Biosimilar Awareness Implementation Framework

Joint submission from Cancer Council Australia & Clinical Oncology Society of Australia (COSA).

Cancer Council is Australia's peak national non-government cancer control organisation. Its members are the eight state and territory Cancer Councils.

The Clinical Oncology Society of Australia (COSA) is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

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Cancer Council Australia and COSA welcome the opportunity to provide input to the Biosimilar Awareness Implementation Framework and to be recognised as key stakeholder organisations for future consultation on the availability of biosimilar medicines in Australia.

We emphasise that evidence must exist to show the biosimilar is comparable to (and as clinically effective as) the biological reference product. Given the potentially high biosimilar load, oncology and haematology specialities must be included in biosimilar discussions. The option to prescribe a biosimilar medicine must not compromise efficacy or confer an increase in toxicity. Reduced product price or potential cost savings cannot be a primary driver for approving and subsidising the use of this class of medicine. Patients must have access to and understand the information provided regarding biosimilar medication or the substitution of biosimilar medication to make an informed choice.

Cancer Council Australia and COSA jointly submit the following responses to the consultation questions and provide comment or clarification where relevant.

Consultation questions

1. **What are the main benefits of biosimilar medicines for Australia?** *Please select any two of the following options.*

☐ Biosimilars provide a greater range of treatment options

☐ The lower cost of biosimilars will make them more affordable for the PBS (and therefore to taxpayers)

☐ Other countries are already using them and Australian should have them too

☐ The lower cost of biosimilars will make them more affordable for patients

☐ Biosimilars represent progress

☐ Biosimilars will provide another option for pharmaceutical companies to do business in Australia

☒ Other, please add the details here:

Comments:

The use of biosimilar medicines cannot compromise on patient safety or effectiveness and their availability must be supported by evidence equivalent to the biological reference medication. The regulators and assessors (Therapeutic Goods Administration, Pharmaceutical Benefits Advisory Committee) must review and conclude that a biologic medicine is as safe (or safer), effective and/or has the same or higher level of quality as the reference medicine. Criteria used for substitutability must be clear, objective and based on evidence of safety and efficacy.

The use of biosimilar medicines can contribute to the sustainability of the Pharmaceutical Benefits Scheme and increased market competition in some circumstances. Savings could be used for a wider range of medicines and support the availability of higher value medicines. However, best evidence must show that a biosimilar medicine is comparable with the reference medicine, is safer (or safer), equally effective and confers no increase in adverse effects (e.g. toxicity).

2. **Consider the statement: Biosimilars are equally safe and effective as their reference (original) biologic. To what extent do you agree?**

☐ Strongly agree

☐ Agree

☒ Not sure

☐ Disagree

☐ Strongly disagree

Comments:

According to the framework, biosimilar medications should be highly similar to the reference product they are compared with, but have allowable differences because they are made from living organisms. However, when a proposed biosimilar medicine is evaluated by the TGA according to guidelines (these are currently under review) as sufficiently comparable to the reference product they demonstrate no clinically meaningful differences in terms of safety, purity, and potency from the reference product. The health outcomes which the biosimilar medicine provides is comparable to the reference medication. This evidence must be presented through comprehensive comparability studies. Further application to the PBAC for reimbursement consideration is required.

On this basis, we cannot answer the statement above without reviewing data on the medicine being considered for substitution. Applying the framework to oncology medicines is extraordinarily complex, as antineoplastic drugs are developed to treat (and cure) otherwise terminal conditions, to extend life and to treat a number of other complex cancer-related conditions. It is therefore necessary to consider each medicine on a case-by-case basis.

3. **To what extent do you agree with the following statement? The 10 discussion topics (listed below) identified in the Implementation Framework will support clinicians and patients to make informed decisions about biosimilar medicines available through the PBS.**

   Please state your reasons (Required)

☐ Strongly agree

☐ Agree

☒ Not sure

☐ Disagree

☐ Strongly disagree

Discussion Topics identified in the Implementation Framework

1. A biosimilar medicine is a similar version of an original biological medicine (called the reference medicine), marketed with a different brand name

Comments:

In this statement emphasis should be placed on the word 'similar', and therefore must have a high level of evidence of equivalence for each individual biosimilar. Unlike generic medicines, this cannot be a general statement.

