



Pharmaceutical Benefits Advisory Committee

STATEMENT BY THE PBAC

18 June 2015

Safety of biosimilar medicines

The independent Pharmaceutical Benefits Advisory Committee (PBAC), which makes recommendations to the Australian Government on what medicines should be subsidised for consumers, is keen to reassure the public about the safety of biosimilar copies of biologic drugs.

The PBAC recently made a recommendation to allow biologics to be substituted with biosimilar drugs by clinicians and pharmacists if the biosimilar is found to be a safe and effective equivalent treatment.

The difference between biosimilar drugs and generic drugs is that generic drugs are usually exactly the same as the original patented medicine. Because of both the complex nature of biologics and the way they are made, even though biosimilar drugs act in the same way as the original patented biologic, they may not be exactly the same. However we would not recommend them as substitutable with each other unless the PBAC is sure of their equal safety and effectiveness.

It is important that pharmaceutical companies earn a fair return on their investment in new drugs, which is what the patent period ensures. However, as with the introduction of generic drugs in the past, many expensive, high-use biologic drugs are coming off patent in the next five to 10 years in Australia and this presents an opportunity for other companies to produce these biologics which may make the drugs more affordable.

The Australian Government and the PBAC are concerned that the introduction of biosimilars may lead to the spread of misinformation, as has happened in other countries, which will slow the progress of the development of these medicines.

As a result the PBAC is keen to put patients' minds at ease and has placed on its website this advice to try to put this issue into perspective backed by scientific evidence: <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-04/2015-04-biosimilars.pdf>

According to PBAC guidelines, if the biosimilar is approved by the Therapeutic Goods Administration as a safe and equally effective treatment compared to another drug, the PBAC will then consider listing the biosimilar drug on the PBS.

During this assessment process, the PBAC will also consider whether the biosimilar drug should be listed to allow substitution by a doctor or pharmacist. This will be done on a case by case basis.

If the PBAC recommends the biosimilar should be substitutable this provides the option for clinicians and pharmacists to offer patients the choice of taking the original biologic drug or the substitute biosimilar drug, just as they currently do with generic versions of synthetic molecule drugs.

The PBAC's recommendation would, as always, give patients the ultimate choice as to which version of the drug they receive, again, just as they currently do with generic versions of synthetic molecule drugs.

Also, clinicians would still have the ability to indicate a biologic drug is not to be substituted for a biosimilar for their patient if they do not consider it appropriate in that particular case (i.e. this just requires them to tick brand substitution not permitted on the prescription). This process is already familiar to clinicians as it is the current process for generic versions of synthetic molecule drugs.

PBAC will be meeting with stakeholders to consult on the application of this recommendation to provide feedback to the committee on how this initiative can successfully apply in practice.