Press Release

EU pharmaceutical legislation must support a competitive off-patent industry to deliver equitable access to medicines

For Immediate Release
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Medicines for Europe has shared its vision on the future of EU pharmaceutical policy in the public consultation on the general EU pharmaceutical legislation. This is an important milestone on the road to improving access to medicines across the EU.
Generic, biosimilar and value added medicines are drivers of equitable access to medicines in Europe, accounting for close to 70% of prescription medicines. They are the backbone of public health and ensure the sustainability of healthcare systems by bringing price competition at patent expiry and doubling access to medicines without impacting European healthcare budgets.

Medicines for Europe looks for the review of the pharmaceutical legislation to prioritise:

- **A fit-for-purpose, efficient and fully digitalised medicines regulatory framework**: Current Marketing Authorisation procedures must be optimised including digital friendly processes across the EU Network of regulators. The legislation should foresee a regulatory assessment to avoid the unnecessary and unethical repetition of clinical studies. It also must support the single global development of off-patent medicines and incentivise value added innovation in the off-patent sector.
- **Clear policies that incentivise manufacturing investments:** Europe needs clear policies to incentivise manufacturing investments while supporting open markets in trade agreements. The EU market must meet the ambition of remaining a manufacturing leader by actively rewarding supply reliability and greener manufacturing, while ensuring healthy long-term competition among multiple suppliers. The EU must stop short-term cost-containment policies and duplicative obligations on manufacturers.
- **Strong Competition on day one after patent expiry:** to remain a global pharmaceutical manufacturing leader, the pharmaceutical legislation must ensure that off-patent competition can happen from day 1 after patent or regulatory exclusivity expiry, by clarifying the Bolar exemption and legally banning patent linkage in all EU member states.
- **A competitive and balanced single market for multi-source medicines:** The current legislation focuses on supply-side policies. There is substantial room to tackle policy failures on the demand-side. A competitive internal market depends on a balance between the rewards to manufacturers and their obligations to supply safe, efficacious and high-quality medicines.

The full Medicines for Europe response to the EU consultation can be found in the document attached.

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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 Twitter @medicinesforEU.

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