Australian Government
Department of Health and Aged Care

Active Ingredient Prescribing

User Guide for Australian Health Practitioners

March 2024

Contents

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.

The Department of Health and Aged Care has developed resources to support prescribers' decision-making when prescribing by active ingredient name. These resources are derived from resources previously developed by the Australian Commission on Safety and Quality in Health Care. These include the:

- Active Ingredient Prescribing – User guide for Health Practitioners
- List of Excluded Medicinal Items (LEMI), a list of medicines and supplementary pharmaceutical benefits excluded from meeting the requirements of active ingredient prescribing. Prescribers can prescribe medicines on this list by brand name only, and
- List of Medicines for Brand Consideration (LMBC), which includes medicines where the inclusion of brand name in addition to active ingredient is recommended for patient safety.

The Department's Active Ingredient Prescribing Working Group (AIPWG) reviews medicines against the principles in this Active Ingredient Prescribing User Guide to derive the LEMI and LMBC. Anyone can request medicine(s) for AIP consideration 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 consider medicines for inclusion in the LMBC require the initiator to provide evidence of expert clinical advice in support of the request with respect to the principles set out in Box 2 of this user guide.

Expert clinical advice involves consulting with qualified healthcare professionals to ensure the evidence provided is well informed in support of the request. When seeking expert clinical advice, consult qualified healthcare professionals such as doctors or specialists who possess expertise and authority to prescribe the therapeutic good in question.

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

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

Introduction

Purpose

- To provide an overview of AIP.
- To provide guidance for when prescribers may consider prescribing by brand name in addition to active ingredient, in the interest of safety and/or practicality.

Scope

AIP is mandatory for all PBS and RPBS prescribed medicines. However, the principles of AIP are encouraged to be applied when prescribing all medicines in all health care settings.

Situations where AIP is not mandated, and requirements are out of scope include:

- Handwritten prescriptions
- Computer generated paper-based National Residential Medication Charts
- Prescriptions generated through a free text function in prescribing software
- Medicines containing four or more active ingredients
- Items listed under the 'Various' section of the General PBS and RPBS schedule
- Medicines not registered for use in Australia, including Special Access Scheme medicines.

Context

AIP supports the Government's broader strategy and commitment to ensure consistent and standardised medicines information. Medicines literacy is an important part of health literacy. Being familiar with the active ingredient name for medicines is essential to consistent communication and optimising health outcomes. The Government is committed to safe and quality use of medicines as described in the National Medicines Policy and led by the Australian Commission on Safety and Quality in Health Care.

The Government has a responsibility to ensure that the PBS is managed in a fiscally responsible and sustainable way, so that the Australian community can continue to be able to access affordable medicines into the future.