The Implementation Framework must be clear about what this sentence means in its entirety and ensure clarity that a biosimilar medicine *is not* the same as a generic version of a drug. A biological medicine is a medicine that contains one or more active substances made by or derived from a biological source. It is not a generic brand medicine because generic medicines are copies of brand-name drugs, have the same active ingredient, and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. That means the brand-name and the generic are bioequivalent.

2. Biosimilar medicines are rigorously tested and evaluated prior to approval, just as biological medicines are.

Comments:

If the biosimilar medicine passes the Therapeutic Goods Administration (TGA) evidence review of safety, quality and efficacy to be available on the market, it can then (like all pharmaceutical products) be considered for PBS listing by the Pharmaceutical Benefits Advisory Council. Evidence for each item must be presented and considered separately. Assessment cannot rely on combined data.

The TGA review process provides confidence that the biosimilar medicine has been tested and shown to have the same safety profile and health outcomes, which includes the same level of side-effects as the reference product. The PBAC provides an assessment of the clinical effectiveness and cost effectiveness of the medicine to determine whether a biosimilar medication can be substitution for the biological reference medicine and receive reimbursement.

3. Biosimilar medicines have been proven to be equally safe and effective as their biological reference medicine

Comments:

The use of the word 'have' is incorrect in this statement and our advice is to change that to 'may' for the reasons stated in response to question two.

4. How the PBAC and the TGA work in conjunction to assess and recommend, regulation and reimbursement of biosimilar medicines.

Comments:

See above notes in question two.

If the biosimilar medicine is approved by the TGA as a safe and equally effective treatment compared to the biological reference, the PBAC will then consider listing the biosimilar medicine on the PBS. In addition, the PBAC will also consider whether the biosimilar medicine should be listed to allow substitution by a doctor and/or pharmacist. This will be done on a case by case basis.

5. The best advances in medicines are ineffective if no one can afford them. The introduction of biosimilars will help ease cost pressure on the PBS

Comments:

This statement is correct however, should be read with the caveat that the evidence must exist to prove that the biosimilar medicine is comparable with the reference medicine, in this case they do support a sustainable PBS, but this must not be at the expense of efficacy or an increase in toxicity.

Medicines that are expensive and/or not listed on the PBAC can restrict access for patients who could benefit from them. This can impact on treatment choice. However, medicines must firstly be safe and effective for use by a patient in the treatment of a particular illness. Biosimilar medication has the potential to offer a more affordable treatment option where appropriate on a case by case basis.

6. The government is committed to consultation and engagement with stakeholder to ensure appropriate information and education materials are made available publicly to consumers, prescribers and pharmacists

Comments:

Oncology and haematology are areas which have a potentially high biosimilar load so these specialities must be included in biosimilar medicine discussions.

The Clinical Oncology Society of Australia (COSA) is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients, and Cancer Council is Australia's peak national non-government cancer control organisation. Its members are the eight state and territory Cancer Councils, therefore we believe it is important that these two organisations are recognised as stakeholders in this process.

The Australian Government has demonstrated a commitment to consultation and engagement by providing the opportunity for input into the implementation framework and ongoing communication and education of biosimilar medication. We hope the opportunity to be a part of developing and disseminating information will continue and that there will be stronger consultation with stakeholders and the public on all regulation relating to access to biosimilar medicines.

7. A more sustainable PBS means the government can continue to list medicines – meaning more patients will benefit from improved access to affordable medicines

Comments:

The current regulation of medicines and medical devices, and reimbursement of products and services has served the Australia population well. However, as the delivery of cancer care

continues to shift to more targeted therapies to treat smaller subsets of cancer, and the increased number of people requiring medicines to treat chronic diseases, there is pressure for these systems to support the sustainable delivery of affordable therapeutic products into the future. This will ensure everyone has access to the treatment they need in a timely manner. Current national reviews into the regulation of medicines and medical devices, Medicare Benefits Scheme and individual item numbers, and the Pharmaceutical Benefits Scheme guidelines all support the direction to ensure systems are sustainable to service patient needs.

