

# **British Society for Rheumatology Position statement on biosimilar medicines (Revised January 2017)**

## **Introduction**

A biosimilar medicine is a biological medicine manufactured to be similar to an existing licensed “reference” biological medicine, with no meaningful differences from the reference medicine in terms of quality, safety or efficacy. The first biosimilars for rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis will be introduced to the UK in February 2015 with further biosimilar drugs to follow.

The introduction of biosimilars has the potential to provide patients with access to a wider range of more cost effective treatments to manage their conditions. The following sets out the BSR recommendations designed to address the uncertainty created by the introduction of these biological medicines. In developing our statement we have consulted widely with a range of groups with an interest in biosimilars, including NRAS, NICE, and ABPI.

## **Recommendation 1: Prescription by brand name**

All biologics and biosimilars should be prescribed by brand name rather than by International Non-proprietary Name (INN). This is in line with existing recommendations from the Medicines and Healthcare Products Regulatory Agency (MHRA) to avoid automatic or accidental substitution of a biosimilar product when the medicine is dispensed by the pharmacist. Where possible, batch numbers should also be recorded to allow clear identification of biological medicines. It is essential to know exactly which product a patient is receiving at any one time.

## **Recommendation 2: Prescription for clinical reasons**

Clinical effectiveness and patient safety should be the overriding principles for prescribing any biologic agent. Prescribing should therefore be made on a case by case basis, based on clinical reasons and not solely as a measure to save money. In all cases, physicians should consider the efficacy, safety and cost-effectiveness profile when making these prescribing decisions.

- New patients: BSR supports the inclusion of biosimilars as a biologic therapy choice for patients initiating a new biologic therapy.
- Switching patients: the decision to switch patients currently receiving a reference product to a biosimilar should be on a case-by-case basis until further data are available to support safe switching. Strong safeguards are required to ensure that patients who have responded well to existing medicine who are switched for non-clinical reasons are closely monitored to ensure efficacy and safety. If patients fail to maintain the efficacy achieved on a reference product then they should have the option of reverting to this.

## **Recommendation 3: Substitution only with the consent of the prescribing clinician**

In the event that the branded biologic or biosimilar prescribed by the clinician is unavailable, the dispensing pharmacist must contact the prescribing clinician to seek advice as to appropriate short-term alternatives. The patient must be kept informed at all times of the discussions taking place in regard to their medicine. Patients should feel empowered to check with both the prescribing clinician and the pharmacist that the medicine dispensed is the same as that prescribed.

## **Recommendation 4: Decisions made in partnership with the patients**

Prescribing clinicians must keep their patients fully informed about the progress of their condition and the medicines they are being prescribed. The BSR supports the shared decision making approach, in which treatment options are discussed in partnership with the patient and any decisions on potential changes to medicines, including the reasons behind these changes, are made

in collaboration with, and with the informed consent of the patient. Furthermore, as with the introduction of any new medicine, prescribing clinicians should make their patients aware of the process for reporting any adverse reactions to the newly prescribed biosimilar. It should be noted that there is an administrative and time cost to ensuring the patient is kept fully informed throughout the switching process.

**Recommendation 5: Registration with the BSR Biologic Registers or other appropriate UK register.**

There should be a robust safety monitoring strategy to protect patients and develop the long term evidence base required to provide patients and clinicians with the necessary assurances on safety and effectiveness. The EMA has recommended that all companies who hold the manufacturing authorisation for biosimilars should participate in existing pharmaco-epidemiological studies including registries that have been set up primarily to monitor safety of the reference medicines.

The BSR **strongly recommends that** all patients starting or switching to biosimilars should be **registered with the BSRBRs** to allow the capture of the same robust systematic data on adverse effects that have been collected for the reference medicines. The data will ultimately allow clinicians and patients to make informed choices about treatment options.

**Background to the BSR position**

*The evidence base on the safety and efficacy of biosimilars*

Whilst we acknowledge that prior to marketing authorisation each new biosimilar agent will have undergone a stringent comparison against the reference medicine taking into account safety and efficacy, there remain some doubts of the strength of the evidence. For example, the equivalence clinical trials for each biosimilar are conducted within a small trial population and no clinical trial is undertaken for each licensed indication of the reference products, weakening the evidence used to support extrapolation of indications from reference treatments. Furthermore, there appears to be little evidence of the safety and effectiveness of switching to biosimilars in patients who are stable on a reference agent and a lack of knowledge of the long term safety of biosimilar drugs which may have subtly different immunogenic profiles.

In rheumatology, the clinical trials have been of new users only, with no trial of direct substitution from an originator drug for rheumatological or autoimmune diseases. This is significant, as biosimilar medicines will be available for use at many different points along the treatment pathway, including as first biologic, subsequent biologic after previous failure and, for the first time, as a substitute biologic for patients who are well controlled on a reference agent.

*Addressing the gaps in the evidence base*

Real-world data provides essential evidence of the safety and effectiveness of therapeutic agents in clinical practice. Although current EMA recommendations require manufacturers to undertake post marketing surveillance on all new licensed products and the use of patient registries is supported by NICE, there is no statutory mandate for clinicians to collect data routinely. The BSR believes that it is best practice to record data on all UK patients starting biosimilars in a consistent and systematic way and to monitor adverse events over the long term. We would like to support rheumatologists in this goal. The BSR Biologic Registers already provide well established tools for logging drug use and adverse events in cohorts of patients currently receiving biological agents and are the BSR's preferred mechanism by which patient data on biologics should be collected.