORK FOR THE 21st CENTURY

Digitalise, harmonise and automate the medicines regulatory framework

MEDICINE MANUFACTURING

Invest in a competitive off-patent medicines manufacturing industry to make it greener, digital and strategically autonomous

IN HEALTHCARE

Create a policy for affordable innovation on off-patent medicines

COMMITMENT

OUR

- → Drive competition in pharma markets to increase access and sustain healthcare budgets.
- → Invest in affordable off-patent innovation to solve healthcare and patient challenges.
- > Improve supply chain security and reduce shortage risks.
- Provide transparency on temporary disruption of supply.

- → Invest in the digitalisation of regulatory and supply chain activities to align with future EU IT systems.
- → Find ways to reduce regulatory burdens for regulators and industry while maintaining science based high standards.
- > Find a balance regarding important investments in sustainability and access to affordable essential medicines.

- → Invest in EU manufacturing and in more secure supply chains.
- → Train a highly skilled workforce for R&D and high technology manufacturing in Europe.
- → Develop and manufacture more complex medicines for future healthcare needs.
- → Export medicines for global access and a strong economy.

- → Co-create off-patent R&D with the healthcare community to improve existing therapies with the latest technologies.
- → Provide solutions to improve population level health outcomes and address major healthcare challenges through investment in better access to generic, biosimilar and value added medicines.
- → Take advantage of digital opportunities to improve healthcare delivery and outcomes.

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- > Support pro-competitive measures in the pharma and intellectual property legislations, especially to stop delays to generic and biosimilar entry.
- → Facilitate earlier entry of generics and biosimilars to increase competition and availability in all Member States.
- Create a framework for Value added medicines development.
- > Tackle the economic root causes of medicine shortages and facilitate a solidarity-based allocation of medicines across the EU to solve shortages.
- → Reform tender policies with EU quidance on medicine procurement.

- Fast-track the digital and regulatory efficiency chapters of the new EU pharmaceutical legislation.
- → Enable more regulatory flexibility to prevent shortages, notably by accelerating the introduction of EPIL
- → Introduce a clear shortage prevention and mitigation policy (instead of overreporting) by investing in a single digital, interoperable and automated shortage management platform.
- → Align approval regulation with the latest science, experience, and global single development to improve access and reduce unethical duplication.
- → Align biosimilar medicines with learnings from experience and science.
- → Address environmental challenges without undermining access or the risk/benefit of affordable essential medicines.

- → Adopt a Critical Medicines Act to foster open strategic autonomy in healthcare by restoring Europe's manufacturing competitiveness and reducing dependency risks for essential medicines.
- → Support investments in new greener and automated technologies for manufacturing and upskilling the workforce.
- → Agree on a harmonised list of critical and essential medicines for EU public
- → Reform off-patent markets by including security of supply, the environment and multi-source competition as critical components of purchasing.
- → Secure the EU's role as a strong global health actor.

- → Recognise and reward off-patent innovation in EU legislation while avoiding evergreening abuses.
- → Give the healthcare community a voice to improve their essential and critical off-patent medicines and tackle wellknown adherence or access to care
- → Allow the industry to invest in digital combinations to address major healthcare challenges for patients with coherent regulation and market
- → Reform markets for antibiotic medicines to address antimicrobial resistance.

About 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 in Europe. 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.

Our members represent and account for:











190,000 highly skilled direct employees



400 manufacturing sites



The use of off-patent medicines has liberated over

€100 billion

systems



100% increase in patient access to treatments for illnesses such as diabetes, hypertensión and epilepsy

Over 10 years



5.8 billion patient treatment days to European patients using biosimilar medicines



€50 billion saved using biosimilar medicines between 2006-2023



which amounts to €10 billion in 2023 alone

Our presence across europe





#Levelling up the European Health Union























