Allaying Patient Anxiety Around Biosimilars

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The availability of reliable, up-to-date information about biosimilars is crucial if patients are to understand these agents. A new position paper highlights what is needed to assist physicians, patient organizations, and patients.

The rapidly expanding availability of biosimilars has the potential to significantly widen patient access to new treatments.

A new position paper by the Committee for People with Arthritis/Rheumatism (PARE) released at the European League Against Rheumatism (EULAR) Annual Congress in Rome highlights what is still needed to assist physicians, patient organizations, and patients in the understanding and assessment of biosimilars.

The science of biosimilars and how these agents are introduced are not straightforward for the lay person to understand. Therefore, the implications of biosimilar treatments have led to anxiety and skepticism among patients.

“The availability of reliable, up-to-date information about biosimilars is crucial to the patient's understanding of biosimilars. Patients and patient organizations need evidence-based information that allows them to make informed decisions and choices about treatment and patient care. Never is this more important than when new medicines are being introduced,” stated Diana Skingle, Chair EULAR Standing Committee for PARE.

Pharmaceutical manufacturers are developing biosimilars at a lower cost than the original biologic medicines, “possibly making them more widely accessible to patients and offering more treatment options to physicians,” noted Skingle.

One of the patient concerns noted in the paper is that biosimilars may be approved after only very short or limited trials without sufficient time to consider any longer term effects. The paper notes that the active substance of a biosimilar must be similar, in molecular and biological terms, to the active substance of the reference biologic.

“However, both are made of complex molecules which are made using living organisms. Due to this inherent complexity and batch-to-batch variation of biologics, this leads to varying degrees of biosimilarity,” Skingle stated.

This leads to questions about whether biosimilars increase immunogenicity and will lead to side effects that are the same as the reference biologic.

Safety is a paramount issue for patients and providers, including pharmacovigilance. This is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Under the EU pharmacovigilance legislation, patients themselves can report suspected side effects directly to national authorities. “It is important therefore for patients to be able to determine which national public health institution authorizes, tracks and monitors medicines in their country,” Skingle stated.

The paper points out that physicians must ensure that the brand name of the biologic being prescribed always appears explicitly on the prescription.

There are no recommendations on whether a biosimilar should be used interchangeably with its reference medicine. “So there is no certainty that it will not take place,” she stated.

Patients may also be anxious that lower-priced biosimilars may increase pressure on clinicians to prescribe the newer alternative on the basis of cost alone, not on clinical efficacy.

As more evidence-based data on biosimilars becomes available, reliable codes of practice, recommendations and points to consider developed by EULAR “would also be highly appreciated by the European rheumatic and musculoskeletal diseases (RMD) patient community and help to build confidence and widen their understanding of the use of biosimilars for the treatment of RMDs,” Skingle stated.