# Press release

# Twenty years of the Legal Affairs Conference: Driving Europe's Competitiveness and Timely Access to Medicines

Athens, Greece
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Europe's overhaul of pharmaceutical legislation – encompassing the reform of the Supplementary Protection Certificate (SPC) system, the review of the SPC Manufacturing Waiver, and the forthcoming Biotech Act - represents a decisive moment for medicines policy. Taken together, these reforms have the potential to expand patient access to medicines while strengthening Europe's off-patent medicines sector and industrial competitiveness.

Timely access to generic, biosimilar and value added medicines depends on a patent system that prevents unjustified delays to competition after loss of exclusivity. Europe now has a clear opportunity to put in place the policy safeguards needed to uphold high standards, protect patients' interests and reward genuine innovation rather than evergreening:

- a long overdue curb on the misuse of the divisional patent system
- a Biotech Act that supports Europe's competitiveness without expanding costly intellectual property rules affecting patient access
- a strong health industrial policy, backed by a targeted review of the SPC Manufacturing Waiver, to support timely access to generic and biosimilar medicines and reinforce key provisions of the Pharmaceutical Legislation, including the Bolar exemption.

The SPC MW is at the centre of the recently published 2026 Industry Report on the SPC Manufacturing Waiver. The report makes clear that the waiver must now be fine-tuned through the Biotech Act, alongside clear European Commission guidance to curb frivolous litigation by SPC holders. This litigation continues to delay competition, weaken EU manufacturing and erode the very benefits the waiver was meant to deliver.

**Speaking at the 20th Legal Affairs Conference, Medicines for Europe President Steffen Saltofte said:** *"Europe has a unique opportunity to shape the future of its pharmaceutical sector and strengthen manufacturing in Europe. The evolution of the patent system over the past 20 years has made one priority clear: Europe should support genuine innovation and ensure timely competition from generic and biosimilar medicines. This approach*

*will unlock broader access to medicines for patients and reinforce resilient, sustainable healthcare systems across Europe."*

## 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.