Australian Government
Department of Health, Disability and Ageing

Active Ingredient Prescribing

User Guide for Australian Health Practitioners

May 2026

Contents

1. Preface

In October 2019 the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*, and the *Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019* mandated Active Ingredient Prescribing (AIP) for all Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) prescribed medicines. This was in support of the Australian Government's broader strategy and commitment to ensure consistent and standardised medicines information. These measures support the sustainability of the PBS and a viable long-term market for medicines in Australia.

In 2023, the National Health (Pharmaceutical Benefits) (Active Ingredient Prescribing—Excluded Pharmaceutical Benefits) Instrument 2023 replaced the 2019 instrument for Pharmaceutical Benefits Scheme (PBS) medicines. The Active Ingredient Prescribing—Excluded Pharmaceutical Benefits instrument is amended when changes are required.

The Department of Health, Disability and Ageing (the Department) has developed the resources outlined in this user guide to support prescribers' decision-making when prescribing by active ingredient. These resources are based on materials previously developed by the Australian Commission on Safety and Quality in Health Care.

The Department reviews medicines against the principles in this user guide to develop the List of Excluded Medicinal Items (LEMI) and List of Medicines for Brand Consideration (LMBC). Anyone can request that a medicine be considered for inclusion in the LEMI or LMBC by completing the Request for Consideration Intake Form and emailing it to the AIP inbox.

From 1 September 2023, requests to include medicines in the LMBC must be supported by evidence of expert clinical advice against the principles set out in Box 2 of this user guide.

Expert clinical advice involves consulting qualified health professionals to ensure the evidence provided in support of a request is well informed. When seeking expert clinical advice, consult health professionals such as medical practitioners or relevant specialists with expertise in prescribing the therapeutic good in question.

Information about medicines considered to date for inclusion in the LEMI or LMBC is available in the outcomes register.

2. Acknowledgements

The content of this user guide was originally developed by the Australian Commission on Safety and Quality in Health Care in consultation with:

- Australian College of Midwives
- Australian College of Rural and Remote Medicine
- Australian Dental Association
- Australian Digital Health Agency
- Australian Medical Association
- Australian Nursing and Midwifery Federation
- Australian Primary Health Care Nurses Association
- Consumers Health Forum of Australia
- Department of Veterans' Affairs
- Generic Biosimilar Medicines Association
- Medical Software Industry Association
- Medicines Australia
- NPS MedicineWise
- Optometry Australia
- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia
- Royal Australian College of General Practitioners
- Society of Hospital Pharmacists of Australia
- State and territory health departments
- Therapeutic Goods Administration

3. Introduction

Purpose

- Provide an overview of active ingredient prescribing (AIP).
- Provide guidance on when prescribers may consider specifying a brand name in addition to the active ingredient, in the interests of safety and practicality.

About active ingredient prescribing

Active ingredient prescribing (AIP) supports the safe prescribing, dispensing and appropriate use of medicines. Under AIP, prescribers must include active ingredient names when preparing prescriptions, so most medicines are prescribed by active ingredient rather than brand name. AIP applies to most medicines listed on the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS), with some exceptions.

The AIP initiative aims to help people understand what medicines they are taking by:

- increase consumer health literacy
- standardise descriptions of medicines
- support pharmacists and other health professionals to identify active ingredients clearly
- promote uptake of generic and biosimilar medicines
- encourage sustainable prescribing practices
- align Australian prescribing with international practice

Why it is important

The same active ingredient can appear in different forms, such as tablets and liquids, and under different brand names. Recognising medicines by active ingredient helps reduce the risk of double dosing, accidental use of an ingredient a person is allergic to, and harmful interactions with other medicines.

