

# STANCE OF THE SPANISH SOCIETY OF RHEUMATOLOGY ON BIOSIMILARS

The Spanish Society of Rheumatology (SER, by its Spanish acronym) declares its unequivocal commitment to the sustainability of the public health system in our country and will undertake all measures to ensure its continuity without lowering the quality of care. The marketing authorization given by the European Medicines Agency (EMA) for biosimilar agents (BS) represents a superb opportunity to enhance healthcare efficiency and to improve access to biologic therapies for patients with rheumatoid diseases.

#### BOARD OF DIRECTORS

##### President

Dr. José Luis Andréu Sánchez

##### President-elect

Dr. Juan Jesús Gómez Reino Carnota

##### Vice presidents

Dr. Fernando Pérez Ruiz

Dr. Héctor Corominas i Macías

##### General Secretary

Dr. Alejandro Escudero Contreras

##### Deputy Secretaries

Dr. Juan Muñoz Ortego

Dra. Lucía Silva Fernández

##### Treasurer

Dr. Juan Miguel Sánchez Bursón

##### Accountant

Dr. Eugenio Chamizo Carmona

##### Chairs

Dr. Alejandro Balsa Criado

Dr. Miquel Àngel Belmonte Serrano

Dra. María Galindo Izquierdo

Dra. Rosa García Portales

Dr. Miquel Àngel González-Gay Mantecón

Dr. Julio A. Medina Luezas

Dr. Javier Narváez García

Dr. Rubén Queiro Silva

Dra. Montserrat Romerá Baures

Dra. Elisa Trujillo Martín

Dra. Marta Valero Expósito

Dra. Beatriz Yoldi Muñoz

Given this new prospect, with increasing supply of biologics, SER considers that it is essential to maintain the freedom of medical prescription, based on the patient's characteristics and individual circumstances, while also not forgetting the economic considerations deriving from that action.

A BS is a biological drug containing a version of an active substance from an original biologic product that has been already authorized (reference medicinal product). In order to be approved, a BS must demonstrate that the present variation, or any difference from the original drug, will have no negative effects on safety and effectiveness. Therefore, once a BS has been authorized, regulatory agencies guarantee that there are no significant differences from the original biologic in terms of quality, effectiveness, and safety.

Thus, with regard to BS drugs, SER wants to bring to light the following:

1. A biosimilar drug is a biologic drug that has proven biosimilarity with its reference medicinal product based on in vitro studies. It is indistinguishable in terms of quality, biologic activity, safety and effectiveness within the framework of randomized, double-blind, head-to-head trials.
2. The choice of a target to block, and an active agent to use is the prescriber's responsibility, and must be exclusively decided upon within a doctor-patient relationship context, taking into account the disease characteristics, expected comorbidities and informed patient consent.
3. Once the target to block and the active agent have been chosen, it is the doctor's responsibility to select an innovative drug or BS. This must be strictly decided within the context of the doctor-

patient relationship. Safety and cost/effectiveness should be taken into account with this decision.

4. The exchange of a biologic for its BS must be carefully carried out by the prescriber with the patient's consent. In the case of patients with stable disease, an exchange between the reference biologic and its biosimilar may be acceptable, although it must be individualized and with the patient's consent.
5. Currently, there is no scientific evidence on efficacy and safety regarding the exchanging between different BSs for the same reference drug. This should be taken into account if the prescriber recommends an exchange, and patients should be informed about this issue.
6. It is understood by SER that healthcare institutions must guarantee that all biologic agents and BSs used to manage rheumatic diseases which are financed by the health authorities in our country, must be available in all hospitals of the national healthcare system.
7. BSs are subject to safety monitoring, the same which is used for their reference medicinal product. For this reason, there is a need to favor their inclusion in the specific pharmacovigilance registries currently under development. SER has extensive experience with these registries and can carry out such safety studies.
8. The traceability of biological drugs is a quality measure that allows for the specific assignment of suspected adverse reactions to each batch and product. Currently, a given BS is assigned the same International Common Denomination (ICD) as the one assigned to an innovative drug. For this reason, prescriptions must be written out by brand name in order to achieve proper traceability.
9. In the case that the reference biologic agent has more than one indication, extrapolation of indications must be justified according to EMA standards.
10. An optimal use of BSs requires a continuous dialog and interaction among physicians, hospital pharmacies, patient

associations, and regulatory agencies. The overall aim is to maintain patients' right to healthcare and to offer them high quality, effective and safe products.

11. Within this framework, SER will periodically issue updates in light of new evidence; the next update is estimated to take place in two years' time.

#### PATIENT ASSOCIATIONS SUPPORTING THIS DOCUMENT:

