Access to medicines and security of supply should be central to EU pharma and IP legislation reforms in Europe

Malta, 13 June 2023

Generic and biosimilar medicines significantly lower healthcare treatment costs and are essential for enabling competition and vastly improved access to medicines. The stated aim of the EU pharmaceutical and IP legislative reform is to encourage the immediate launch of generic and biosimilar medicines once IP protections expire. The 2023 Medicines for Europe Legal Affairs Conference debated these much-needed reforms for access to medicines.

The Bolar exemption should be harmonised and expanded in an unequivocal way to stop well documented, abusive litigation and achieve its stated objective of immediate competition, removing all legal uncertainties for European developers. This includes a clear ban of unlawful patent linkage in Europe, in line with the recommendations of the Pharmaceutical Sector Inquiry Report of 2009.

The reform of the Supplementary Protection Certificate (SPC - which extends certain patent exclusivities) system has also been debated, with a focus on the necessary safeguards in the proposed Unitary SPC to avoid unnecessary litigation on invalid SPCs and ensure effective upfront scrutiny of SPCs.

In line with its objective of investing in EU manufacturing security of supply, Medicines for Europe presented an **Industry Report** on the experience with the SPC manufacturing waiver since it took effect on 1st July 2022. The Report shows that efforts to use the waiver to invest in EU development and manufacturing are severely hampered by frivolous litigation due to legal uncertainty and too short timelines for day-1 launch in Europe at SPC expiry. This undermines the security of manufacturing supply and reduces competition in the EU market.

Speaking at the Legal Affairs 2023 Conference, Sergio Napolitano, General Counsel and External Affairs Director at Medicines for Europe said *"Now is the time to tackle unnecessary delays to generic and biosimilar medicine access. The pharmaceutical and IP legislation should clearly put a stop to abusive patent linkage. Pricing and reimbursement as well as procurement patent linkage in many Member States, together with EPO policies allowing abuses of divisional patents, unduly delay generic and biosimilar medicine launch at IP expiry. This directly harms healthy competition and patient access to medicine, burdening already challenged healthcare budgets with unnecessary costs. Europe has an unmissable opportunity to update the regulatory system and stimulate a stronger European manufacturing industry for secure patient access to medicines."*

Resource hub

These issues were discussed during the 17th Legal Affairs Conference of Medicines for Europe, which was held in Malta, with over 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/lac23/

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.