Press Release

European Parliament report calls for increased use of off-patent medicines to improve patient access

Strasbourg, 24 November 2021

The European Parliament has adopted a report calling for increased use of off-patent medicines in Europe to improve patient access, highlighting lessons learned during the Covid-19 pandemic and urging the European institutions to address them directly in future healthcare policy initiatives.

The Parliament, in its own initiative report, stresses the central role of generic, biosimilar and value-added medicines as the European Commission works to revise the legislative framework of the European pharmaceutical industry. Off-patent medicines already account for close to 70% of those used by patients in Europe.

The call for increased use of off-patent medicines also implies a tailored regulatory pathway for value added medicines innovation, an area where the EU has been lagging behind the US for years[1].

The report highlights that an efficient and optimised regulatory system for pharmaceuticals is also a priority. This includes digitalising regulatory processes and embracing environmentally friendly solutions like electronic patient information leaflets.

The report calls on the European Commission to actively remove barriers to competition from loss of exclusivity. This includes reviewing the use of intellectual property incentives and assessing the framework for off-patent orphan and paediatric medicines. Adapting these frameworks could enable increased access for the rare disease population but a level playing field is needed to facilitate the development and manufacturing of these medicines.

Commenting on the European Parliament vote, Medicines for Europe President ad-interim, Rebecca Guntern said: "*It is highly encouraging to see the European Parliament take such clear directions to increase access to off-patent medicines. I am particularly pleased to see the European Parliament factor in the lessons learned from COVID-19. Generics, biosimilars and value-added medicines are key pillars for the long-term resilience and sustainability of European healthcare systems. The review of the EU pharmaceutical legislation is a one-time opportunity to make sure Europe has a fit-for-purpose, efficient, digital and simplified regulatory framework. We look forward to continuing our work with the European institutions and Member States in the coming months. We cannot afford to miss this opportunity.*"

[1] For more on this, see https://www.cep.eu/fileadmin/user_upload/cep.eu/Studien/cepInput_Off_Patent_Innovation/cepInput_Incentivising_Pharmaceutical_Off-Patent_Innovation_in_the_EU.pdf

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

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.