

Overseeing biosimilar use

Guiding principles for the governance
of biological and biosimilar medicines
in Australian hospitals

May 2015

Council of Australian Therapeutic Advisory Groups

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Recommended citation: Council of Australian Therapeutic Advisory Groups. Overseeing biosimilar use. Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals. CATAG, 2015.

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Design by O'Kelly Branding and Design.

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Contents

Contents	3
Executive summary	4
Overview	5
Purpose.....	5
Definitions.....	5
Biological medicine.....	5
Innovator biologic.....	5
Biosimilar.....	5
Background.....	6
Introduction.....	6
Biosimilars.....	6
Therapeutic Goods Administration evaluation of biosimilars.....	6
GUIDING PRINCIPLES	7
Guiding principle 1: The governance of biologics/biosimilars within the hospital system should be no different to that of any other medicine.....	7
Guiding principle 2: The selection of a biologic/biosimilar as first-line therapy in treatment-naïve patients should be subject to evidence of safety, efficacy and cost-effectiveness.....	7
Guiding principle 3: Biologics/biosimilars should be prescribed by both the active ingredient name and the brand name.....	8
Guiding principle 4: A biologic is not interchangeable with its biosimilars at dispensing and should only be substituted with the prescriber’s knowledge and consent.....	8
Guiding principle 5: Patients should be fully informed when receiving treatment with a biologic/biosimilar.....	8
Guiding principle 6: 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.....	8
Guiding principle 7: The selection of a biologic/biosimilar as second-line therapy should be in accordance with a treatment pathway approved by the drug and therapeutics committee.....	9
Guiding principle 8: There should be a patient-centred pharmacovigilance framework within each hospital or health service to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy.....	9
References	10
APPENDICES	11
Appendix 1: Glossary.....	11
References for Glossary.....	11
Appendix 2: How these guiding principles were developed.....	12
Disclosure.....	12

Judicious, appropriate, safe, effective and cost-effective use of medicines in a health service organisation requires a commitment to the overall governance of the medicines management system within the organisation.

For Australian hospitals the Council of Australian Therapeutic Advisory Groups (CATAG) recommends that governance of medicines be achieved via a drug and therapeutics committee (DTC) and has described the roles and responsibilities of such committees in the 2013 publication [Achieving effective medicines governance. Guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals.](#)

An increasingly important area of relevance to DTCs and medicines governance is the use of biologic therapies, including biosimilars.

Biologic therapies encompass both innovator biological therapies and biosimilar therapies. A biosimilar is a subsequently developed ('follow-on') variant of the innovator biologic. However, each biologic/biosimilar is unique and cannot be considered as bioequivalent. A biosimilar is not a generic version of the innovator biological therapy.

For these reasons, and in accordance with current international opinion CATAG has prepared these guiding principles to assist Australian hospitals provide good governance and decision-making in relation to their use of biologic therapies.

The guiding principles for biologics/biosimilars are:

Guiding principle 1. The governance of biologics/biosimilars within the hospital system should be no different to that of any other medicine.

Guiding principle 2. The selection of a biologic/biosimilar as first-line therapy in treatment-naïve patients should be subject to evidence of safety, efficacy and cost-effectiveness.

Guiding principle 3. Biologics/biosimilars should be prescribed by both the active ingredient name and the brand name.

Guiding principle 4. A biologic and its biosimilars are not interchangeable at dispensing and should only be substituted with the prescriber's knowledge and consent.

Guiding principle 5. Patients should be fully informed when receiving treatment with a biologic/biosimilar.

Guiding principle 6. 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.

Guiding principle 7. The selection of a biologic/biosimilar as second-line therapy should be in accordance with a treatment pathway approved by the drug and therapeutics committee.

Guiding principle 8. There should be a patient-centred pharmacovigilance framework within each hospital or health service to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy.

These guiding principles should be considered in conjunction with other resources for DTC and prescriber decision-making, such as CATAG's [Rethinking medicines decision-making in Australian hospitals. Guiding principles for the quality use of off-label medicines.](#)

Overview

Purpose

These guiding principles are produced by the CATAG to provide guidance for good governance and decision-making in relation to use of biologic therapies in Australian hospitals.

