Press Release

Parliament's Legal Affairs Committee calls for a stronger SPC Manufacturing Waiver to boost biomanufacturing in Europe

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As the EU works to strengthen its life sciences ecosystem, secure medicine supplies and attract manufacturing investment, the SPC Manufacturing Waiver offers a targeted way to support growth, jobs, and medicine development and production in Europe. The European Parliament's Legal Affairs (JURI) Committee recognised this potential in its Biotech Act report by proposing that the waiver be extended to biosimilar medicines. This timely change would help Europe retain its leadership in biosimilar development and manufacturing.

Medicines for Europe remains deeply concerned about extending Supplementary Protection Certificates (SPCs), as longer monopoly rights delay competition and access to medicines. However, we applaud the Legal Affairs Committee's strong support for biosimilar manufacturing through the waiver.

Adrian van den Hoven, Director General of Medicines for Europe, said: *"Europe needs policies that encourage investment, manufacturing and innovation across the pharmaceutical ecosystem. Extending the SPC manufacturing waiver to biosimilar medicines would bring jobs, R&D and production to Europe at no additional cost. We should seize this opportunity to preserve Europe's leadership in biosimilars."*

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.

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