Allens in the Healthcare sector

The healthcare sector faces great change and opportunities in delivering patient wellbeing.

Allens draws on its many decades working with the healthcare industry to deliver insight and innovative advice across every stage of the product lifecycle.

Our team’s deep understanding of the healthcare sector is augmented by an extensive background in life sciences, with many members of our team holding doctorates in advanced sciences and having worked in pharmaceutical and biomedical research around the world.

Leading advice

Our lawyers and patent attorneys help leading industry players to navigate the rapidly changing regulatory landscape and manage patents, transactions and disputes.

We partner with clients to provide strategic advice at all stages of research and product development, in addition to advising in relation to marketed products.

We are also delighted to have the opportunity to work with emerging biotech companies as part of the Allens Accelerate offering for startups and emerging companies.

Your feedback

Please contact us if you would like to discuss the challenges and opportunities presented by biologics and biosimilars.

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Allens is an independent partnership operating in alliance with Linklaters LLP
Biologic medicines and biosimilars in the Australian landscape

**KEY ISSUES**
In exploring the challenges and the opportunities, key issues include:

1. To what extent should biologic medicines be provided protection from competition and how should this be done?
2. How should the safety, efficacy and quality of biosimilars be assessed?
3. What is the appropriate way to ensure that potential improved access and affordability arising from competition occurs once any relevant protection has expired?

**THE CHALLENGES & OPPORTUNITIES**

Allens is engaging with stakeholders on the challenges and opportunities presented by biosimilars. As part of this engagement, we highlight a number of key issues for discussion and comment.

- Biologic medicines such as antibodies, cellular therapies and recombinant proteins work with our bodies to provide targeted treatments for a wide range of diseases and present significant opportunities.
- However, the costs, and risk, of bringing such products to market can make them expensive, particularly because:
  - the time and cost to ensure they are safe, efficacious and of an appropriate quality.

- As biologics may not be structurally identical, a biosimilar shown to be safe and effective for one indication may not be for another. Despite this being critical for biosimilar success, there is no agreed basis for determining when to allow extrapolation from proven indications to others.

- Studies demonstrating exactly how comparable the follow-on biologic product is to the reference product are required if the product is to rely on the data provided for the reference product. This poses difficulties where the reference product is not well characterised (or the characterisation is proprietary to the original manufacturer). In addition, the Therapeutic Goods Administration (TGA) may require different and more detailed clinical data than applications made in other major markets—a further barrier to biosimilar entry.

- The risks are exacerbated by uncertainties as to when follow-on biologics can enter the market, and the basis on which those products can compete in the market.

- For biosimilar products, there are opportunities for improved access to and affordability of therapies. The challenge is to facilitate this in a way that provides sustainable benefits, both from the development of new medicines and from the improved access and affordability arising from competition by biosimilars.

**COMPETITION ISSUES ON THE HORIZON**

It is unclear how the ACCC will approach matters involving biosimilars. In particular, the question of substitutability is critical for the purposes of defining markets and for assessing the competitive constraints faced by suppliers of biologic medicines. The ACCC’s assessment of substitutability will be influenced by the practices of industry participants, particularly hospitals and buying groups such as State Purchasing Authorities. However, the regulatory landscape, including interchangeability or a ‘flagging’ of biosimilars, will be important in determining whether biosimilars are substitutable for originators.

**WHAT ARE BIOLOGIC AND BIOSIMILAR MEDICINES?**

A ‘biologic medicine’ is a medical product made or derived from a natural source that can be used to treat or prevent diseases and medical conditions.

A ‘follow-on biologic’ is a reproduction of an originator biologic medicine (the ‘reference product’) intended to have the same (a biosimilar) or improved therapeutic properties (a biobetter).

Follow-on biologics are not necessarily structurally identical to the reference product and are therefore not exact copies like ‘generic’ medicines. When a follow-on product is biosimilar it may not be interchangeable for patients in day to day use.