Definitions

Biological medicine

(Also known as biologic)

A medicine whose active substance has a large, complex, inherently heterogeneous molecular structure, which can only be made by or derived from a living organism (eg, bacterium, yeast, human/animal cell line).⁽¹⁾ Biologics vary in complexity from cellular therapies to small, highly purified proteins.

Biologics include:^(2, 3)

- biotechnology-derived proteins (eg, biologic enzyme replacement therapies)
- immunological medicines (eg, monoclonal antibodies and vaccines)
- other biological products, including polysaccharides (eg, low molecular weight heparins) and synthetic hormones.

Biologics encompass innovator biologics and biosimilars.

Innovator biologic

(Also known as an originator or reference product)
A novel biologic that is not considered 'similar' to any other registered biologic.

Biosimilar

(Also known as similar biological medicinal product [SBMP]; similar biotherapeutic product; or 'follow on' variant of a biologic)

A biosimilar is a subsequent molecular ('follow on') variant of an already registered off-patent biological medicine (the innovator biologic) that:

- has a demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies, and
- has been evaluated by the Therapeutic Goods Administration (TGA) according to its guidelines and other relevant European Union (EU) guidelines adopted by the TGA.⁽³⁾

Importantly, a biosimilar is not a generic* version of the innovator biologic and is not considered to be bioequivalent.⁽³⁻⁵⁾

Note: In this document, 'biologic/biosimilar' is used to indicate both the innovator and/or biosimilar products (as the current definition of 'biosimilar' only refers to the follow-on product).

* Medicines are considered generic equivalents if they have the same quantitative composition of therapeutically active substances, same pharmaceutical form, produce the same therapeutic response and have the same safety and efficacy properties (bioequivalence). (Office of Parliamentary Counsel. Therapeutic Goods Regulations 1990 as amended.)

Background

Introduction

The patent protection of several important, top-selling innovator biologics has expired, or will be expiring over the next few years, and it is likely that a number of biosimilars will enter the Australian market.

Biosimilars will introduce the potential for improved cost-effectiveness of biologics, which may result in:

- economic efficiencies
- expanded access via broader patient eligibility or broadening of approved indications
- potential for improved clinical outcomes.

Hospital drug and therapeutics committees and prescribers will need to carefully consider the clinical evidence, opportunities and risk of harm associated with the introduction of biosimilars into clinical practice.

Biosimilars

Biosimilars are considered similar but not necessarily identical versions of off-patent innovator biologics, as they are produced using different manufacturing processes, usually by different sponsors (pharmaceutical companies).^(2, 6)

Biologics are considerably more complex than chemically synthesised medicines. Even the simplest biologics are highly purified protein products consisting of more than one molecular entity, and are usually mixtures of many closely related molecular species.^(2,7) This within-product micro-heterogeneity can be substantial and may be associated with additional risk of adverse effects due to the potential to stimulate antibody formation.^(2,7)

All biologics are sensitive to slight changes in manufacturing processes, which cannot be replicated exactly by a follow-on manufacturer, as they do not have access to the exact innovator manufacturing processes, the innovator's molecular clone and original cell bank, or the active drug substance.⁽²⁾

A biosimilar will have the same encoding DNA sequence as the innovator, and analytical tests can characterise the molecular mass, protein content, glycosylation pattern, in-vitro activity, physicochemical integrity, stability, impurities and additives of a biosimilar; however, the two products may differ in other key attributes, and modern

equipment cannot confirm that they are exact copies of another biologic due to their large size and complex tertiary structure.^(4,6,8)

The registration process for biosimilars considers the comparative safety and efficacy demonstrated in a robust series of analytical and clinical studies.⁽³⁾ However, subtle differences between biologics may not be fully apparent until greater experience in their use has been established.⁽⁵⁾ For example, rare adverse drug reactions, particularly events that are immune mediated, may not be detected in conventional clinical studies.

