

A streamlined, digital regulatory framework is the foundation for equitable access to medicines

Brussels, 27 September 2023

The off-patent medicines sector accounts for almost 70% of medicines dispensed in Europe, helping to manage the most prevalent chronic diseases including cancer, auto-immune conditions, cardiac disease, and diabetes. Value added medicines promise affordable, patient-centred innovation which can address serious health needs.

These medicines are regulated by a network of the European Medicines Agency and national agencies which requires agility and modern technology to thrive. The revised EU pharma legislation should prioritise five improvements to ensure that medicines reach the patients and healthcare professionals who need them in a timely manner, with a fit for purpose regulatory framework and efficient regulatory processes.

The Pharmaceutical law reform shall

- Simplify the framework to reduce delays and duplications.
- Invest in a digital interconnected network of medicine agencies. This would reduce the strain on agency resources and improve the monitoring and prevention of shortages.
- Adopt modern technology such as electronic product information leaflets so that patients have the most up to date and easy to read information on their medicines.
- Prevent the unnecessary and unethical repetition of clinical studies for off-patent medicines by integrating scientific progress, supporting single development, and embracing international regulatory convergence and cooperation.
- Ensure flexibility for generic, hybrid and fixed dose combination Marketing Authorisations (MA) to use either the centralised or the decentralised (national) procedures.

Commenting at the Medicines for Europe Regulatory Affairs conference, Deputy Director General and Head of Regulatory Affairs, Beata Stepniewska said *“This conference brings together the regulatory community for the first time since the publication of the new EU pharmaceutical legislation. The last revision in 2004 was a step forward for EU harmonisation and better scientific regulation of medicines. Since then, there have been spectacular advances in scientific and digital technologies that the regulatory framework needs to catch up with. We have also learned from the Covid-19 pandemic, which showed the speed with which the medicines industry could respond when smart flexibility was introduced in the regulatory system. I am confident that the legislation can deliver a truly digitalised, flexible, and optimised regulatory framework, so that companies can continue to manufacture and supply essential medicines for the benefit of all European patients in a timely manner.”*

Resource hub

For more information on the Regulatory Affairs conference, see

<https://www.medicinesforeurope.com/events/phvrac23/>

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.