HAH Bulletin
ISSUE #7 SEPTEMBER 2021

He Ako Hiringa
Learning Always

Biosimilars: A promising new era

A biosimilar medicine is highly similar in all essential aspects to an approved brand of biologic (reference medicine). Because biosimilars are not *identical* to their reference medicines, they are not considered generic medicines.[1,2]

For regulatory approval, a biosimilar must demonstrate high biosimilarity to the reference medicine in structure, biological activity, and efficacy and safety profiles; this is achieved through comprehensive comparability studies. Biosimilars rely on the safety and efficacy shown by the reference medicine during its clinical use and therefore require less clinical data for regulatory approval. They are considered therapeutically equivalent to the reference medicine within their approved indications.[1,2]

Compared with their reference medicines, no relevant differences in adverse effects have been shown with biosimilars during periods of safety monitoring, and no increased immunogenicity – the ability of the biologic to induce immune responses – has been identified in published studies to 2019.[1,2]

Immunogenicity

Clinical immunogenicity studies are generally required for *all* biological medicines, including biosimilars.

These studies assess clinical impact, describe measures for managing potential immunogenicity risks and provide data on any antidrug antibody (ADA) development.[2]

Immunogenicity is not a safety concern in itself and most often an immune response to a biologic does not result in clinical consequences. Severe reactions due to increased immune responses are very rare. The more common response is ADA development, which may be only transient, but could negate therapeutic effect or reduce efficacy.[2]

Although a biosimilar's safety and efficacy will be highly comparable to its reference medicine, its immunogenicity profile *may* prevent changing between products.[3] Therefore, prescriber and patient must agree to switching,[1] so they are alert to new adverse effects or efficacy changes. Substitution of biologics at dispensing should only occur with prescriber agreement.[3] For all biologics, brand name prescribing and batch number recording is recommended.[1]

For more information see:
- *tinyurl.com/biologicalmeds*
- *bpac.org.nz/2020/biosimilars.aspx*

References are available online at AkoHiringa.co.nz

aHAH MOMENT!

Increased access, treatment options with biosimilars

Biological medicines have markedly changed prognoses for many conditions such as cancers, diabetes and autoimmune diseases.

These medicines are active substances derived from biological sources and manufactured using sophisticated biotechnology; they target specific receptors or proteins involved in disease progression. Typically large, complex molecules with inherent variation, biologicals differ from conventional medicines, which are generally small, well-characterised compounds.[1,2]

As biologics' patents expire, biosimilars – highly similar versions of approved biologic brands – will be competitively marketed. This will lead to cost savings, increased access and treatment options, and improved patient outcomes.[2]