Checklist for governance of biologics and their biosimilars

Version 1 — 2021

Introduction

The CATAG Guiding Principles support medicines governance committees* in achieving effective medicines management governance and promote national consistency. The *Guiding Principles for the governance of biologics and their biosimilars* are a guide against which the medicines governance committees may review their responsibilities for the prescription, preparing, dispensing, administering and monitoring of biologics.

About this checklist

This checklist is based on the Guiding Principles and should be used to identify any gaps and/or areas for improvements for your hospital or health service organisation.

Each section commences with the Guiding Principle, accompanied by a list of questions, which can be answered 'yes' or 'no'. If the answer is 'no', this is an area the committee may wish to investigate further and endeavour to improve.

Definitions

The term '**reference biologic**' is used to refer to a biologic that is registered in Australia and where that registration was based upon a full regulatory evaluation of quality, safety and efficacy data. This product is typically the first brand of that biologic available and as such may be referred to as the originator or innovator biologic.

A **biosimilar** is a highly similar version of an already registered reference biologic.

Biologics in this document encompasses both reference biologics and biosimilars.

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* Medicines governance committees include drug and therapeutics committees, medicines advisory committees or equivalent, medication safety committees.

GUIDING PRINCIPLES FOR THE GOVERNANCE OF BIOLOGICS AND THEIR BIOSIMILARS		YES	NO	COMMENT
Guiding principle 1: **Biologics, as for all medicines should be subject to good governance processes that are timely and based on the evaluation of evidence of safety, efficacy and cost-effectiveness**	Does the formulary and individual patient use application processes consider **ALL** of the following: efficacy, cost-effectiveness, safety and other considerations such as storage, administration devices and patient education requirements?	☐	☐	
	Does the approval process for formulary listings and individual patient use applications for biologics include consultations with the relevant medical specialists?	☐	☐	
	Does the committee approve protocols for indications of use and the order of use (treatment pathways) for biologics?	☐	☐	
	Does the hospital or health service have a patient-centred pharmacovigilance framework to monitor and report outcomes and any adverse effects associated with biological therapy?	☐	☐	

GUIDING PRINCIPLES FOR THE GOVERNANCE OF BIOLOGICS AND THEIR BIOSIMILARS		YES	NO	COMMENT
Guiding principle 2: **Across all aspects of a patient's healthcare journey, ensure the appropriate and safe documentation and communication of biological medicines, including active ingredient and, where appropriate brand name, including adhering to the principles of active ingredient prescribing.**	Is there appropriate and safe documentation and communication of biologics across the patient's healthcare journey, to avoid inadvertent switching?	☐	☐	
	Is the brand name and batch number recorded at dispensing, to facilitate the traceability of the medicine in the event of an adverse event?	☐	☐	
	If multiple brands of a biologic are stocked is there a DTC approved governance process to ensure accuracy is maintained in prescribing, dispensing, and administration of the medicine, to avoid documentation errors and ensure traceability regarding the brand(s) a patient has received?	☐	☐	

GUIDING PRINCIPLES FOR THE GOVERNANCE OF BIOLOGICS AND THEIR BIOSIMILARS		YES	NO	COMMENT
Guiding principle 3: **Switching programs, between reference biologics and its biosimilar or between biosimilars, should be agreed by the drug and therapeutics committee in conjunction with clinical teams and other stakeholders.**	Is there an evaluation process for any proposed switches which considers safety, efficacy, cost-effectiveness and the potential impact for patients on long-term therapy?	☐	☐	
	Does the DTC work with clinical teams, decisions makers and other stakeholders to agree on any switching program for biologics?	☐	☐	
	Is the frequency of switching of biological products minimised in the hospital or health service?	☐	☐	
Guiding principle 4: **At dispensing, either the reference brand or its biosimilar can be supplied when they have been determined to be substitutable and the selected brand is appropriately documented and communicated.**	In hospitals does substitution of biologics by a pharmacist at the time of dispensing occur as part of an approved treatment pathway?	☐	☐	
	Are any proposed changes of brand, discussed with the prescriber, when substitutions of brands could result in confusion or have a negative impact on patient adherence?	☐	☐	

GUIDING PRINCIPLES FOR THE GOVERNANCE OF BIOLOGICS AND THEIR BIOSIMILARS		YES	NO	COMMENT
Guiding principle 5: **Patients should be actively engaged in shared decision making when considering and receiving treatment with biologics, at initiation or switching.**	Is it routine practice to provide patients unbiased evidence-based and relevant information about their biologics?	☐	☐	
	Is it routine practice to instruct patients to be familiar with their preferred biologic brand, to avoid inadvertent multiple switching?	☐	☐	
	Is it routine practice for appropriate information and education on administration devices to accompany the supply of the biologic?	☐	☐	