Biosimilar concerns of rheumatology patients being addressed by national program

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To address the fear and insecurity expressed by rheumatology patients on being switched from a biologic to a biosimilar treatment for their arthritis, the Danish Rheumatism Association has participated in a national programme designed to ensure patients received independent information about biosimilars, along with closer monitoring of prescriptions to provide reassurance about their safety. The results of this initiative were presented today at the Annual European Congress of Rheumatology (EULAR) 2017.

When the first biosimilar was approved in Denmark in 2015, the national council for the use of expensive hospital medicines (Rådet for Anvendelse AF Dyr Sygehusmedicin, RADS) announced that they found the biosimilar infliximab equal to the original reference product (Remicade) in efficacy and safety. Based on this, RADS made a recommendation for hospitals to use the less expensive infliximab biosimilar for both treatment-naïve patients and patients already on Remicade, unless there were medically justified reasons not to do so.

By the first quarter of 2016, this biosimilar covered around 97% of infliximab consumption in Denmark.2 There are now two biosimilars approved by the national authorities in Denmark, and used in the treatment of patients with arthritis.

Although the switch to a biosimilar would obviously save money for the healthcare system while ensuring the same benefits for patients, this decision caused considerable insecurity among patients, who were afraid

of biosimilars and their effectiveness and safety profile. Also, physicians did not seem comfortable about explaining the principle of biosimilarity; hence, patients remained uncertain about the change that had been introduced to their treatment.

Patient anxiety was further aggravated by hospitals and regions in Denmark putting different information on biosimilars on their websites.

An initial small study of how this shift from biologic to biosimilar had taken place in different regions, conducted by the Danish Rheumatism Association, revealed that although most patients were told about the change in their treatment, they received a lack of information from their doctors about the new biosimilars.

Also, while nearly all patients on a biological drug are registered in a national database, which records which drug the patient has been prescribed, it is not registered on a batch-level, which makes it more difficult to monitor safety.

"In order to change this situation, we started a dialogue with politicians and the authorities on a national level and hospital administrations on a regional level," said Ms. Lene Mandrup Thomsen from the Danish Rheumatism Association, Gentofte, Denmark. "The purpose was threefold: to improve the registration of biologics and biosimilars on a batch-level, the provision of more independent patient information and the involvement of patients in the decision-making process," she explained.

The new national plan, launched in August 2015 and implemented throughout 2016, consisted of four parts:

- 1) Monitoring efficacy and safety of biologics and biosimilars on a batch level2) Information campaign targeting both health

professionals and patients3) Digital solutions to aid easy reporting of side effects from health professionals and patients4) Focus on monitoring patient safety by the authorities

In addition to this national plan, hospitals on a regional level have invited a representative from the Danish Rheumatism Association to participate in a working group, with the objective of including the patient perspective in future national recommendations for the use of biological drugs and biosimilars.

Provided by European League Against Rheumatism