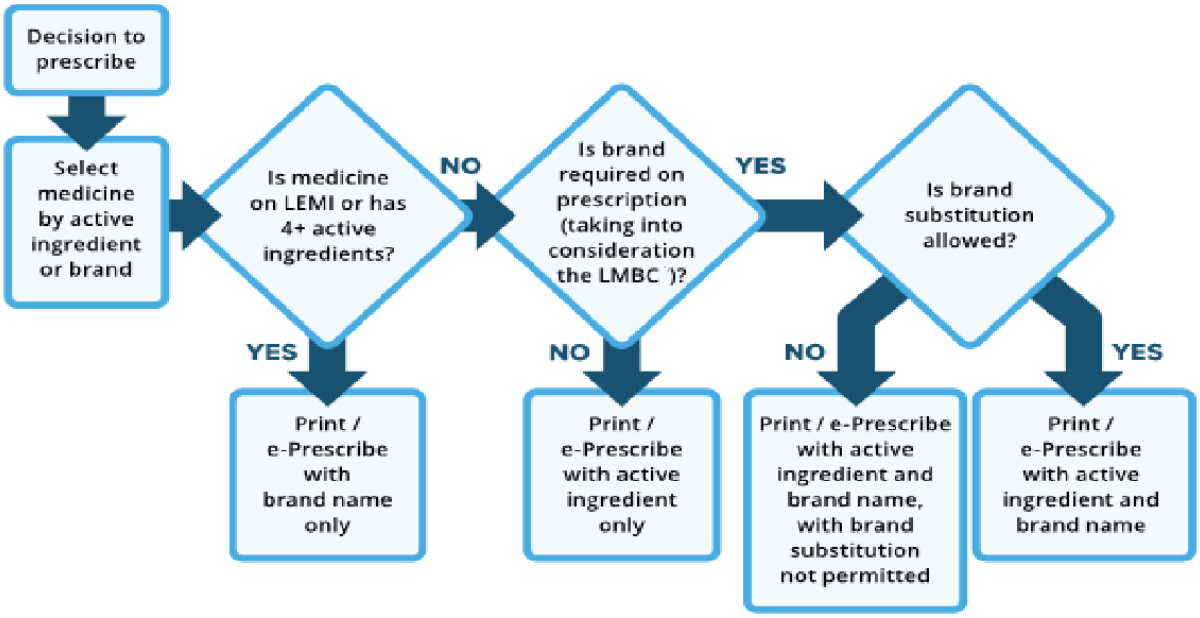
Prescribing medicines by their active ingredient(s), where clinically safe and appropriate, is seen as international best practice. The AIP aims to:

- Improve safe and quality use of medicines through consistent and standardised descriptions of medicines.
- Increase patient understanding of the medicines they are prescribed and dispensed to reduce the risk of dosing errors and increase compliance.
- Promote the uptake of generic and biosimilar medicines to support the sustainability of the PBS.

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 brand. Prescribers are encouraged to consider their patient's specific needs, and the principles outlined below when prescribing.

2. Prescribing medicines by brand

There are prescriptions that are exempt from meeting AIP requirements, including handwritten prescriptions, prescriptions for medications containing four or more active ingredients, prescriptions prepared using the 'free text' function within 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, with no requirement to include active ingredient. However active ingredient name(s) may also be included if practical and safe to do so.

Principles for prescribing by brand

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. Products contain four or more active ingredients
2. Vaccines have varying strains, components, or immunisation regimens
3. Items are non-medicinal items, listed under the 'Various' section of the General PBS Schedule or 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
4. Inclusion of active ingredients has been deemed impractical (for example, dermatologicals, ocular lubricants)

3. Prescribing medicines by brand in addition to active ingredient

Prescribers can include brand name in addition to active ingredient on a prescription, if they believe it is clinically necessary or for patient safety. A prescriber can choose the option to include brand name in the prescribing software, in which case the prescribing software will generate the prescription with the active ingredient followed by the brand name. Prescribers can still indicate if brand substitution is not permitted, considering the clinical needs of their patient.

Additional inclusion of brand is important for some high-risk medicines, such as insulins, and for consumers at high risk of medical complications. There are circumstances where it may be preferable to include the brand name. This is mainly to avoid miscommunication between clinicians, to prevent selection error, and to ensure accuracy when interpreting and dispensing the prescription.

The List of Medicines for Brand Consideration (LMBC) has been developed to support prescribers when prescribing by brand in addition to active ingredient. It includes medicines recommended for consideration of additional brand specification to prevent medication incidents and consumer harm. Prescribers are encouraged to consider the LMBC and decide on the additional need for brand specification as part of shared decision-making with the patient. From a safety perspective, it is important to recognise that active ingredient names can be complex and may confuse some consumers. Prescribers should consider this as they assess consumers and discuss their medicines with them.

Principles for prescribing by brand in addition to active ingredient

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 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 formulation of the same active ingredient and strength have different dosing and/or rates of administration
4. Different formulation of the same active ingredient and strength have different release characteristics. This includes 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 ingredients names may cause confusion, unless differentiated by strength and/or dose form
8. Delivery devices have different instructions for use and consumer familiarity with one product is an important contributor to consumer compliance, medicines continuity 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.
- Differences in product appearance may cause confusion and impact adherence
- Switching between medicine brands is not considered to be in the patient's best interest.

