Press release

New EU medicine laws will strengthen equitable access, timely competition and resilient supply chains

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The now adopted General Pharmaceutical Legislation and Critical Medicines Act are two major reforms for Europe's pharmaceutical sector. One defines the rules for medicine access, safety, efficacy and quality while the other tackles the economic root causes of medicine shortages. The focus now turns to implementation, to translate the rules into better access for patients across Europe and more resilient supply chains.

The **General Pharmaceutical Legislation** should ensure that:

- Medicines become more available for patients across Europe through harmonised rules for generic and biosimilar medicines competition on day-1 of intellectual property expiry.
- Reduce shortages and improve information about medicines by leveraging the digitalisation of in the regulatory network and advancing digital product information (ePI) and regulatory procedures where possible.
- Complex legal requirements such as shortage prevention plans and Environmental Risk Assessments are streamlined to achieve their objectives without having to conduct redundant studies or duplicative bureaucratic procedures.

The **Critical Medicines Act** makes health security an essential part of European legislation for the first time. Member States must ensure that:

- Security of supply criteria such as most economically advantageous tender (MEAT) award criteria and multi-winner tenders are the rule rather than the exception for medicine procurement.
- Solidarity between Member States prevails in a demand or supply shock so as not to deliver medicines to patients rather than hoarding through stockpiles.
- Strong financial incentives for investment in generic and biosimilar medicines production in the EU are secured in the next EU budget.

Commenting on the adoption, **Medicines for Europe Director General Adrian van den Hoven said:** *"Today's adoption marks an important milestone for patients access and medicine security of supply. We will engage with stakeholders and the EU to deliver on their promises: equitable access to medicines for patients across Europe, timely competition and health security for Europe."*

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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.

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