16th Legal Affairs Conference
Dolce Sitges Hotel, Sitges (Barcelona)
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Press Release

Smart reform of EU pharma and IP legislation key to boosting access to essential medicines

For Immediate Release

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Generic and biosimilar medicines lower healthcare treatment costs dramatically and are essential for enabling access to medicines. The EU has therefore made the prompt launch of generic and biosimilar medicines a high priority objective of the Pharmaceutical Strategy for Europe. The 2022 Medicines for Europe Legal Affairs Conference debated the much-needed reforms to ensure timely access to medicines.

Delays to competition should be immediately tackled by amending European Patent Office (EPO) rules allowing the misuse of divisional patents, by expanding the scope and harmonising the Bolar exemption, and by banning patent linkage in Europe. These necessary reforms are all aligned with the recommendations of the Pharmaceutical Sector Inquiry Report of 2009.

Conference participants also debated the features and safeguards of an anticipated Unitary Protection Certificate (UPC) system, linked to Supplementary Protection Certificate (SPC – which extends certain patent exclusivities) reform. The system should enable a single unified SPC legal challenge to reduce Internal Market legal fragmentation.

Medicines for Europe is also carefully monitoring the practical implementation of the SPC manufacturing waiver, which comes into effect from 1st July 2022. Europe needs a well-functioning SPC waiver to increase manufacturing and industry resilience in Europe.

Speaking at the Legal Affairs 2022 conference, Sergio Napolitano, General Counsel and External Affairs Director at Medicines for Europe said: *It is high time to tackle unnecessary delays to generic and biosimilar medicine access. The Pharmaceutical Strategy should address the interplay between IP and regulatory matters by leveraging the Bolar exemption to prevent clearly abusive patent linkage. Pricing and reimbursement patent linkage in many Member States, together with poor policies allowing abuses of divisional patents, delays patient access to medicine and burdens healthcare budgets with unnecessary costs. The Pharmaceutical Strategy must deliver on its stated objective of ensuring timely access to generic and biosimilar medicines.*

Resource hub

These issues were discussed during the 16th Legal Affairs Conference of Medicines for Europe, which was held in Sitges, Barcelona, with around 100 participants comprising European Commission officials, General Counsel,

industry leaders and experts from around the world. For more information on the conference, see https://www.medicinesforeurope.com/events/lac2022/

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. 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.