GESA
Gastroenterological Society of Australia

POSITION STATEMENT

GESA-AIBDA Position on Biosimilars Substitution

The Gastroenterological Society of Australia (GESA) and Australian Inflammatory Bowel Disease Association (AIBDA) looks forward to the introduction of biosimilars to the Australian market and the price competition that will ensue, enabling more efficient use of the finite health budget. However, we are writing to raise concerns about the new interpretation regarding how biosimilar agents may be assessed and dispensed introduced in the recent Bill before parliament as the Proposed Amendments to the National Health Act 1952 on 27th May 2015.

More specifically the section on page 3 as follows:

3 At the end of section 85
Add:

Brand or pharmaceutical item that is biosimilar or bioequivalent to listed item is taken to have the same drug

(9) If:

(a) a listed brand of a pharmaceutical item (the listed brand) has a drug; and

(b) another brand of the pharmaceutical item, or a brand of another pharmaceutical item, is biosimilar or bioequivalent to the listed brand;

then, for the purposes of this Part, the other brand or pharmaceutical item is taken to have the same drug as the listed brand.

Biologic medicines are highly targeted and costly medications that have greatly improved the quality of life for millions of patients worldwide with a number of different clinical conditions. In Australia we have been fortunate to have had a number of these agents listed on the PBS. These are large, complex proteins, which unlike traditional pharmacological agents require complex biological processes to be synthesized. These drugs are prone to triggering a reaction from the patient's immune system against them, with potential for loss of response and severe reactions.

Biosimilars are biopharmaceutical drugs designed to have active properties similar to an originator biological medicine that has previously been licensed. Because they, like the originator drugs, are large, complex biologically produced molecules they are not the same as generic drugs which have exactly the same physiochemical properties as the originator molecule. As a result, biosimilars are required to undergo extensive testing to demonstrate *in vitro* similarity and in at least one clinical indication, equivalent clinical efficacy.

There are, however, no data to support the safety and long-term efficacy of switching between an originator molecule and its biosimilar. Despite the proven similarity it cannot be assumed that there might not be significant and clinically relevant differences between the originator and biosimilar drugs. Another important difference is that all biologic medicines tend to slightly evolve over time with a change in manufacturing processes such that today's originator biologics are different from the same drug produced a decade ago. Biosimilars are only required to demonstrate similarity at

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market entry and not be continually referenced to the originator product. This is likely to further amplify changes between the originator and biosimilar over time as each undergoes slight changes without comparison to each other. This variation also introduces further risks of substitution if another biosimilar enters the market since it will only be referenced against the originator molecule and not against any currently available biosimilar, which may be more different from the new biosimilar.

As there is no evidence available about the safety and ability to substitute between one biologic and another, the Therapeutics Goods Administration (TGA) has been unable to comment on whether biosimilar agents should be marked as substitutable. The proposed legislation will make this the responsibility of the Pharmaceutical Benefits Advisory Board (PBAC). In the absence of evidence of differences in safety, applying the new 'relevant considerations', the PBAC may apply the default position and advise the Minister that the biosimilar can be marked as substitutable.

We strongly oppose such recommendations of biosimilars as interchangeable on the grounds of patient safety. Our position is in line with that of the Council of Australian Therapeutic Advisory Groups, which has outlined guiding principles for the prescribing and dispensing of biosimilars. These include that biologics/biosimilars should only be prescribed by both the active ingredient name and the brand name and that a biologic is not interchangeable with its biosimilars at dispensing and should only ever be substituted with the prescriber's knowledge and consent. In addition, the switching between a biologic and its biosimilars should be in accordance with a Drug and Therapeutics Committee–approved treatment protocol that includes a monitoring plan and there should be a pharmacovigilance framework to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy. Should a biosimilar be able to be dispensed without the knowledge of the prescriber or the patient, then this not only subjects the patient to an unknown risk of an adverse reaction, but it also makes pharmaco-surveillance and pharmacovigilance of such adverse reactions almost impossible.

This position is also that of other international societies such as the European Crohn's and Colitis Organisation, the American College of Rheumatology and the American Academy of Dermatology.

The current fixed prescribing rules for dose intervals of biologics do not allow for the clinical reality that many patients require dose escalation to maintain clinical remission. This is not achievable under the current PBS schedule and the pharmaceutical companies that supply these originator biological medicines have been giving compassionate supply in order for clinicians to be able to provide increased doses and recapture clinical response and remission. With the introduction of biosimilars, and if they are considered substitutable, it is not known if the biosimilar pharmaceutical companies will offer a similar compassionate access program. Also, there are significant concerns that if substitution of the originator and biosimilar product occur without the prescriber's control, then the potential legal ramifications of providing compassionate access to additional biologic drug where the actual prior source of the biologic agent is not known, may prevent these companies from continuing to offer this compassionate program. This will result in a significant proportion of patients losing response to this therapeutic class with many facing surgery and impaired quality of life.

Since there have been no clinical trials to assess the efficacy and safety of biosimilars in Inflammatory Bowel Disease, we also believe that there should be centralised collection of data on the efficacy, rates of loss of response, and safety of biosimilar agents. Delegating such responsibility to local health providers will not generate data with sufficient power and data completeness to assess this adequately. The obvious repository of this data should be the PBS, since it already has data on all patients currently receiving therapy. If substitution at a pharmacy level was allowed, this would prevent accurate data being collected and potentially reduce any cost savings made by being unable to analyse cost efficacy.

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In conclusion, GESA and its specialist IBD association, the Australian Inflammatory Bowel Disease Association (AIBDA) does not support the substitution of biologic agents with biosimilars, or vice versa, at the pharmacy level. For scientific reasons this could significantly compromise patient safety. It remains imperative that both the prescribing physician and the patient are aware of which exact medication the patient is receiving.

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