CATAG
Council of Australian Therapeutic Advisory Groups

OVERSEEING BIOSIMILAR USE:
GUIDING PRINCIPLES FOR THE GOVERNANCE OF BIOLOGICAL AND BIOSIMILAR MEDICINES IN AUSTRALIAN HOSPITALS

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CATAG

Council of Australian Therapeutic Advisory Groups

- **The Council of Australian Therapeutic Advisory Groups (CATAG)** is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents. Supported by funding from NPS Medicineswise.

- CATAG aims to standardise and improve medicines use primarily (but not exclusively) in the hospital sector across Australia through information sharing advice and advocacy activities.

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SETTING THE SCENE: BIOSIMILARS

- Timeliness: patent expiry of innovator products allowing for biosimilars to enter market
- Uniqueness and complexity of biological and biosimilar paradigm
- Lack of guidance for DTCs and health professionals
- Developing a consistent framework for Australian hospitals.
  - The principles outlined and the associated processes have been applied for some time in a number of Australian public hospitals prior to CATAG producing its guidance.
- Dynamic nature of Australian Health System

DEFINITIONS

- Biological medicine (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:
  - 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.

DEFINITIONS

- Innovator biologic: A novel biologic that is not considered ‘similar’ to any other registered biologic

- Biosimilar: similar biotherapeutic product; or ‘follow on’ variant of a biologic (also know as a similar biological medicinal product [SMBP])
  - 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.
  - Importantly, a biosimilar is not a generic version of the innovator biologic and is not considered to be bioequivalent.

PURPOSE & INTENT

- To provide guidance for good governance and decision-making in relation to the use of biologic therapies in Australian hospitals
- **The principles in the guidance are to be considered in totality and not in isolation**
- To provide an overall framework for facilitating:
  - appropriate first line therapy choice and;
  - potentially switching patients from one biological product to another under the auspices of a Drug and Therapeutics Committee and individual hospital medicines governance processes including the use of protocols.

THE ROLE OF DRUGS AND THERAPEUTICS COMMITTEES (DTCS)

- DTC are fundamental to supporting medicines governance in hospitals.
- DTC assessment and approval of a biosimilar should be based on evidence of safety, efficacy and cost effectiveness within a DTC approved protocol.
- When comparable safety and efficacy can be demonstrated, selection of biological products for hospital use will be determined by considerations of local policies and circumstances and strategies that maximise efficient resource utilisation within the acute sector

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 needs to be transparent and accountable, base on evidence of safety, efficacy and cost-effectiveness according to local polices and circumstances
- Further guidance for DTCs:

  "Achieving effective medicines governance. Guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals"

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.

- Both the innovator biologic and biosimilar can be considered appropriate for first line therapy when **supported by evidence**
  - **Clinical review of safety, efficacy and cost-effectiveness**
- TGA approved vs non TGA approved
- Decisions about products should be determined by a high-level clinical formulary
- Strategic purchasing based on cost effectiveness where comparable safety and efficacy has been demonstrated

GUIDING PRINCIPLE 3

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

- Biosimilars unique and should be prescribed by both the active ingredient and trade-name 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.

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.

- 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.

- Patients are to be informed about decisions and choices when receiving tx
- Advise about therapeutic options:
  - Safety, benefits, potential harms and the differences between therapies
- Advise of changes to tx
- Monitoring of adverse reactions
- Provide written information

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.

- The decision to switch should a clinical decision based on appropriate monitoring and patient response
- Switching based on a treatment protocol approved by a DTC
  - Protocol needs to outline a clear well-justified plan for monitoring benefits and potentially harmful effects
- Switching requires appropriate clinical input and monitoring
- Avoid repeated switching between agents

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.

- An individual may not benefit from the biologic/biosimilar recommended as first-line but may benefit from an alternative
- Where alternatives are available, second-line treatment options should be specified in the associated treatment pathway
- Use evidence for safety, efficacy and cost-effectiveness to inform second-line therapy
- Where comparable safety and efficacy is demonstrated, second-line therapy will be the second most cost effective tx approved for the indication
  - Subject to formulary management and local safety considerations such as storage and educational requirements

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.

- TGA requires a comprehensive risk-management plan outlining the pharmacovigilance procedures to be implemented
- Prescribers, other health care professionals and consumers responsibility to identify, monitor and report ADRs
- DTCs central role in appropriate governance of:
  - Biological/biosimilar approval
  - Use and monitoring outcomes and ADRs
- Pharmacovigilance: post marketing surveillance identifies rare ADRs and long-term safety. Needs to be a shared responsibility – partnerships
- Hospital pharmacovigilance:
  - Effective identification and traceability of biologics/biosimilars at all stages of care
  - Advisable to record batch numbers to assist with traceability

DEVELOPMENT OF THE GUIDING PRINCIPLES

- 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.
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