



# Australian Rheumatology Association

## **ARA Position Statement** **on the Introduction of Biosimilars for the Treatment of Rheumatic Diseases**

- The Australian Rheumatology Association (ARA) welcomes the introduction of biosimilars to the Australian market. We recognise the potential for competition to reduce prices and provide savings to the health budget. The ARA would like to see these savings reinvested in health, including broadening access for patients who need these therapies and currently do not meet the stringent requirements for subsidised treatment.
- The ARA strongly recommends an enhanced program of surveillance and pharmacovigilance for these agents and urges the government to commit to this as soon as possible. This should include a process whereby electronic prescribing permits accurate collection of data, linked to the individual patient. Prescribers must also have information on what is actually dispensed to the patient in real time.
- Biosimilars are not generic forms of the originator and should not be considered as such. Biologics (including biosimilars) are large complex heterogeneous molecules. Both can provoke an immune response (immunogenicity) in a patient, which may have implications for safety and efficacy.
- Biosimilars are manufactured in different systems and may undergo post-translational changes that can differ from the innovator product eg glycosylation.
- The introduction of biosimilars to Australian market has relied on the same approach used in small molecule generic drugs. Application of an 'a' flag to an originator and its biosimilar by the Pharmaceutical Benefits Advisory Committee (PBAC) results in an automatic price reduction at listing, but also means that the drugs are deemed to be interchangeable at the pharmacy counter and can be swapped without reference to the prescriber. It is possible to override unauthorised substitution by 'ticking the box' on prescriptions to prevent substitution.
- The decision to prescribe any medication should rest with the prescriber, in consultation with an informed patient. Substitution should not occur without the knowledge and consent of the patient.
- Consumer medicine information (CMI) leaflets should clearly state the indications for which a biosimilar is approved and specify for which indications there are specific data on the performance of the biosimilar and which information is derived from studies on the originator.
- Determination of interchangeability should be within the role of the regulator, the Therapeutic Goods Administration (TGA).
- Decisions regarding interchangeability and extrapolation of indications should be based on evidence, and where evidence is not available, this should be made clear in all communications relating to these products.
- There is a growing body of evidence that transition from the originator drug to a biosimilar is safe and efficacious. The duration of these clinical trials is relatively short (around 1 year), and typically involves a single indication for which the originator drug is approved. There are no data around repeated switches, and until further evidence is available, this practice should be avoided.
- The ARA believes the adoption of a naming convention is essential to facilitate tracking. Until a decision is made, we recommend prescribing by brand name and ticking the 'brand substitution not permitted' box to provide certainty about what has actually been dispensed to the patient.

## **The ARA has provided advice for prescribing biologics/biosimilars as below:**

When prescribing, ***please consider the points below to safeguard your patients and avoid confusion:***

- Biosimilar bDMARDs are available in Australia now. In the case of infliximab and etanercept the biosimilars have been deemed interchangeable with the originator, and approved across all adult indications for the originator. Biosimilars of other bDMARDs are likely to follow in the near future and it is likely that more than one biosimilar of any given reference drug is likely to be approved.
- The PBAC has deemed that the biosimilar can be ***can be substituted for the originator at the pharmacy without reference to the prescriber.***
- This means that every time the patient presents to a pharmacy to have a script filled, they may receive either the originator or the biosimilar ***and*** you do not have to be told.  
This will also apply to ***repeats of prescriptions that you are writing now.***
- Please consider this when prescribing- you can choose to tick the '***Brand Substitution not permitted***' box at the top of the prescription. The pharmacist must then dispense the drug you have written- your choice of either the originator or the biosimilar- otherwise legally they MUST contact you.
- Australia has not yet adopted a naming convention for these drugs, so ***we advise prescribing by brand name.*** This will help in tracking if an adverse event occurs.
- If you prescribe a biologic agent such as 'infliximab' or 'etanercept' or you prescribe by brand name and do not 'tick the box', the patient may be dispensed EITHER the originator or the biosimilar ***each and every time*** they present to the pharmacy.
- Encourage your patients to ***keep packaging***, or photograph the actual medicine dispensed and its barcode and bring this to every consultation.
- Enrol your patients on bDMARDs into the Australian Rheumatology Association Database (ARAD) to allow pharmacovigilance of both innovator and biosimilar agent. Permission to Contact Forms available at <https://rheumatology.org.au/members/documents/ARADPTC.pdf>

### **Definitions.**

Biologic- a medicine made by or extracted from living organisms. Examples include hormones, cytokines, enzymes and antibodies.

Biosimilar- (SMBP, similar biological medicinal product/follow-on biologic)- a biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product (WHO). A copy of an existing biologic medicine. It usually requires full clinical development-preclinical and clinical data- with bioequivalence sufficient to get regulatory approval via a defined pathway.

Interchangeability-designation that allows a biosimilar to be substituted for its reference product without prescriber input i.e. at the pharmacy counter.

Switching- a single transition from the biologic to a biosimilar or vice versa.

Extrapolation- occurs when a biosimilar is permitted to be used across all indications for the originator, even when clinical trial data is not available for all of those indication

Substitution- situation in which a biologic drug may be replaced by a biosimilar or vice versa if the drugs have been deemed as interchangeable by the regulator, without input from the prescriber.

## References.

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Biosimilars Working Group  
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