8. Biosimilars will become increasingly available over the coming years and provide prescribers and patients more treatment options

Comments:

Trends suggest this is the case. It has been reported that 5 of the top 10 medicines subsidised by PBS are biologics. Biologics has grown from 4% of PBS budget 10 years ago to 25% today. Three biosimilar medicines are listed on the PBS for the indication of cancer.

9. When a biosimilar has been 'a' flagged for substitution at the pharmacy level the prescriber can indicate a prescription should not be substituted if they feel it is not suitable, as is the usual practice.

Comments:

There must be strong guidance for substitution at the pharmacy level, as by the nature of biosimilar medicine is more complex than simple generic substitution.

The authority of a prescriber to indicate a medicine is not to be substituted at a pharmacy level has been noted as a condition of introducing the potential for PBAC to assign 'a' flagging to biosimilar medicines. Pharmacy level substitution categorisation 'a' flagging must be supported by data. This requires additional explanation to ensure patient comprehension of the message, and the ability to substitute at a pharmacy level is approached with caution.

10. The Australian Government supports the increased use of biosimilar medicines to increase access to, and cost effectiveness of, these valuable medicines.

Comments:

It seems to be the case as the Australian Government intends to deliver the implementation framework and is currently updating the Guidelines to review biosimilar medicines. PBAC has recently recommended its first biosimilar medicine for 'a' flagging.

4. Are there any additional areas that need to be communicated to consumers and/or patients? How would you communicate this?

- Create a glossary of terms and provide definitions including (but not limited to):
    - 'What is biosimilar medicine?'
    - 'What is a biological reference medicine?'
    - Generic medicine (and the difference between biosimilar and generic medicines)
    - Pharmacy level substitution ('a' flagging)

- Explain potential patient and prescriber conversations/scenarios relating to the option to choose a biosimilar medication:
    - Clear explanation of what a biosimilar medicine is and what the impact is of choosing to use this over the biological reference drug
    - How a likely discussion with the prescriber/doctor about biosimilar medicines will play out? Discuss option on a case by case basis, doctor can indicate whether the medicine can or cannot be substituted for a biosimilar version by the pharmacist.
    - What will happen at the pharmacist level when a patient presents a prescription? Pharmacy level substitution (dispensing one brand of medicine instead of another equivalent and interchangeable brand of the same medicine at the pharmacy level without needing to go back to the prescriber.)

- Clearly explain the following topics using patient information and education tools such as fact sheets; booklets; patient information from the pharmaceutical manufacturer, answers to frequently asked questions:
    - Biosimilar medicine safety, including related side effects and intended health outcomes
    - The regulatory process of safety and efficacy review that biosimilar medicines must pass
    - Why they are cheaper than the biological reference medicine and does this impact on outcomes?
    - What does it means to switch from a biological reference medicine to a biosimilar medicine?

- Ultimately, ensure users of the health care system are provided a consistent message, and that patients are provided with all the information they require, in a format they understand, to be actively involved in making a treatment decision with their health care practitioner or pharmacist (where appropriate) to consider the biosimilar medicine option. Prescribers must be confident and accurate in the delivery of information to individual patients during a consultation and must be prepared to answer possible questions to support the principle of a patient's right to choose.

- Materials provided to patients and those provided to prescribers, including communication delivery skills, must be varied to suit the patient or health professional audience. These reference documents must be tailored to the intended user.

5. Are there any additional areas that need to be communicated to clinicians - especially doctors (as prescribers), nurses and pharmacists? How would you communicate this?

Ensure that patients understand the alternative treatment options available for their case including biosimilar medicines, and understand the related intended health outcomes, effects and cost.

6. Please describe any existing biosimilar communication programmes or activities you are aware of, that you think are working well and why? *Please provide detail*