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 which can cause patient harm if the wrong type, brand, strength, form or device is given. Insulins are available in multiple strengths and formulations of similar looking and 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) offers different absorption and uptake to the original formulations. They share the same strength and form, without the brand name, the OV formulations are difficult to differentiate from the original formulations (both available as a cream or ointment). These 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 two brands are not interchangeable although they share the same strength and dose form. The two brands are only distinguished by the number of vials in the pack and the container size of the diluent. They are included on the LMBC in line with **principles 1 and 5.**

Documenting the decision to specify by brand

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

The AIP lists

There are two AIP lists:

- The List of Excluded Medicinal Items (LEMI), a list of medicines and supplementary pharmaceutical benefits excluded from meeting AIP requirements, and can be prescribed by brand name only. This list is derived from the principles provided in Box 1 above.
- The List of Medicines for Brand Consideration (LMBC), which includes medicines where the inclusion of brand name in addition to active ingredient is recommended for patient safety. This list is derived from the principles provided in Box 2 above.

Management of the lists

The LEMI and LMBC were originally developed after review of the New Zealand, Ireland and the United Kingdom documents that clarify brand prescribing and define the situations where exceptions to active ingredient prescribing should be implemented.

The Department's AIPWG reviews medicines against the principles in this user guide to derive the LEMI and LMBC. Anyone can request for a medicine(s) to 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 in support of the request with respect to the principles set out in Box 2 of this user guide. The AIPWG reserves the right to seek additional independent expert clinical advice.

The outcomes of these reviews are summarised in the Active Ingredient Prescribing Outcome Register. The Outcome Register replaces the *Active ingredient prescribing - Issues register* developed

by the Australian Commission on Safety and Quality in Health Care. The issues register includes past recommendations and actions from the Commission's Active Ingredient Prescribing Advisory Group. The Commission's Issues register is no longer being updated and the last version (December 2022) is available on request from the Commission.

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

Prescribing software

The Australian Medicines Terminology (AMT) is a national, standards-based approach to identify and name 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.

The reference sets support the identification of AMT Medicinal Product Unit of Use (MPUU) and Medicinal Product Pack (MPP) concepts associated with the LEMI and LMBC and are available for use by prescribing software vendors and developers to assist with meeting AIP requirements. The reference sets include the medicinal product names referenced by the AMT Medicinal Product (MP) concepts for all Australian medicines that can be prescribed, including non-PBS drugs.

The Medication Software Industry Association (MSIA) has also provided a Software Vendor Resource Document. This supports prescribing software vendors to allow prescribing by active ingredient, with or without the inclusion of brand name, as deemed appropriate by the prescriber.

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 the pharmaceutical domain in Australia and across the world is defined using International Non-proprietary Names (INN). Active ingredient prescribing is the use of the INN when prescribing. For more information about the INN, please visit: 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 get, comprehend, communicate, calculate, and process information about their medicines. Improved medicine literacy helps consumers make informed decisions on the safe and effective use of their medicines. AIP is expected to improve clarity and knowledge about medicines, leading to improved shared decision-making, whilst reducing medication errors because of confusion and potential double dosing.

Consumers now have access to comprehensive views of their prescribed and dispensed medicines through the My Health Record system. A consumer's increased awareness of active ingredient names

will ensure that platforms, such as My Health Record, are supporting Australians to make informed decisions on the safe and effective use of their medicines and potentially improve health outcomes.

