Biosimilars—clinical perspectives in rheumatology

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Universitätsmedizin Berlin and the University of Massachusetts Medical School have been analyzing clinical data on biosimilars that have already been approved for use. The term 'biosimilars' refers to drugs that mimic the effects of biologics. A particular focus of the article, published in the current issue of *Nature Reviews Rheumatology*, is the efficacy of biosimilars that have already been approved for the treatment of rheumatic diseases within the past three years.

Drugs produced using biotechnology are among the most expensive medicines available. Biosimilars that offer a real alternative are becoming increasingly available on the market. The promise of biosimilars is that, once patent protection has elapsed for established biologics, more patients will be able to access effective and well-tolerated drugs. This is particularly true in relation to preparations used in the treatment of patients with cancer and autoimmune diseases, which also include drugs used for the treatment of rheumatic diseases. In 2001, as part of a project led by the European Medicines Agency, step-by-step guidelines were introduced to regulate the approval of these products, and to acknowledge the specific differences that distinguish biosimilars from traditional medicines. Biosimilars are complex proteins which, although not required to be identical to their originator products, have to be similar to them in terms of both effect and tolerability.

One of the main differences is of course that biosimilars are, or are set to be, available at significantly lower prices than those of the originator products. Prof. Dr. Thomas Dörner, from the Medical Department,

Division of Rheumatology and Clinical Immunology at Charité, stresses that "the introduction of these medicines needs to be handled in a responsible manner, and requires the input of experienced practitioners." Prof. Dörner adds that "the decision as to which medicine a patient is to be given should remain the responsibility of the treating physician. What must not be allowed to happen is what is currently happening with traditional generics, namely that pharmacies automatically substitute one product for another."

For their article, the authors analyzed a wealth of information on the development of biosimilars. Their review, which covers almost every biological drug available, also addresses the enormous variations currently seen in approval processes across the globe. Their findings suggest that the introduction of biosimilars into clinical practice must go hand-in-hand with the creation of national registers, which allow data on potential side effects to be collated. The authors conclude that the approval and introduction of biosimilars offer access to both established and new treatment options. Biosimilars are also likely to reduce the costs associated with the treatment of inflammatory diseases in the fields of rheumatology, dermatology, and gastroenterology.

More information: Thomas Dörner et al. Biosimilars in rheumatology: current perspectives and lessons learnt, *Nature Reviews Rheumatology* (2015). DOI: 10.1038/nrrheum.2015.110

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