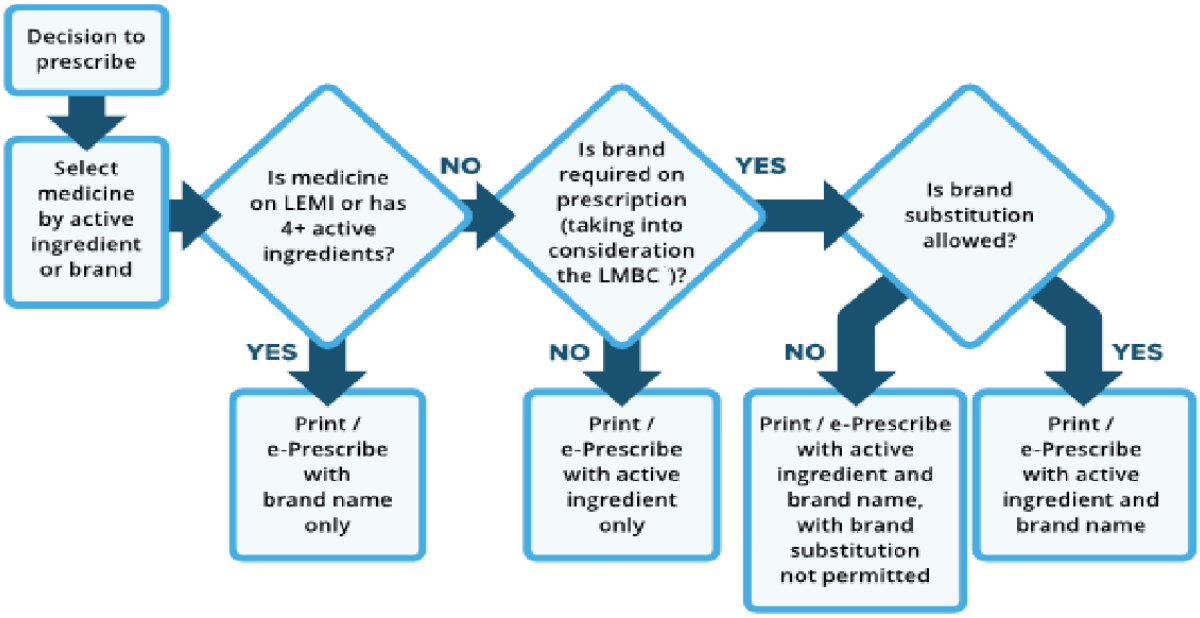
AIP also encourages discussions between consumers and healthcare providers about generic and biosimilar medicines, which may improve understanding and reduce out-of-pocket costs.

AIP supports the Government's broader commitment to consistent, standardised medicines information and the safe, quality use of medicines. Medicines literacy is an important part of health literacy, and familiarity with active ingredient names supports clearer communication, shared decision-making and better health outcomes. It also supports the long-term sustainability of the PBS by encouraging clinically appropriate use of lower-cost generic and biosimilar medicines.

4. Active ingredient prescribing overview

Prescribing process

Figure 1: Prescriber decision process under active ingredient prescribing



Options for active ingredient prescribing

1. Prescribing medicines by active ingredient without brand

Most medicines can be prescribed by active ingredient without the need to specify a brand. Prescribers are encouraged to consider the patient's specific needs and the principles outlined below when prescribing.

2. Prescribing medicines by brand

Some prescriptions are exempt from AIP requirements, including:

- handwritten prescriptions, prescriptions for medicines containing four or more active ingredients, prescriptions prepared using the 'free text' function in prescribing software, and prescriptions for medicines on the List of Excluded Medicinal Items (LEMI). The LEMI is legislated and includes medicines that can be prescribed by brand name without a requirement to include the active ingredient, although the active ingredient name may also be included where practical and safe to do so.

The circumstances in which prescribing should be by brand only, and the principles for inclusion in the LEMI, are described in **Box 1 under** Prescribing by brand – List of Excluded Medicinal Items (LEMI).

3. Prescribing medicines by brand in addition to active ingredient

Prescribers can include a brand name in addition to the active ingredient on a prescription if they consider it clinically necessary or important for patient safety. When this option is selected in

prescribing software, the prescription will show the active ingredient followed by the brand name. Prescribers can also indicate that brand substitution is not permitted, based on the clinical needs of the patient.

Including the brand name in addition to the active ingredient is important for some high-risk medicines, such as insulins, and for consumers at greater risk of harm. In some circumstances, it may be preferable to include the brand name to avoid miscommunication between clinicians, reduce selection errors, and support accurate interpretation and dispensing of the prescription.

The List of Medicines for Brand Consideration (LMBC) has been developed to support prescribers when deciding whether to include a brand name in addition to the active ingredient. It identifies medicines for which additional brand specification may help prevent medication incidents and consumer harm. Prescribers are encouraged to consider the LMBC and determine whether brand specification is needed as part of shared decision-making with the patient. From a safety perspective, it is also important to recognise that some active ingredient names are complex and may be confusing for some consumers.