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 seek to have a registered product listed for reimbursement under the PBS and/or RPBS. The PBS and RPBS are underpinned 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. Pharmaceutical companies can manufacture and sell active ingredients as generic medicines once the patent for the originator brand medicine has expired. Generic medicines contain the same active ingredient as the existing medicine and must be bioequivalent to the originator brand. Bioequivalence is demonstrated by conducting a 'bioavailability' study. More information on biopharmaceutic studies can be found on the TGA website at www.tga.gov.au/resources/resource/guidance/biopharmaceutic-studies.

Biological medicines, including biosimilar medicines1, contain one or more active substances that are derived from living cells or organisms. The TGA assess the reference biological medicine and biosimilar brand for therapeutic equivalence. Products listed on PBS/RPBS for which enough evidence of therapeutic equivalence is provided are deemed interchangeable. When a prescriber prescribes a biological medicine for the first time, it is entirely appropriate to select the therapeutically equivalent biosimilar. Similarly, when a consumer is established on a biological or

[1] Therapeutic Goods Administration. Generic medicines. Prescription medicines: registration of new generic and biosimilar medicines. Australian Government Department of Health and Aged Care. Available from www.tga.gov.au/prescription-medicines-registration-new-generic-medicines-and-biosimilar-medicines [Accessed 15 Aug 2023]

biosimilar medicine, a prescriber can substitute for another brand if therapeutic equivalence has been proven.

The PBAC recommends the substitutability of brands on the PBS based on the TGA's advice. If the PBAC considers a generic/biosimilar and originator/reference products as bioequivalent, these products are referred to as a-flagged, and can be substituted at the pharmacy level without needing to go back to the prescriber, but in consultation with the patient. These medicines are annotated with the "a" symbol that appears immediately before the brand names of a particular strength on the 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 consistent with PBS legislation. In addition, prescribers must prepare dose-specific prescriptions with the number of active ingredient(s) needed for a single infusion or injection using milligrams or other relevant units of measure. This is in line with guidance on the Efficient Funding of Chemotherapy (EFC) arrangements.[2] While brand name may be specified, PBS claims will be calculated based on the most efficient combination of vial sizes offered across all brands.

This is important if the biosimilar is a more cost-effective choice. However, there is no evidence to support uncontrolled switching between brands once treatment is established. Therefore, the biologicals and biosimilars should be described by brand in addition to active ingredient to support consistency and monitoring of care.

Conclusions

The Government is committed to increasing the uptake of generic and biosimilar medicines. This is to decrease out of pocket expenditure for consumers, to improve the financial sustainability of the PBS, maintain prescriber and consumer choices regarding medicines. To fully support medicine accessibility without compromising safety and efficacy, it is recognised that not all medicines are interchangeable and that where clinically appropriate, the brand name should be specified to prevent patient harm.

Active ingredient prescribing increases the understanding and knowledge of the active ingredients in medicines and assists to educate and familiarise prescribers, pharmacists, and the community regarding the availability and acceptability of lower cost medicines.

[2] Pharmaceutical Benefits Scheme. Efficient funding of chemotherapy program, 2020. Australian Government Department of Health and Aged Care. Available from www.pbs.gov.au/info/browse/section-100/chemotherapy [Accessed 2022 Nov 25].

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
- Advice and counsel patients about the use of active ingredient terminology to improve communication and health literacy.
- Encourage the uptake of generic and biosimilar medicines when appropriate by assuring their bioequivalence and suitability.
- Adopt clinical prescribing software which conforms with PBS/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 the health literacy of all
- Confirm with patients when substituting a generic or biosimilar medicine
- Encourage the uptake of generic and biosimilar medicines when appropriate by assuring their bioequivalence and suitability
- Educate patients and the community when it is important to use the same brand of medicine.

For Consumers

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

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	Denotes that brand substitution for these PBS items may be undertaken by pharmacists at the point of dispensing, with the patient's consent, without differences in clinical 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.

Term	Definition
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 brand or existing medicine. A generic brand has its dosage form, strength, route of administration, quality, and performance characteristics, and intended use, therapeutically identical 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.

Term	Definition
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.