**September 2023**

**3487 characters (max 4000)**

Medicines for Europe, representing manufacturers of generic, biosimilar and value added medicines across Europe, welcomes the proposals to review the EU general pharmaceutical legislation.

As the off-patent sector accounting for 70% of medicines dispensed in Europe covering 80% of therapeutic areas, we fully share the goals of ensuring that all patients across the EU have timely and equitable access to safe, effective and affordable medicines, through better competition, a more efficient regulatory system and a framework conducive e to manufacturing and continuous innovation.

Focusing on the provisions of the Regulation, we would stress the importance of:

1. **Ensuring predictability and legal certainty to prevent delays in access to generic and biosimilar medicines, by rejecting the proposed transferable exclusivity vouchers for novel antimicrobials**. The vouchers would lead to the extension of monopolies on the most profitable blockbuster drugs, thus breaking the founding principle of the relationship between innovation and reward, unduly delaying patient access to the more affordable off-patent products and dramatically increasing costs for healthcare budgets. To address the AMR challenge, instead of transferring the costs of funding antimicrobials to patients with already limited and unequitable access to blockbuster drugs, Europe should establish a Union multi-country pull incentive scheme to improve innovation, development and access to both novel and existing antibiotics, such as the revenue guarantee mentioned both in the December 2021 and June 2023 EPSCO Council Conclusions.

2. **Establishing a clear European strategy to prevent and mitigate shortages**. We support the proposed harmonised definitions of shortages and critical medicinal products, but are concerned about extending shortage notifications from 2 to 6 months which would lead to shortage “false alarms” as happened in Italy and Canada. Instead, a single digitalised and automated reporting system would allow marketing authorisation holders to report shortages as soon as they are aware, without placing an unnecessary burden on either them or the competent authorities. We support the introduction of shortage prevention plans with a risk-based approach, based on a single coherent list of critical medicines or essential medicines with no alternatives to avoid the generation of countless resource-intensive and unnecessary reports, instead allowing manufacturers to focus their resources on preventing and mitigating actual shortages.

3. **Ensuring an efficient regulatory system that delivers on medicine availability**. While the proposal already foresees several key provisions to optimise regulatory operations, including a shortened marketing authorisation (MA) procedure from 210 to 180 days, it would be critical to ensure the possibility for generic, hybrid and fixed dose combination products marketing authorisations applicants to choose between the centralised and the decentralised procedure. Moreover, removing the requirement for generic and biosimilar manufacturers to duplicate packaging and brand names for use patents by better adapting labelling to the use patent landscape and avoiding confusion among patients due to duplicate MA applications.

We are ready to continue the dialogue with the co-legislators, the Commission, patients and other stakeholders to improve medicines’ availability, accessibility and affordability and achieve an open strategic autonomy in healthcare.