Press Release

Failure to launch: white paper explores the role of inappropriate use of IP in blocking access to generic and biosimilar medicines

Findings call for clear policy change to remove access barriers

For Immediate Release

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Patient access to medicines in Europe depends on a thriving generic and biosimilar medicines sector. The sector provides almost 70% of dispensed medicines in Europe helping patients and healthcare professionals manage some of the most challenging health conditions such as cancers, respiratory diseases, auto-immune conditions, diabetes, COVID-19 and others.

A new white paper explores the misuse of certain intellectual property tools that block generic and biosimilar medicines for the first time since the findings of the European Commission Pharmaceutical Sector Enquiry in 2009.

The findings stress the importance of a high quality patent system, address elements that delay or discourage competition, such as the misuse of patent thickets or divisional patents, product hopping or pricing strategies, as well as systemic issues like patent linkage, that regularly delay the launch of generic and biosimilar medicines.

Commenting on the launch of the white paper, Medicines for Europe General Counsel and External Relations Director Sergio Napolitano said "t*his white paper informs stakeholders on IP issues that limit the full potential of the generic and biosimilar medicines sector. The paper provides clear legal alterations and competition law recommendations for policy makers to initiate reforms in the upcoming EU pharmaceutical strategy and Intellectual Property Action Plan.*"

Medicines for Europe Executive Committee member James Burt (Accord Healthcare) commented "*Competition in the medicines sector has long relied on off-patent medicines to increase patient access. This report shows that there are still barriers in the system. To ensure timely access to generic and biosimilar medicine, the EU should implement the recommendations of this report.*"

Note

The full report "*Anatomy of a failure to launch: A review of barriers to generic and biosimilar entry and the use of competition law*" can be accessed here. It is authored by Pinsent Masons and co-sponsored by Medicines for Europe and Accord Healthcare. The report was launched at a dedicated webinar, with the participation of the European Commission DG Grow, DG Competition, the Polish government, industry representatives and Pinsent Masons.

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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.