Therapeutic Goods Administration evaluation of biosimilars

Due to the complexity of biologics/biosimilars, the standard approach for demonstrating bioequivalence for most chemically derived medicinal products is not appropriate.⁽⁹⁾ More rigorous testing is required by the TGA for biosimilars than for generic chemical products.^(3,4,9)

To meet TGA approval for registration in Australia, each biosimilar must be evaluated individually, using both clinical and laboratory-based comparability studies to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy of each new biosimilar.⁽⁵⁾

The TGA process for evaluating biosimilars is described in the July 2013 document, '*Evaluation of Biosimilars*'.⁽³⁾

The TGA approach to extrapolation of indications has been adopted from the European Medicines Agency (EMA) guideline on *Similar biological medicinal products containing biotechnology-derived proteins as active substances: non-clinical and clinical issues*, which states:

In case the originally authorised medicinal product has more than one indication, the efficacy and safety of the medicinal product claimed to be similar has to be justified or, if necessary, demonstrated separately for each of the claimed indications. In certain cases, it may be possible to extrapolate therapeutic similarity shown in one indication to other indications of the reference medicinal product. Justification will depend on, eg, clinical experience, available literature data, whether or not the same mechanisms of action or the same receptor(s) are involved in all indications. Possible safety issues in different subpopulations should also be addressed.^(3,10)

GUIDING PRINCIPLES

These guiding principles assist Australian hospitals to provide good governance and decision-making in relation to their use of biologic therapies.

GUIDING PRINCIPLE 1

The governance of biologics/biosimilars within the hospital system should be no different to that of any other medicine.

Decision-making and medicines management processes should be transparent and accountable, and based on evidence of safety, efficacy and cost-effectiveness according to local policies and circumstances.

For general guidance on these matters, refer to

- *Achieving effective medicines governance. Guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals*⁽¹¹⁾
- *Rethinking medicines decision-making in Australian hospitals. Guiding principles for the quality use of off-label medicines*⁽¹²⁾
- *Managing medicines access programs in Australian hospitals. Guiding principles for governance in Australian hospitals*⁽¹³⁾

on the [CATAG web site](#), as well as relevant local policies.

GUIDING PRINCIPLE 2

The selection of a biologic/biosimilar as first-line therapy in treatment-naïve patients should be subject to evidence of safety, efficacy and cost-effectiveness.

Consideration of which innovator biologic/biosimilar is to be used as first-line therapy for treatment-naïve patients should involve clinical review of the safety, efficacy and cost-effectiveness for each biologic, as demonstrated in published clinical trials.

It is important to understand that both the innovator biologic and any biosimilar can be considered appropriate as first-line therapy when supported by evidence.

If a biosimilar has been approved by the TGA as an alternative option to the innovator biologic for a particular indication, both medicines will be registered in Australia and are considered by the TGA to have comparable safety and efficacy for that indication.

If a biologic/biosimilar has not yet been evaluated by the TGA, or has not been approved for a specific indication or sub-population, local assessment will be required to fully consider the product in terms of safety, efficacy and cost-effectiveness before approval can be given for clinical use in hospitals.

To maximise efficient resource utilisation and equity of access, biologics/biosimilars should be evaluated and purchased strategically within the local health system.

Ideally, decisions about the products, indication and order of use (treatment protocols) should be determined by a high-level clinical formulary committee in consultation with relevant medical specialists.

When comparable safety and efficacy can be demonstrated, the purchasing strategy should consider the most cost-effective biologic/biosimilar as the first-line treatment option, subject also to formulary management and local safety considerations such as storage, and educational requirements.

When a biologic/biosimilar therapy is clinically appropriate in an approved indication, all treatment-naïve patients should be started on the biologic/biosimilar approved for first-line use.

As the stimulation of antibody production in patients by biologics/biosimilars is highly unpredictable with current technologies,⁽⁴⁾ it is not possible to determine to which biologic/biosimilar a patient will have the optimal response.

Thus all treatment-naïve patients should be started and evaluated on the biologic/biosimilar recommended as first-line therapy for the patient's indication or circumstances (in accordance with local policy) before a subsequent clinical assessment and decision is made to trial the patient on an alternative biologic/biosimilar.

GUIDING PRINCIPLE 3

Biologics/biosimilars should be prescribed by both the active ingredient name and the trade name.

Biologics/biosimilars are unique and should be prescribed using the full names of both the active ingredient and the tradename of the product to be given.

This exception to the usual hospital-prescribing best practice requirement to name only the active ingredient(s) (or non-proprietary drug names) in hospital prescriptions is to ensure that the specific biologic/biosimilar medicine prescribed for a patient is used.⁽¹⁵⁾

GUIDING PRINCIPLE 4

A biologic is not interchangeable with its biosimilars at dispensing and should only be substituted with the prescriber's knowledge and consent.

