

Position Statement

Biosimilar Medicines

Background

A biosimilar medicine is a version of an already registered biological medicine that has a demonstrable similarity in physiochemical, biological and immunological characteristics, efficacy and safety based on comprehensive comparability studies. Biosimilars are evaluated by the Therapeutic Goods Administration using specific guidelines to establish that similarity, efficacy and safety as with other prescription medicines.

Access to biosimilars, as with most prescription medicines, is dependent on being listed on the Pharmaceutical Benefits Scheme (PBS) with the Pharmaceutical Benefits Advisory Committee (PBAC) making recommendations to the Government on such listings. PBAC recommendations include the indications for which a medicine can be listed and subsidised and when it can be substituted for a biologic.

Biologics are going to play an increasing role in the management of diseases into the future but they are expensive and restricted in use. We already see biosimilars being used in the hospital setting and specialist clinics. It is predicted that they will be increasingly dispensed in the community as patients learn to self-administer or have advanced home care support for conditions treated with these medications.

The wider introduction of biosimilars should bring down costs and increase their use.

The PBS Sustainability and Access Package announced as part of the 2015 Budget included provision for biosimilars to be substituted for biologics at the pharmacy level – known as ‘a’ flagging. The ‘a’ annotation against the PBS brand names indicates whether a pharmacist can substitute biosimilar medicines for reference biologics at the point of dispensing, without reference to the prescriber.

PBAC has confirmed that it does not have a policy of automatic ‘a’ flagging and that any such recommendations would be made on a case-by-case basis.

CHF's position

1. In line with the National Medicines Policy safe and effective medicines should be available to consumers at the lowest possible cost. Patients should not have to pay more for a biosimilar than a reference brand.

2. CHF supports the effective, safe and successful entry of biosimilars into the Australian market. This is in the interest of consumers as they will have access to a wider group of therapeutic options.
3. CHF recognises that price competition is an important strategy for achieving a sustainable PBS. The lower prices which should eventuate from the increased availability of PBS subsidised biosimilars will slow the growth in expenditure on the PBS and allow new innovative medicines to be funded and allow more consumers access to these life enhancing medications.
4. Decisions regarding approval of biosimilars must be driven by sound science and within a robust regulatory framework. CHF expects robust policy and regulation will govern 'a' flagging of biosimilar medicines and their reference biologics. This is essential to build public confidence.
5. CHF supports PBAC's decision to make case-by-case recommendations with regard to 'a' flagging and expects that PBAC will take into account appropriate information and additional expert opinion.
6. CHF supports a comprehensive education programme with reliable information for consumers, clinicians and pharmacists. This is an important component of ensuring confidence and greater uptake of biosimilars. Education should be developed and implemented with involvement from all three groups.
7. Consumers should always be engaged at all stages of the prescribing process, need to be fully aware of the implications of any substitution and have the right to refuse it. Consumer consent and consultation when substituting is critical.
8. Given the nature of biologics and biosimilars clinicians also need to be part of the process of deciding which medicine is given to a consumer and continue to have the right to indicate that no substitution should occur. Ideally, the decision to substitute a biosimilar product should be made by the prescribing provider.
9. Prescribers can indicate they do not wish to pharmacy level brand substitution to occur and it is an offence under the PBS legislation for a pharmacist to dispense a brand other than that specified on the prescription by the prescribing doctor. CHF expects this legislation and these practices will be upheld, enforced and reinforced in clinician education.
10. Biosimilars must have distinct names allowing them to be distinguished from each other and their reference products. This is essential for ongoing pharmacovigilance.
11. One of the issues that needs addressing is the quality of evidence around switching between biosimilars which is a critical part of the process if pharmacy level substitution is ever to be allowed. It is clear that the lack of evidence of any harm from switching does not necessarily mean that there is no harm. More work needs to be done on collecting such data and including it in future submissions for approval and post market monitoring.

CHF

CHF is the national peak body representing the interests of healthcare consumers with a network reaching millions of Australian consumers. Our members are diverse: they cover organisations and individuals with key conditions and issues across the health system and also include professionals and research bodies with an interest in healthcare consumer affairs.