The circumstances in which prescribing should be by brand name in addition to the active ingredient, and the principles for inclusion in the LMBC, are described in **Box 2 under** Prescribing by brand in addition to active ingredient – List of Medicines for Brand Consideration (LMBC).

5. The AIP lists: LEMI and LMBC

List of Excluded Medicinal Items (LEMI)

The circumstances where prescribing should be by brand only and principles for inclusion in the LEMI are described in **Box 1**.

BOX 1: PRESCRIBING BY BRAND NAME

Prescribe by brand name where:

1. The prescription is handwritten.
2. The prescription is written on a paper-based medication chart in a residential aged care facility.
3. The medicinal item contains four or more active ingredients.
4. The item is listed under the 'Various' section of the RPBS Schedule, including items such as non-absorbed treatments, bandages, tapes and dressings, allergens, diagnostic agents, oral rehydration salts, general nutrients, food supplements and vitamin supplements.
   ATC - V - VARIOUS
5. For some PBS items, including the active ingredient has been deemed impractical or unsafe. The Department reviews medicines against the principles in this user guide and has identified the following Anatomical Therapeutic Chemical (ATC) groups as appropriate for the LEMI.

Classification ATC groups appropriate for the LEMI:

– Vaccines – ATC J07 - VACCINES

– Allergenic extracts and antivenoms – ATC V01 - ALLERGENS

– Ocular lubricants – ATC S01XA - Other ophthalmologicals subset S01XA01

– Nutritional food products, amino acid formulations, nutrient products – ATC V06 - GENERAL NUTRIENTS

– Diagnostic agents – ATC V04 - DIAGNOSTIC AGENTS

LEMI list formats

1. A complete list of medicines and supplementary pharmaceutical benefits that are excluded from AIP requirements and may be prescribed by brand name only. This list is derived from the principles in Box 1.

- This list is represented in CSIRO AMT datasets distributed by the National Clinical Terminology Service to support best-practice prescribing and align with AIP principles across all medicines, regardless of PBS status.

2. The PBS List of Excluded Medicinal Items (LEMI), which further defines PBS items considered impractical or unsafe for active ingredient prescribing under the National Health (Pharmaceutical Benefits) (Active Ingredient Prescribing—Excluded Pharmaceutical Benefits) instrument. This list is derived from the principles in Box 1, point 5.

List of Medicines for Brand Consideration (LMBC)

THE GUIDING PRINCIPLES FOR WHEN PRESCRIBING SHOULD BE BY BRAND NAME IN ADDITION TO ACTIVE INGREDIENT, AND PRINCIPLE FOR INCLUSION IN THE LMBC ARE DESCRIBED IN BOX 2.

BOX 2: PRESCRIBING BY BRAND NAME IN ADDITION TO ACTIVE INGREDIENT NAME

Prescribing by brand name in addition to the active ingredient should occur where there is a risk of confusion that could lead to incorrect dosing or administration. The guiding principles are:

1. Medicines are not therapeutically equivalent or have not been assessed as being therapeutically equivalent.
2. Medicines have a narrow therapeutic index and minor changes in bioavailability of different brands of the same active ingredient may be clinically important.
3. Different formulations of the same active ingredient and strength have different dosing requirements and/or rates of administration.
4. Different formulations of the same active ingredient and strength have different release characteristics, including modified-release formulations.
5. Different brands of the same active ingredient and strength have different dosing regimens for the same indications
6. Different brands of the same active ingredient and strength have different dosing regimens for different approved indications
7. Similarity of active ingredient names may cause confusion unless differentiated by strength and/or dose form.
8. Delivery devices may require different instructions for use, and familiarity with a particular product may be important for adherence, continuity of therapy or safety.
9. Certain medicines listed on the PBS/RPBS that may require prescriptions authorised under specific authority required procedures.

The LMBC has been developed to support prescribers and is not prescriptive. Prescribers may additionally specify brand, considering the needs of their patient, where:

- there is a known allergy or intolerance to excipients
- there are differences in product appearance may cause confusion and affect adherence
- switching between medicine brands is not considered to be in the patient's best interests

LMBC list formats

- The complete AMT concepts List of Medicines for Brand Consideration (LMBC). This list is derived from the principles in Box 2 above.

