Press release

Pharma reform should provide for more timely patient access in Europe

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The revision of the European pharmaceutical legislation, the reform of the Supplementary Protection Certificate (SPC) system and the review of the SPC manufacturing waiver are now fundamental reforms to stimulate a strong off-patent industry in Europe whose medicines account for the vast majority of the medicines dispensed in Europe. The European Union is getting closer to a reformed pharmaceutical legislation. A good and balanced incentives system for pharmaceuticals is essential to support the development, production, and supply of generic, biosimilar and value-added medicines.

Timely access to generic and biosimilar medicines is needed to ensure that the patent system is well equipped to prevent misuses or abuses that delay generic and biosimilar competition at patent or SPC expiry. Europe now has an unmissable opportunity to include the right guardrails in the unified patent system for high quality standards in the interest of patients and rewards true innovation over evergreening. Carefully assessing the validity of SPCs before their enforcement is essential to avoid unnecessary litigation, patient access delays and lost savings for healthcare systems.

A strong industrial policy for generic medicines the manufacturing of generic medicines and active pharmaceutical ingredients must include a broad Bolar exemption and a thorough review of the elements of the SPC manufacturing waiver that prevent full exploitation of its potential. This is at the core of the recently published 2025 Industry Report on the SPC manufacturing waiver. The Report stresses the importance of a fine-tuning of the SPC waiver Regulation and the publication of a European Commission guideline to tackle frivolous litigation by SPC right holders that delay timely competition and undermine EU manufacturing.

These policy priorities were discussed at the 19th Legal Affairs Conference of Medicines for Europe in Brussels, with Members of the European Parliament, Member States officials, patients associations, General Counsels and patent and legal experts.

Speaking at Medicines for Europe's Legal Affairs Conference, General Counsel Sergio Napolitano said "*This is a key moment that will shape the future of the EU pharmaceutical sector. From the pharmaceutical legislation reform to the SPC reforms, there is one common denominator: timely access of generic and biosimilar medicines. This can be achieved by carefully balancing the incentive system, stopping IP abuses and supporting an industrial policy for off-patent medicines.*"

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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 LinkedIn and X @medicinesforEU.