**September 2023**

**3971 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 across 80% of therapeutic areas, we fully share the goals of ensuring that all patients in the EU have timely and equitable access to safe, effective and affordable medicines, through better competition, an efficient regulatory system and a framework conducive to manufacturing and continuous innovation.

Focusing on the Directive, we would stress the importance of:

1. **Ensuring predictability and legal certainty to prevent delays in access to generic and biosimilar medicines, by:** a) clarifying the Bolar provision to allow immediate day-1 competition after IP expiry, through the inclusion of the supply of EU produced APIs for obtaining marketing authorisations (API supply, offer, export, manufacturing) and all necessary regulatory and administrative steps (MA/P&R list/tender bids); b) modulating market protection rather than data protection, to ensure that in case the originator manufacturer does not supply the product to all EU markets, generic or biosimilar medicines would be approved in time to supply the underserved markets; c) ensuring the cumulative data and market protection period does not exceed the current 11-year cap.

2**. Establishing a clear European strategy to prevent and mitigate shortages, by:** a) increasing the visibility and transparency of the supply chain through a single interoperable reporting system, leveraging existing data sources like the European Medicines Verification System; b) allowing faster pan-European implementation of electronic product information, starting with hospital products, thus enabling faster reallocation of medicines across Member States.

3. **Ensuring an efficient regulatory system that delivers on medicine availability**. The proposal already foresees several key provisions to optimise regulatory operations but we still see areas where optimisation can go further to ensure faster patient access to affordable treatments by: a) avoiding limiting the mutual recognition procedure within a year of MA granting b) offering a pragmatic path for the national competent authorities to opt-in national procedures by allowing them to recognise for public health reasons the MA procedure within 5 days after the procedure has been closed c) ensuring a greater flexibility in choosing the marketing authorisation route d) adjusting the ownership of the ASMF to the legal entity that has ultimate responsibility for the ASMF.

4. **Adopting a science-driven and risk-based environmental risk assessment (ERA) to reduce the environmental footprint while safeguarding patient access**. We support the development of a streamlined process for referencing originator ERA for generic, biosimilar and fixed-dose combination products in order to avoid unnecessary duplication of efforts and delays in access to medicines. In addition, we recommend: a) ensuring that post-MA ERA condition is sufficient for authorisation of products where ERA is not (yet) available b) adopting AMR-related measures for products with a confirmed high risk of developing resistance.

5. **Supporting affordable innovation to address patient needs via a clear pathway for value added medicines**. The proposal recognises the importance of repurposed value added medicines with a non-cumulative 4-year data protection. We recommend including in the scope all relevant changes which deliver significant benefit to patients, such as repositioning, reformulation and complex combinations, while ensuring the article is not misused for evergreening practices.

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.