    - This list is represented in CSIRO AMT datasets distributed by the National Clinical Terminology Service to support best-practice and align with AIP principles across all medicines, regardless of PBS status.
- The high-level List of Medicines for Brand Consideration (LMBC). This list is also derived from the principles in Box 2 above.

Applying the principles for LMBC inclusion

Clinicians may consider medicines for inclusion where there is potential to misinterpret a prescription and the brand name is required for differentiation. Clinicians should review the active ingredient name, strength and/or form of a medicine when applying the nine principles for LMBC inclusion. The examples below give further detail on how to apply some of these principles:

- Insulins are high-risk medicines that can cause patient harm if the wrong type, brand, strength, form or device is supplied. They are available in multiple strengths and formulations with similar-looking and similar-sounding active ingredient names. Insulins are included on the LMBC in line with **principles 3, 7 and 8**. See the Safer insulin prescribing factsheet for more information.
- Betamethasone dipropionate in an 'optimised vehicle' (OV) has different absorption and uptake characteristics from the original formulations. Because the OV and original formulations share the same strength and dose form, they can be difficult to differentiate without the brand name. These medicines are included on the LMBC in line with **principle 4**.
- Two brands of C1 esterase inhibitor injection have different dosing regimens for the same indication. The brands are not interchangeable, although they share the same strength and dose form. They are distinguished only by the number of vials in the pack and the container size of the diluent. These medicines are included on the LMBC in line with **principles 1 and 5**.

Documenting the decision to specify a brand

Prescribers may document their decision to specify a brand in the patient's record and My Health Record to support treatment continuity.

6. Management of the lists

The LEMI and LMBC were developed to support consistent application of active ingredient prescribing principles and to clarify when brand prescribing may be required for safety or practicality.

The Department reviews medicines against the principles in this user guide to develop the LEMI and LMBC. Anyone can request that a medicine be considered for inclusion in the LEMI or LMBC by completing the Request for Consideration Intake Form and emailing it to the AIP inbox.

Requests to consider medicines for inclusion in the LMBC require the initiator to provide evidence of expert clinical advice against the principles set out in Box 2 of this user guide. The Department reserves the right to seek additional independent expert clinical advice.

The outcomes of these reviews are summarised in the Active Ingredient Prescribing Outcome Register. This register replaces the *Active ingredient prescribing - Issues register* developed by the Australian Commission on Safety and Quality in Health Care. The issues register contains past recommendations and actions from the Commission's Active Ingredient Prescribing Advisory Group, is no longer updated, and the final version (December 2022) is available from the Commission on request.

Medicines newly registered or cancelled from the ARTG are also regularly reviewed by the Department.

Prescribing software

The Australian Medicines Terminology (AMT) provides a national, standards-based approach to identifying and naming medicines. AMT reference sets for medicines on the LMBC and LEMI are available from the National Clinical Terminology Service, which is governed by the Australian Digital Health Agency and operated by CSIRO's Australian e-Health Research Centre.

These reference sets support identification of AMT Medicinal Product Unit of Use (MPUU) concepts associated with the LEMI and LMBC, and can be used by prescribing software vendors and developers to help meet AIP requirements.

The Medication Software Industry Association (MSIA) has also published a Software Vendor Resource Document. This resource supports prescribing software vendors to enable prescribing by active ingredient, with or without inclusion of a brand name, where appropriate.

7. Active ingredient prescribing background

Medicines naming

The active ingredient of a medicine is the therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action. The brand or trade name of a medicine is the name given to the medicine by the manufacturer. The same active ingredient may be marketed under a range of different brand names.

The approved nomenclature for active ingredients in Australia and internationally is based on International Non-proprietary Names (INN). Active ingredient prescribing uses the INN when prescribing. For more information about INN, visit the World Health Organization website: www.who.int/teams/health-product-and-policy-standards/inn/guidance-on-inn.

Medicines literacy and safer communication

Medicines literacy is the degree to which individuals can obtain, understand, communicate, calculate and process information about their medicines. Improved medicines literacy helps consumers make informed decisions about the safe and effective use of medicines. AIP supports clearer communication about medicines, promotes shared decision-making, and reduces the risk of medication errors caused by confusion or double dosing.

Consumers can now access more comprehensive information about their prescribed and dispensed medicines through My Health Record. Greater familiarity with active ingredient names can help people interpret this information more confidently, support informed decisions about medicine use, and improve communication with health professionals.