In accordance with TGA requirements for the Product Information of a biosimilar, replacement of an innovator biologic with a biosimilar, or vice versa, should only take place with the approval and consent of the prescriber.⁽³⁾

Substitution should generally not occur; however, in certain circumstances substitution may occur in accordance with a DTC-approved treatment protocol that allows substitution.

Substitution under a DTC-approved protocol should be communicated to the prescriber.

GUIDING PRINCIPLE 5

Patients should be fully informed when receiving treatment with a biologic/biosimilar.

As for any medicine, it is important for patients to be fully informed about decisions and choices when receiving treatment with a biologic/biosimilar.

Patients should be advised about the therapeutic options and the safety, benefits and potential harms of the various therapies, including any differences between therapies.⁽¹⁶⁾

Patients should also be advised if any changes (including substitutions) are made to their treatment.

Information provided to the patient about potential adverse reactions associated with treatment will facilitate partnerships between patients and clinicians in monitoring for adverse reactions and implementing adverse-risk-mitigation strategies.

Information should also be available in writing to promote patient understanding, for example, the Consumer's Medicine Information (CMI) leaflet.

GUIDING PRINCIPLE 6

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.

When to switch between a biologic and its biosimilars should be a clinical decision based on appropriate monitoring and patient response.⁽³⁻⁵⁾

Switching should be in accordance with the biologic/biosimilar treatment protocol approved by the DTC. This protocol should outline a clear well-justified plan for monitoring beneficial and potentially harmful effects.

Due to the potentially different immunological profiles of biologics/biosimilars, the decision to switch a patient who has already received therapy with a specific biologic/

biosimilar to another requires appropriate clinical input and monitoring, and for the patient to be informed.

It is likely that treatment response and adverse effects will be similar between a biologic and its biosimilars, as comparative testing is undertaken as part of the TGA approval processes.^(7,14)

However, it is possible that a patient who experiences adverse effects from one biologic/biosimilar may exhibit a different immunological response to an alternative biologic/biosimilar.⁽⁷⁾

Similarly, it is possible that a patient who experiences a measured clinical response to one biologic/biosimilar may show a different clinical response with an alternative biologic/biosimilar.

As with all therapeutic agents, it is recommended to avoid repeated switching (e.g. re-switching on discharge if switching has occurred on admission) between agents. If switching does occur both the patient and all their healthcare providers need to be aware.

GUIDING PRINCIPLE 7

The selection of a biologic/biosimilar as second-line therapy should be in accordance with a treatment pathway approved by the drug and therapeutics committee.

As immunogenicity profiles can differ between a biologic and its biosimilars and between patients, an individual patient may not benefit from the biologic/biosimilar recommended as first-line therapy, but may experience benefit from an alternative biologic/biosimilar.

Therefore, when alternative products are available, second-line treatment options should be specified in the associated treatment pathway.

Hospitals and health service organisations should use evidence for safety, efficacy and cost-effectiveness to inform choices for second-line therapy, in a similar way to determining first-line therapy.

When comparable safety and efficacy can be demonstrated, second-line therapy will be the second most cost-effective biologic/biosimilar approved for that indication, subject also to formulary management and local safety considerations such as storage, and educational requirements.

If multiple comparable biologics/biosimilars are available, the products should be selected according to cost-effectiveness.

GUIDING PRINCIPLE 8

There should be a patient-centred pharmacovigilance framework within each hospital or health service to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy.

The TGA requires the product sponsor to develop a comprehensive risk management plan outlining the pharmacovigilance procedures to be implemented, as detailed in the Australian and adopted EU guidelines.⁽³⁾

In hospitals, prescribers, other healthcare professionals and consumers have a responsibility to identify, monitor and report any adverse or unexpected adverse effects.

Hospital or health service DTCs have a central role in providing appropriate governance of biologic/biosimilar approval, use and monitoring for outcomes and adverse effects, including unexpected adverse effects within

its jurisdiction.

