Sociedad Española de Reumatología

POSITION STATEMENT OF THE SPANISH SOCIETY OF RHEUMATOLOGY ON BIOSIMILAR DRUGS

The Spanish Society of Rheumatology (SER) hereby expresses its unequivocal commitment to the sustainability of the health system in our country and our steadfast alignment with all measures designed to ensure continuity without reducing the quality of care. In this sense, we believe that the advent of biosimilar drugs (BSs) will facilitate the access of rheumatic patients to biological therapies.

In an era when promising new biological therapies are increasingly available, SER considers essential to preserve physicians' freedom to prescribe the drug(s) best suited to the characteristics and circumstances of each patient, while responsibly bearing in mind the economic costs at hand.

The requirements and rules authorizing BSs are very strict and there is great consistency among the major regulatory agencies regarding their use. This helps ensure that the granting of a given BS is based on a proven demonstration that the innovative aspects of the drug do not compromise concerns relating to its safety and clinical efficacy.

SER, in line with the European Medicines Agency (EMA), believes that BSs cannot be equated to a generic. While the latter constitutes a chemically exact copy, a BS may nonetheless exhibit potentially relevant differences in their structure since such innovative drugs do not share identical production processes.

Therefore, SER aims to point out the following characteristics of BSs:

1. A biosimilar drug is a biological agent that is produced according to EMA-specific requirements and its similarity to the reference drug - in terms of quality, biological activity, safety and efficacy - must be shown as part of comparative, randomized, double-blind clinical trials.

2. The choice of an innovative drug or BS is the responsibility of the prescribing physician.

3. BSs cannot be equated to generic drugs of their reference drugs, as they are not substitutable. Switching a biological drug with its BS is an act only physicians should performed, with the consent of the patient.

4. SER understands that for the highest quality healthcare, clinical institutions should ensure that all BSs and biologics reimbursed by the health authorities of our country for the management of rheumatic diseases must be available to all hospitals participating in the National Health System.

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5. Since BSs, as their reference drugs, are subject to safety monitoring, it is necessary to create specific pharmacovigilance registries. SER has extensive experience with such registries, and is willing to carry out these safety studies.

6. Traceability of biological drugs is a valid concern, enabling authorities to assign suspected adverse reactions to specific batches and products. As BSs currently utilize the same DCI as the innovator drug, any prescriptions should be made using the trademark name in order to facilitate proper traceability.

7. In those instances in which the reference biological agent has more than one indication, any extrapolation of indications must be justified by the standards of the EMA and, if necessary, be individually proven via double-blind randomized clinical trials that directly compare the BS with the reference drug. Demonstrations of a BS' efficacy and safety for a particular indication may not be the same as for a secondary indication in which the biological reference drug has shown efficacy and safety.

8. Optimal use of BSs requires continual dialogue and interaction between doctors, pharmacologists and regulatory agencies, with the goal of preserving patient health rights, in order to offer products of equal effectiveness and safety.

9. SER's position regarding BSs will be regularly updated in light of new evidence; we estimate the next update to be made within 2 years.

PATIENT ASSOCIATIONS SUPPORTING THIS DOCUMENT:

ACCIÓN PSORIASIS

AECOS
Asociación Española contra la Osteoporosis

AESS
Asociación Española de Síndrome de Sjögren

CEADE
Coordinadora Española de Asociaciones de Espondilitis

CONARTRITIS
Coordinadora Nacional de Artritis

FELUPUS
Federación Española de Lupus

LIRE
Liga Reumatológica Española