Medicines approval in Australia

Before a medicine can be commercially supplied in Australia, the Therapeutic Goods Administration (TGA) must assess it for quality, safety, and efficacy with approval to be included on the ARTG.

Medicine affordability

A pharmaceutical company may apply to have a registered product listed for reimbursement under the PBS and/or RPBS. The PBS and RPBS are governed by different legislation and serve different purposes.

The PBS is the main mechanism through which the Government subsidises the cost of medicines for the treatment of Australian patients. It provides timely, reliable, and affordable access to a wide range of medicines and medicinal products for Australians. The Government receives advice from the Pharmaceutical Benefits Advisory Committee (PBAC) about the listing of medicines on the PBS, under the National Health Act 1953. When considering a medicine proposed for PBS listing, the PBAC is required by legislation to give consideration to the effectiveness and cost of the medicine, including by comparing the effectiveness and cost with that of alternative treatments.

In contrast, the RPBS is based primarily on the principle of compensation to war veterans and their eligible dependants for injury or death related to war service. Through the *Veterans' Entitlements Act*

1986, the Department of Veterans' Affairs provides a wide range of pharmaceuticals and wound dressings at a concessional rate for the treatment of eligible veterans, war widows/widowers, and their dependants.

Generic and biosimilar medicines

The TGA defines a generic medicine[1] as an additional brand of an existing medicine. Once the patent for the originator brand has expired, other companies may manufacture and market generic versions containing the same active ingredient. Generic medicines must meet the same standards for quality, safety and efficacy as the originator brand, and must demonstrate bioequivalence. More information on biopharmaceutic studies is available on the TGA website at www.tga.gov.au/resources/resource/guidance/biopharmaceutic-studies.

Biological medicines, including biosimilar medicines, contain one or more active substances derived from living cells or organisms. The TGA assesses reference biological medicines and biosimilar brands for quality, safety and efficacy, including whether there is sufficient evidence of therapeutic equivalence. Where therapeutic equivalence has been established, a prescriber may choose a biosimilar brand when initiating treatment and may also consider switching between equivalent brands when clinically appropriate.

The PBAC recommends brand substitutability on the PBS based on TGA advice. If the PBAC considers a generic or biosimilar brand and an originator or reference product to be bioequivalent, these products may be 'a-flagged' and can be substituted at the pharmacy level, with the patient's consent, without returning to the prescriber. These medicines are annotated with the "a" symbol that appears immediately before the relevant brand names on the PBS Schedule. For more information on brand equivalence flagging, visit the PBS website at www.pbs.gov.au/info/healthpro/explanatory-notes/section2/section-2-symbols.

Special considerations

Prescribers should prescribe cytotoxic chemotherapy by active ingredient in accordance with PBS legislation. In addition, dose-specific prescriptions must be prepared using the quantity of active ingredient needed for a single infusion or injection, expressed in milligrams or other relevant units of measure. This approach is consistent with the Efficient Funding of Chemotherapy (EFC) arrangements.[2] While a brand name may be specified where needed, PBS claims are calculated based on the most efficient combination of vial sizes offered across all brands.

For biological and biosimilar medicines, continuity of therapy may be especially important once treatment has been established. In these circumstances, specifying the brand name in addition to the active ingredient can support monitoring, continuity of care and safe switching practices where clinically appropriate.

8. Conclusions

Active ingredient prescribing supports safer, clearer and more consistent communication about medicines. It can improve medicines literacy, reduce the risk of confusion and double dosing, and support the appropriate use of generic and biosimilar medicines.

At the same time, this guide recognises that some medicines are not suitable for prescribing by active ingredient alone. The LEMI and LMBC support prescribers to decide when brand specification is necessary to protect patient safety and support practical prescribing.

9. Recommendations

For prescribers

- Adopt the guidelines for active ingredient prescribing into your practice.
- Become familiar with the active ingredient prescribing principles, LEMI and LMBC. This will assist in identifying when specifying the brand name on a prescription may be required.
- Advise and counsel patients on the use of active ingredient terminology to improve communication and health literacy.
- Encourage the uptake of generic and biosimilar medicines when appropriate by explaining their bioequivalence and suitability.
- Use prescribing software that conforms with PBS and RPBS requirements.

