5-Point Pharmaceutical Action Plan to sustain investment in Europe, for Europe

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Medicines for Europe, the European off-patent medicines Association which supplies 70% of prescription medicine in Europe, proposes as 5-point Pharma Action Plan to work with President von der Leyen and the European Union to sustain investments in Europe.

Building on the expertise of Covid-19 and Ukraine after the Russian invasion, we firmly believe that we can be stronger by working together to save pharmaceutical manufacturing and jobs in Europe, serve patients and protect access to medicines.

Medicines for Europe is and will remain on the European team and we will do everything we can to sustain medicines manufacturing in Europe.

1. **Continue diplomatic efforts to prevent the imposition of tariffs on EU medicines.**
   [timeline: immediate]
   a. Tariffs will exacerbate US shortages of critical medicines. Our industry has consistently helped the US to tackle shortages during major crises like Covid-19, after hurricanes and when there are quality or manufacturing problems. For the 100 medicines on the US FDA shortage list, 70% of shortage mitigation supplies come from outside the US – including from our industry.
   b. The US relies totally on non-US manufacturers for 41% (93/227), and mainly on non-US suppliers for 62% (141/227), of medicines on the US Essential Medicines List. Tariffs will increase US dependence on China for critical medicines including antibiotics. For many medicines and active pharmaceutical ingredients, the EU is the only alternative to China. The US will need 10 years to build its own manufacturing from scratch and this will be unprofitable for years even with tariff protection.

2. **Amend legislations that harm industry competitiveness and patient access.**
   [timeline 2 months]
   a. Our industry is contributing to the Green Deal objectives, we are investing heavily in water efficiency, reducing pollution and greenhouse gas emissions from production, and we will continue to do so. But we need to **restore the prevalence of pharmaceutical regulation over non-sectorial regulations (food law, environmental law, chemicals law) so that the pharmaceutical sector and public health are not trapped by conflicting regulations that inadvertently harm patients**. This would be in line with the key principles of the 2019 Commission Strategic Approach to Pharmaceuticals in the Environment to "*ensure that actions to address the risk do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals*". Given its scientific expertise and central role in regulating medicines, we believe the EMA is best placed to take the lead on pharmaceutical-related aspects of environmental policy in Europe.
   b. The **Urban Wastewater treatment directive** imposes an unprecedented massive levy on medicines consumption and will cause a tsunami of shortages of diabetes, epilepsy, antibiotic and hospital medicines, whose prices would have to dramatically increase (up to 900% for diabetes medicine metformin) for patients. Medicines should be urgently exempted from this levy, which is going to disproportionately affect generic medicines due to their high volumes and narrow margins.

c. **Any future restrictions on the use of chemical substances should not affect patient access to medicines, nor impact the security of supply or force production outside Europe.** The PFAS restriction proposal is particularly concerning, as it would only exempt APIs, while PFAS are also crucial in production processes, raw materials, excipients and packaging.

3. **Accelerate adoption of the pharmaceutical legislation to ensure access**
[timeline 3-6 months]
   a. The Commission should support Council and Parliament negotiations to adopt the legislation.
   b. Medicines for Europe is ready to work towards a compromise on the incentive system that would stimulate competition with a harmonised and extended Bolar exemption. The latter is key for competition and for manufacturing of essential medicines and API in Europe[1] while unlocking equitable and timely access for patients. **An extension of IP will not stop pharmaceutical companies from transferring their production to the US as some have already announced and, as stressed in the Draghi Report, the *"evidence is overwhelming that competition stimulates productivity, investment and innovation"*.** On the contrary, an IP extension will bankrupt public health budgets which already struggle to finance the reimbursement of expensive drugs.
   c. Digitalisation is also needed for competitiveness and to reduce shortages. The legislation should introduce digital leaflets to make medicines accessible everywhere and EU track and tracing systems used to predict shortages[2].

4. **Accelerate life sciences and health industrial strategies for security and competitiveness**
[timeline 9-12 months]
   a. The **Critical Medicines Act should** move forward with security of supply criteria for medicines procurement and robust state aid reform (as stressed in the Draghi Report). This is now pivotal to maintain EU manufacturing in Europe.
   b. The **Biotech Act** should be fast forwarded to incentivise biotech manufacturing, including biosimilar medicines where our industry has invested heavily in Europe (in Slovenia, Poland, Spain, Germany, Austria, etc.).

5. **Allow an open channel of cooperation between the off-patent medicine industry and the Commission President**
[timeline 1 per month for 9 months]
   a. We remain committed to Europe's security of supply and to patient access to medicines.
   b. The new US Trade Policy compels us to work together to support EU manufacturing jobs in Europe.
   c. To succeed, we will need the Commission President leadership to deliver based on a clear calendar of actions.

[1] Article 85 of the Pharmaceutical Directive (the Bolar exemption) should include all regulatory and administrative procedure to have generic and biosimilar medicines on the market the day after protections expire.
[2] EMVS data system.