EFPIA response to the revision of the pharma package:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

EFPIA supports the objectives of enhancing the availability and accessibility of medicines, while fostering a competitive innovation environment in Europe. We welcome the proposal to future-proof the EU regulatory framework, maximising the use of expedited pathways, optimising regulatory decision-making processes, and reducing unnecessary administrative burdens. Similarly, the introduction of TEV for antimicrobials is a step in the right direction, although improvements are needed to ensure it can deliver effectively.

However, we have serious concerns that measures within the legislation will accelerate the erosion of the EU innovative industry base, discouraging medicine R&D investment, jeopardising jobs and growth as well as negatively impacting patients' access to the latest treatments:

1. The proposal to shorten Regulatory Data Protection and Orphan Market Exclusivity, coupled with conditions that hinder innovators' ability to recover incentives, will accelerate existing negative trends. For example, the 25% decline in European R&D investment and the reduction in Europe's global share of clinical trials from 25% to 19%. The proposals are contrary to the EU Heads of State call (March 2023) for incentives to drive innovation to be strengthened, rather than reduced, to restore Europe's competitiveness and meet the needs of patients.

2. To incentivise research efforts focused on meeting the needs of European patients, it is crucial to develop a patient-centered, more inclusive definition of unmet medical need. By encouraging incremental and breakthrough advances in prevention, treatment and care, Europe can ensure that no patient is left behind.

3. EFPIA applauds the achievements of the current OMP and Paediatric Regulations as European success stories. The proposed weakening of the OME regime will slow that progress, undermining the European orphan drug ecosystem and future investment in rare disease research. For paediatric medicines, the absence of a clear obligations framework in their development will hinder rather than support new developments in paediatric medicines in Europe.

4. The Bolar exemption expansion beyond marketing approval poses a threat to the enforcement of fully valid IP rights, further jeopardising EU competitiveness. Timely generic competition already exists. This expansion undermines the integrity of the IP system innovators rely on to continue their substantial investment in researching and developing novel therapies in Europe for European patients.

5. EFPIA members are committed to reducing the potential impact of manufacturing, use and disposal of medicines on the environment. However, the possibility to refuse or restrict marketing authorisation solely on environmental grounds poses a significant threat to the established authorisation system and could delay or prevent patient access to life-saving medicines. This in a context where other overly strict chemicals and environmental policies

are being developed that will drive manufacturing to other regions, undermining Europe's strategic autonomy.

6. Policy solutions on addressing shortages should be proportionate to the risk, improve cooperation, and leverage digital technologies. Developing prevention plans for all medicines without a risk-based approach would strain resources for both industry and regulators. Similarly, earlier notification of shortages will have limited impact if the available data in the supply chain (EMVS, ECDC) is not effectively used to provide early visibility of shortage risks.

EFPIA is committed to working with all stakeholders to close the competitiveness gap with other regions of the world, while taking action now to create faster, more equitable and sustainable access to medicines. Our industry is in a unique position to help create a healthier, more resilient and prosperous future for Europe.

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