For pharmacists

- Become familiar with the active ingredient prescribing principles, LEMI and LMBC.
- Educate and counsel patients and the community about the use of active ingredient terminology to improve communication and medicines literacy.
- Confirm with patients when substituting a generic or biosimilar medicine.
- Encourage the uptake of generic and biosimilar medicines when appropriate by explaining their bioequivalence and suitability.
- Educate patients and the community when it is important to use the same brand of medicine.
- Use prescribing and dispensing software that conforms with PBS and RPBS requirements.

For consumers

- Become familiar with the active ingredient name of the medicine you are taking.
- Have constructive discussions with health professionals about any concerns you have regarding your medicine.

10. Glossary

Term	Definition
Active ingredient	The approved pharmaceutical ingredient in a product, substance or compound that produces its biological effect in the body.
'a'-flagged PBS item	Indicates that pharmacists may substitute one brand for another equivalent brand of the same PBS item at the point of dispensing, with the patient's consent, without a clinically significant difference in effect.
AMT reference set	Reference sets serve as a mechanism for creating subsets of content from AMT. Each of these reference sets is used to represent a set of AMT components for a specific purpose within a defined scope.
Bioavailability	The rate and extent of absorption of the medicine.
Bioequivalence	Two medicines are bioequivalent if there is no clinically significant difference in their bioavailability.
Biological/ biological medicine	A medicine whose active substance is made from, or contains, human cells or human tissues, or live animal cells, tissues or organs. This definition specifically excludes vaccines, recombinant products, plasma derived products, blood and blood components, haematopoietic progenitor cells used for haematopoietic reconstitution, in vitro diagnostic devices, and samples of human cell or tissue that are solely for diagnostic purposes in the same individual.
Biopharmaceutics	The study of the ways that the physical and chemical properties of drug substances, drug products and routes of administration affect bioavailability. Biopharmaceutic studies of new medicines typically include the investigation of bioavailability, relative bioavailability and bioequivalence of different dosage forms or formulations, and the effect of food or antacids on their bioavailability.
Biosimilar	A biosimilar medicine is a highly similar, but not identical version of an already registered reference biological medicine. A biosimilar medicine has a demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies as evaluated by the TGA. Marketed under different brand names to the reference biological medicine, and generally only after the patent on the reference biological medicine has expired. Also known as similar biological medicinal products (European Union); similar biotherapeutic products (World Health Organization); subsequent entry products (Canada); follow-on products.
Brand name or trade name	The name given to a medicinal product by the manufacturer. The use of the name is reserved exclusively for its owner.
Drug	Any substance that causes a change in an organism's physiology or psychology. All medicines are drugs, but not all drugs are medicines.
Generic brand / generic medicine	A generic brand is an additional brand of an originator or existing medicine. It contains the same active ingredient as the originator or existing brand. A generic brand has the same dosage form, strength,

Term	Definition
	route of administration, quality, performance characteristics and intended use, and is therapeutically equivalent to the originator brand medicine.
Interchangeability	If two or more medicines are considered interchangeable, the prescriber may choose to prescribe either of the medicines for a consumer to treat the same condition. However, the pharmacist must dispense as prescribed. This generally occurs between two different medicines, rather than brands or biosimilars of the same medicine.
Medicines	Drugs for the treatment or prevention of disease. Also known as medications, medicinal products.
Narrow therapeutic index	A narrow therapeutic index is where the range between effective dose and the dose at which adverse toxic effects are produced is narrow, and small variations in plasma concentrations can result in an insufficient therapeutic response or toxicity.
Pharmacist	A person who is registered as a pharmacist under the Australian Health Practitioner Regulation Agency (AHPRA), which in association with the Pharmacy Board of Australia has been deemed professionally qualified to prepare and dispense medicines.
PBS prescriber	Doctors, dentists, optometrists, midwives, and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.
Reference brand	The biological or generic medicine that was the first brand to market.
Substitution	The practice of dispensing one brand of a medicine instead of another brand of the same medicine at the pharmacy level without needing to go back to the prescriber, but in consultation with the patient.
Switching	Decision by the treating medical practitioner to change between branded (reference) medications and their corresponding generic products, between generic products, or from a generic product to a branded medication during treatment.
Therapeutic equivalence	Medicines are therapeutically equivalent only if they are pharmaceutically equivalent and can be expected to have the same clinical effect and safety profile when administered to consumers under the conditions specified in the labelling.