*Position Statement of the Spanish Biosimilar Medicines Association (Biosim)*

# FEEDBACK ON EVALUATION AND REVISION OF THE EU GENERAL PHARMACEUTICALS LEGISLATION

The Spanish Biosimilar Medicines Association (BIOSIM) welcomes the opportunity to comment and give feedback on the document (Combined Evaluation Roadmap/Inception Impact Assessment) about the Evaluation and revision of the EU general pharmaceuticals legislation.

BIOSIM represents 14 manufacturers of biosimilar medicines supplying close to 90% of dispensed prescription medicines in Spain. Spanish biosimilar market accounted for almost €700 million in 2020.

According to García-Goñi et al. (2021)[1] the utilization of biosimilar medicines in the Spanish NHS have generated savings of about €2.3 billion in the period 2009-2019. Specifically in 2019, the savings derived from the use of biosimilars relative total pharmaceutical spending in Spain was about 4%.

In the period 2020-2022 annual savings of €1 billion are expected according to the Independent Authority for Spanish Fiscal Responsibility (AIReF). In its "Hospital spending review"[2] AIReF identified that targeting biosimilar penetration, through incentives and other measures, is the most powerful tool to improve hospital pharmaceutical spending efficiency in Spain. Thus, AIReF outlined a plan to promote the use of biosimilars, both for treatment-naïve patients and for patients currently undergoing treatment.

While ensuring the quality and safety of medicines and creating a regulatory environment attractive for innovation and investment, sustainability of European healthcare systems must be a priority within the willingness of the EU to build a stronger European Health Union. Only in this way will it be possible to ensure the viability of welfare state in Europe. When it comes to improve the efficiency in public spending on medicines, the promotion of biosimilar medicines should be comprehensively addressed in the revision of European pharmaceutical legislation as they contribute to ensure that our use of pharmaceuticals is sustainable.

The promotion of biosimilars is in line with the Pharmaceuticals Strategy for Europe since enable better access to biological medicines but it is also in line with the **Health emergency preparedness and response authority** (most essential medicines for COVID19 are off-patent medicines.

[1] García-Goñi M, Río-Álvarez I, Carcedo D, Villacampa A. Budget Impact Analysis of Biosimilar Products in Spain in the Period 2009–2019. *Pharmaceuticals*. 2021; 14(4):348. https://doi.org/10.3390/ph14040348

[2] Autoridad Independiente de Responsabilidad Fiscal (AIReF). Evaluación del Gasto Público 2019. Estudio. Gasto Hospitalario del Sistema Nacional de Salud: Farmacia e Inversión en Bienes de Equipo. 2020 https://www.airef.es/wp-content/uploads/2020/10/SANIDAD/PDF-WEB-Gasto-hospitalario-del-SNS.pdf

In the light of the preceding remarks, we consider that the revision of pharmaceuticals legislation should seek, among other goals, to:

1. Foster access to biosimilar medicines immediately after patent expiry.
2. Promote the utilization of biosimilar medicines.
3. Encourage a competitive biosimilar market.
4. Strengthen biosimilar supply chain resilience.
5. Reduce the dependency on essential active ingredients and medicines.

Specific actions in the development of such an approach are detailed below.

1. Harmonizing the Bolar exemption to cover API supply and all administrative steps needed to effectively launch biosimilar medicines. At the same time, the need for SPCs should be revisited to prevent the expiry of patents from being artificially delayed.
2. Adapting EMA regulation to reduce the need for confirmatory patient trials in specific cases. This attempt would speed up and cheapen the development of new biosimilars, without any impact on the guarantees about their safety and efficacy profiles.
3. Clarifying the framework for duplicate marketing authorization applications (incl. for biologic) and generally improving known hurdles/burdens of the centralized procedures in order to help further secure access to and a level playing field for biosimilar.
4. Encouraging the multiple winner system in public procurement so that several manufacturers supply the market and the inclusion of criteria other than price. These additional criteria should be given significant weight when awarding public contracts (at least 40%).
5. Establishing incentives:
    a. Incentives for pharmaceuticals manufactures to set manufacturing sites within the EU to increase supply capacities across Europe (This action is also in line with the objectives of the **European industrial strategy**)
    b. Prescribing incentives linked to a specific objective of use. Financial incentives may be explored, specially those based on gainsharing agreements in which a portion of the savings are invested back into patient care.
    c. Incentives to encourage the development of orphan medicine biosimilars. Just as there are incentives and other benefits for the research or orphan drugs in Europe, there is a great need for biosimilar competition in this area once patents expire.
6. Implementing a European Observatory on Biosimilar Medicines to monitor aspects such as regulatory issues, industrial production, supply and demand-side policies, public procurement, and utilization rates across European countries. (This action is also in line with the objectives of the **European health data space**)