FIP 2018 Glasgow, Pre-congress Satellite Symposium on Biosimilars
September 1, 2018.

Overcoming the gap between clinical use of biosimilars and education of pharmacists and other healthcare providers

Arnold G. Vulto PharmD PhD FCP, Hospital Pharmacist / Pharmacologist
Honorary Professor, Hospital Pharmacy Erasmus University Medical Center Rotterdam, The Netherlands
Honorary Professor, Catholic University Leuven, Department of Pharmaceutical & Pharmacological Sciences, Belgium.
Liese Barbier PharmD, PhD Student, Catholic University Leuven, Department of Pharmaceutical & Pharmacological Sciences, Belgium.

Biosimilars are versions of already licensed biological medicines that are developed via a completely new drug development paradigm of reversed engineering. The biosimilar development is predominately based on analytical data and the clinical development has a reduced role in comparison with the approval pathway of a new medicine. Consequently, many clinicians and patients have difficulty to accept biosimilars as an equal alternative to their reference-product. As a result, the major benefits of biosimilars – lowered healthcare costs and increased patient access to biologicals treatment– are not fully attained.

As pharmacists we need to understand why various stakeholders are hesitating to accept biosimilars, and subsequently we have to develop strategies to support acceptance. This is highly relevant as of August 1, 2018, in Europe 44 biosimilars of 13 molecules were granted a marketing authorization.

This implicates that the pharmacist has to do his / her homework to be able to look beyond the acquisition cost of the medicine when advising on these products. The pharmacist should study in detail differences between biosimilars. The pharmacist can play a key role in educating and informing physicians, nurses and patients about the biosimilar development paradigm and the use of these new products in clinical practice.

However, many pharmacists and doctors were never properly educated on the intricacies of biological medicines, let stand biosimilars. This deficit was already described penetratingly by the 2008 ASHP Task Force on Science, and they concluded there was no quick fix, but a more fundamental restructure of pharmacy-curricula would be needed.[1] Several more recent surveys have reiterated this message: doctors and pharmacists do not feel comfortable with biologics / biosimilars due to lack of knowledge.[2-4] As a result, all over the world educational efforts were initiated to educate health care professionals on the value of biosimilars. However, it is not easy to reach prescribers, as they are too busy, or they do not see the benefit, or they think they know enough. The latter is called *the illusion of explanatory depth*. It is worth of note that such an important issue in the benefit of reducing healthcare costs is left to the industry when it comes to education.

To complicate matters further, we see in the literature confusing differences in definitions between the USA and Europe when it comes to biosimilars terminology, words like substitution, interchangeability and switching.

In the presentation, several examples of educational efforts about biosimilars will be discussed. Further, special emphasis will be paid to an initiative from the Dutch government to offer biosimilar education to all (professionals in) hospitals, as it was deemed highly beneficial for the healthcare

budget. We believe the same is true for other countries, but in many countries like the USA there are too many conflicting parties involved, as even the FDA commissioner recently said.[5]

In 2017 Li et al. proposed an extensive educational effort directed at undergraduate pharmacy schools, to make pharmacy students familiar with biological medicines including biosimilars.[6] However, it is actually not known how extensive teaching on biotechnology / biologics / biosimilars actually is. We therefor launched this summer an online survey via international organisations of pharmacy schools and the preliminary results will be presented at the symposium.

Relevant background information.

- Cornes and Bennett (2018) Fast facts: Biosimilars, Karger Publishers (around 20€) https://www.karger.com/Book/Home/277615
- EU-commission / EMA information for healthcare professionals: http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf
- And a Q&A document for patients In 23 languages: http://ec.europa.eu/DocsRoom/documents/26643
- Another extensive and very informative guide (free): http://www.researchadvocacy.org/sites/default/files/resources/Biosimilar%20Medicines_Final-download.pdf

References.

1. Report of the 2008 ASHP Task Force on Science. Am J Health-Syst Pharm 2009; 66:1132-1138.

2. Cohen H et al. Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians. Adv Ther 2016; 33:2160–2172.

3. Beck M et al. Knowledge, behaviors and practices of community and hospital pharmacists towards biosimilar medicines: Results of a French web-based survey. mAbs 2017; 9:2, 384-391.

4. O'Callaghan J et al. Assessing awareness and attitudes of healthcare professionals on the use of biosimilar medicines: A survey of physicians and pharmacists in Ireland. Regulatory Toxicology and Pharmacology 2017;88, 252-261.

5. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.html

6. Li E et al. A Framework for integrating biosimilars into the didactic core requirements of a doctor of pharmacy curriculum. Am J Pharmaceut Education 2017; 81(3)article 57.