RESEARCH ROUNDUP

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Editor's Note: The following texts are simplified summaries of the published articles. They do not contain an opinion or an in-depth analysis on the results obtained by the authors. The selection of these works was made based on theme relevance, not a product of a literature review or of a methodological quality selection.

Biosimilars have been a great source of discussion, not only in terms of their interchangeability and quality, but also in relation to how best to assess their economic impact, going beyond merely comparing prices. We have selected two articles that discuss these and other aspects.

Global Acceptance of Biosimilars: Importance of Regulatory Consistency, Education, and Trust

Cazap E, Jacobs I, McBride A, Popovian R, Sikara K.
Oncologist. 2018. [Epub ahead of print May 16]. doi:10.1634/theoncologist.2017-0671.

The overall expectation with biosimilars is that they promote lower treatment costs while providing the same efficacy and safety effects, and consequently allow for a larger number of patients to be treated.

This review article demonstrates the evolution of the global scenario for biosimilars and identifies inconsistencies among regulatory requirements in different regions of the world.

Ongoing efforts to improve regulatory alignment were also analyzed, highlighting the importance of education as a crucial factor in generating trust and acceptance of biosimilars worldwide.

Biosimilars are a matter of interest in all countries, regardless of whether they are rich or developing nations, since there is an expectation of reducing costs and increasing access to treatment. The article may serve as a basis for understanding the regulatory implications that subsequently impacted HEOR issues around the world, as simply comparing prices is already a conduct long discarded in our field.

Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes

Cohen HP, Blauvelt A, Rifkin RM, Danese S, Gokhale SB, Woollett G.
Drugs. 2018;78(4):463–478. doi: 10.1007/s40265-018-0881-y.

Another major discussion related to biosimilars evaluation is regarding the use of health resources for their adoption or replacement of the original product.

To provide an answer regarding the issues of clinical similarity between biological products and their biosimilars, the authors conducted a systematic review of the literature where a total of 90 studies involving 14,225 patients were evaluated.

The authors state that although the use of each drug should be assessed individually, the risk of safety concerns related to immunogenicity or reduced efficacy of biosimilars use remains unchanged after switching from a reference biological drug to a biosimilar drug.

Understanding these factors is of great importance to HEOR professionals as the evaluation of biosimilars must overcome interchangeability barriers. Therefore, real-world data should be collected so that we can truly assess the economic impact that biosimilars will have on a health system.