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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Biologic medicines and biosimilars in the Australian landscape

KEY ISSUES

In exploring the challenges and the opportunities, key issues include:

- To what extent should biologic medicines be provided **protection from competition** and how should this be done?
- How should the **safety, efficacy** and **quality** of biosimilars be **assessed**?
- 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.
- the specific nature of the medicine can mean smaller treatment populations.
- they use biologic methods of manufacture.

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.

Protection for biologic medicines

Does Australia have the right balance between certainty and protection periods to facilitate the sustainable supply of biologic and biosimilar medicines?

1. Can biologic medicines be patented ?

Unlike the US, the High Court of Australia's decision in *D'Arcy v Myriad Genetics Inc* prohibits patenting of 'isolated nucleic acids' but not biologic medicines per se. However, the reasoning in Myriad means that the breadth of the prohibition remains uncertain.

2. Are market and data exclusivity provisions sufficient?

The limited patent protection available in the US has driven extended periods of exclusivity (up to 12 years) for originator biologic medicines. This is provided under the U*S Biologics Price Competition and Innovation Act* as part of the grant of marketing authorisation.

Australia has committed to an effective 8 years exclusivity under the Trans Pacific Partnership. However, there is no targeted protection for biologic medicines.

As with other medicines the data provided by the originator about the active components, if confidential, cannot be used to support a biosimilar for 5 years (data exclusivity) from when the original biologic obtained marketing authorisation. Taking other factors into account this can result in ***6 to 8 years*** protection from biosimilar competition.

Assessment of biosimilars

Are Australia's unique processes necessary to ensure safe medicines, or do they represent a barrier to Australians obtaining timely affordable access to medicines?

3. Does Australia need dedicated regulatory pathways for biologic medicines ?

Currently there are no regulatory pathways specific to follow-on biologics in Australia. This means that the stepwise approaches used in the US do not have clear application here.

4. Comparability is key

Establishing biosimilarity is not dissimilar to the US and the EU. 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.

5. Extrapolation

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.

Improving access and affordability

Will Australia's approach to naming and interchangeability deliver sustainable and certain benefits from biosimilar entry or should alternatives, such as targeted treatment initiation on biosimilars, be considered?

6. What is the best method for regulating interchangeability of biologic medicines?

Determining whether a patient should be allowed to change from a biologic to a biosimilar, or from one biosimilar to another (***switching***), or to treat the biologic and a (or many) biosimilar as identical commodities that can replace each other without concern (***interchangeability***) is a hotly contested issue. This is because it, together with extrapolation, has an impact on whether the products are true competitors.

7. Are naming provisions for biologic medicines appropriate?

Closely linked to the questions regarding interchangeability are issues of naming—should the names of the biologic medicines reflect the fact that they are unlikely to be identical. This might require each biosimilar product to have a different drug name which in turn may influence biosimilar uptake. Australia has recently changed its approach and no longer requires different names.

8. Prioritising safety or affordability for biosimilars

The affordability benefits arising from competition in Australia for generic medicines are driven by a complex statutory scheme, where drug names and interchangeability are key. Interchangeability, known as ***'a-flagging'***, allows brand substitution by dispensing pharmacists.

Biosimilar entry is being shoehorned into the same scheme with the assumption that naming and interchangeability are as simple as for generics. In doing so the usual burden of proof for interchangeability is reversed. Instead of requiring proof from sponsors, Australia's Pharmaceutical Benefits Advisory Committee will assume interchangeability is safe unless it is shown that it is not safe. This represents a substantial departure from international norms where follow-on biologics are considered to be different to the original biologic medicine.

One effect of this practice is that biosimilar manufacturers will be provided with beneficial market access and this may result in faster reductions in the cost of subsidised biologic medicines.

Naming and interchangeability have been generally considered to be matters of safety and efficacy and usually the remit of drug regulators like the FDA and the TGA. However, because of the potential impact on affordability that should come with biosimilar entry, in Australia at least, these issues are contested territory. The result is that the interplay between reimbursement approval and marketing authorisation assumes an important role.

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. Even when a follow-on product is biosimilar it may not be **interchangeable** for patients in day to day use.