Pharmacovigilance is particularly important with the use of recently developed biologics/biosimilars, as clinical trial data are usually insufficient to identify rare adverse effects and there is often limited evidence for long-term safety and efficacy.^(3,5)

Pharmacovigilance of biologics/biosimilars should be a shared responsibility between medical professionals, pharmacists, nurses, consumers and the pharmaceutical industry.⁽⁴⁾

Pharmacovigilance in hospitals should include effective identification and traceability of biologics/biosimilars at all stages of patient care, including prescribing, dispensing and administration, and documentation of any suspected adverse reactions as well as procurement and storage.

It is advisable for hospitals and health professionals to consider recording batch numbers of biologics/biosimilars to assist traceability through all stages of use. Adverse events should be reported to the hospital's or health service's DTC and in the [TGA's adverse drugs reactions reporting system](#)

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16. Australian Government Department of Health, Therapeutic Goods Administration. Biosimilar medicines – information for consumers. 5 November 2013. <https://www.tga.gov.au/biosimilar-medicines-information-consumers> (accessed 21 January 2015).

Appendices

APPENDIX 1: Glossary

Adverse drug reaction: a drug response that is noxious and unintended and that occurs at doses normally used or tested in humans for the diagnosis, prophylaxis or treatment of disease, or for the modification of physiological function.⁽¹⁾

Adverse event: an incident in which harm resulted to a person receiving healthcare.⁽¹⁾

Drug and therapeutics committee (DTC): the group assigned responsibility for governance of the medication management system, and for ensuring the safe and effective use of medicines in the health service organisation.⁽²⁾ These may also be known as a medicines advisory committee, pharmacy and therapeutics committee, drug committee, drug and therapeutics advisory committee or quality use of medicines committee.

Formulary: a continually updated list of medications and related information, reflecting the clinical judgment of physicians, pharmacists and other experts in the diagnosis, prophylaxis or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medicines and medicine-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organisational guidelines.⁽³⁾

Medicine: a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental welfare of people. Prescription, non-prescription and complementary medicines, irrespective of their administration route, are included.^(1,4)

Pharmacovigilance: the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.⁽⁵⁾

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APPENDIX 2: How these guiding principles were developed

These guiding principles were adapted with permission from a similar document produced by the South Australian Medicines Advisory Committee (SAMAC).^{*} Further development work was undertaken in consultation with CATAG member organisations listed below:

- › ACT Health
- › Statewide Therapeutic Drug Committee, (STDC) Tasmania
- › NSW Therapeutic Advisory Group (NSW TAG)
- › Northern Territory Department of Health
- › Queensland Health Medicines Advisory Committee (QHMAC)
- › South Australian Medicines Advisory Committee (SAMAC)
- › Victorian Therapeutics Advisory Group (Vic TAG)
- › Western Australian Therapeutics Advisory Group (WATAG)

During the development of this CATAG document, member organisations undertook consultation, at various stages, with their wider constituents, including hospital drug and therapeutics committees, hospital pharmacy departments and clinicians.

Valuable contribution from the following individuals is also gratefully acknowledged:

- › Mr Steve Morris – Chairman, CATAG. Chief Pharmacist and Executive Director, SA Pharmacy, SA Health
- › Ms Eliana Della Flora and Ms Ashley Symonds– Senior Scientific Officers, South Australian Medicines Advisory Committee, Medicines and Technology Policy and Programs, SA Health
- › Dr Sasha Bennett – Executive Officer, NSW TAG
- › Ms Jane Donnelly, Mr David Lyon and Ms Lisa Pulver – CATAG Coordinators

^{*} South Australian Medicines Advisory Committee. Biosimilars Guiding Principles V 1.0, September 2014. Available at <http://www.sahealth.sa.gov.au/wps/wcm/connect/c4995b804595bf1fbb20bf2ed7c5921e/SAMAC+Biosimilars+Guiding+Principles+Sept+2014.pdf?MOD=AJPERES&CACHEID=c4995b804595bf1fbb20bf2ed7c5921e>.

DISCLOSURE

The Council of Australian Therapeutic Advisory Groups (CATAG) is supported by funding from NPS MedicineWise, an independent, not-for-profit public company funded by the Australian Government Department of Health. This funding is managed via a Services Agreement between NPS MedicineWise and the NSW Therapeutic Advisory Group, an independent, not-for-profit member-based organisation.

The views expressed are those of the members of CATAG and do not necessarily reflect those of the funder.

Conflict of interests: No relevant disclosures.



