Press Release: Reformed incentives system promises better patient access in Europe

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A well-balanced incentives system for pharmaceuticals is essential to support the development, production, and supply of off patent medicines. These medicines account for 70% of medicines dispensed in Europe, for the most serious conditions like cancer, auto immune diseases and cardiovascular disease. The revision of the European pharmaceutical legislation and the reform of the Supplementary Protection Certificate (SPC) system are a unique opportunity to support companies providing the majority of medicines to European patients.

Timely access to generic and biosimilar medicines combined with more investment in EU manufacturing needs the following reforms:

- A unified (or truly European) patent system that ensures the highest possible quality standards in the interest of patients, rewards real innovation over evergreening.
- Increased role of competition authorities in pharmaceutical policies to ensure that new policies are not misused or abused to delay generic and biosimilar competition at patent or SPC expiry.
- A new industrial policy for the manufacturing of generic medicines and active pharmaceutical ingredients that includes a broad Bolar exemption.

These policy priorities were discussed at the 18th Legal Affairs Conference of Medicines for Europe in Ireland. Patent and legal experts, General Counsels and policy makers have also debated the recently published 2024 Industry Report on the SPC manufacturing waiver. The Report stresses the importance of a conducting a thorough review of the SPC manufacturing waiver in 2024 as required by the legislation, which should fine-tune the SPC waiver Regulation and lead to the publication of a European Commission guideline to tackle frivolous litigation by SPC right holders that delay timely competition and undermine EU manufacturing.

Speaking at Medicines for Europe's Legal Affairs Conference, General Counsel Sergio Napolitano said *"Medicines for Europe was created 30 years ago in reaction to the Supplementary Protection Certificate (SPC) in Europe which undermined the competitiveness of the medicine manufacturing industry in Europe. The SPC Manufacturing Waiver, which took 25 years to introduce, needs to be implemented in the spirit of the legislation to exploit all its potential for manufacturing in Europe. In parallel, the EU pharmaceutical legislation reform should ensure the timely launch of generic and biosimilar medicines and introduce a European SPC granting system with the highest quality standards, a clamp down on IP abuses and a supportive industrial policy for off-patent medicines."*

About 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.