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Commentary

Putting the "bio" in "biotherapeutics"/checkpoints for biosimilars/ application of biosimilars

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ABSTRACT / EXECUTIVE SUMMARY

The number of biosimilar medicines on the market is steadily increasing, due, in part, to patent expiration of several top-selling biologic medicines. These three e-learning modules discuss the basic concepts behind biosimilar medicines and highlight key regulatory considerations when using biosimilar medicines in medical practice.

The number of biosimilars approved for use is expected to rise markedly over the next few years. Interest in these products is rising due in part to the impending patent expiration of several top-selling biologic medicines. A biosimilar can be defined as a version of an already-authorized biological medicine, with demonstrated similarity in physicochemical characteristics, efficacy, and safety. It is considered to be "highly similar", but not an exact copy of the originator biologic medicine. Their larger size, complex structure, and the potential to cause immunogenicity set biosimilars apart from small-molecule medicines. Reverse engineering can be used to produce a biosimilar; subsequent changes in the manufacturing process, whether deliberate or due to gradual attribute change, can potentially lead to product divergence and loss of biosimilarity. To avoid this, substantial monitoring and testing are necessary to ensure that the biosimilar remains similar to the originator biologic medicine. The main regulatory guidelines for biosimilars, produced by the European Medicines Agency, World Health Organization, and the US Food and Drug Administration, all specify ongoing pharmacovigilance as essential for better characterizing the safety profiles of biosimilars. These overarching guidelines have been used as the basis for many national and regional regulations, although the advice can vary from country to country: the number of clinical and non-clinical tests required for approval can be different, for example. Currently, the nomenclature system for biosimilars is inconsistent, and not necessarily optimal for ensuring traceability. Regulations on interchangeability and substitution – whether the biosimilar can be expected to produce the same clinical results as the originator biologic medicine, and whether one can be substituted for the other (e.g. by a pharmacist) – also differ from country to country. Clinical data on switching between a biosimilar and its originator biologic medicine is beginning to emerge, but studies to date are generally too short to show possible long-term effects. All of these issues are discussed in depth in this three-part e-learning course, which concludes with a summary of practical implications for the use of biosimilars by healthcare professionals (see http://biosimilars.elsevierresource.com/ for the full course).

Focal points:

- Biosimilar production is expected to increase in the coming years, due to patent expiration of several top-selling biologic medicines
- While biosimilars are considered "highly similar" to their originator biologic medicines, they are not generic copies of these medicines
- Several regulatory guidelines are in place for monitoring biosimilar safety and efficacy
- However, regulations on the substitution and interchangeability of biosimilars varies by country, and further research on the long-term effects of these practices is necessary

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