

TITLE

BIOSIMILAR PRODUCTS SELECTION: CHALLENGES FOR CLINICIANS

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The introduction of similar biological medicinal products (biosimilars) into clinical practice represents new challenges that are not ordinarily presented by small-molecule generic medicines. This is because a biosimilar can only be proven to be similar and not identical to its reference product. In fact, unlike small molecule drugs which normally have a low molecular weight, biosimilars are large, protein molecules with complex structures. For instance, insulin has a molecular weight of 6,000 Daltons whereas aspirin has only 180. Therefore, it is evident that the original biopharmaceutical products and biosimilars are not interchangeable. The clinicians must be aware of this, since it means that patients must be carefully monitored if their treatment is changed between products. Furthermore, the use of biopharmaceuticals requires more knowledge with respect to both the scientific and regulatory issues for these drugs. For example, the current international non-proprietary names (INN) system when applied to biosimilars, means that these drugs can have the same name as the innovator product, which could easily lead to inadvertent substitution. Therefore, particularly in the case of biosimilars, their use requires more communication with both patients and prescribers, since in the case of switching or substitution, more vigilance is required by everyone. From an economic standpoint, biosimilars may provide some cost advantages over the originator biopharmaceutical drug, but not to the same extent as normally seen with generic drugs. Generic drugs can have a discount of up to 80%; however, with biosimilars, this discount will most likely only be 10-30%. Biosimilars may be associated with significant cost aspects including dose penalties (e.g., more drug is required to achieve the same therapeutic effect as achieved with the originator), and switching costs. In conclusion, there are many important issues with respect to biosimilars that still have to be clarified. Biosimilar products have to be tested rigorously against the reference innovator product, and vigilant regulatory oversight will help maintain high standards of quality and control. Patient welfare is foremost and for clinicians, the knowledge that biosimilars are not generics and that there can be potential implications upon clinical outcomes when products are switched will help ensure patient safety.

OBJECTIVES

1. To discuss important problems of biosimilar products including immunogenicity and safety issues when it comes to product selection.
2. To explain current strategies used to evaluate pharmacokinetics and pharmacodynamics of new biosimilar products under development.
3. To share a local experience performed to assess a new insulin biosimilar product for clinical use.