



Medical Software Industry Association Inc.
Australian Government Department of Health

PBS/RPBS Active Ingredient Prescribing

Vendor Resource Document
for Prescribing Software Developers

Prepared by:
MSIA in collaboration with
The Australian Government Department of Health.

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5/11/2020	2.2	Changing terminology around alerts for items on the LMBC per ACSQHC recommendations
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2 Glossary and Abbreviations

Acronym/Term	Description
Active Ingredient Name	Refers to the active ingredient name for a drug, for example <i>Allopurinol</i> . It does not refer to the brand name such as Zyloprim (the originator product), Allosig, Progout, Apotex, APO-Allopurinol etc.
ACSQHC	Australian Commission on Safety and Quality in Health Care.
ADHA	Australian Digital Health Agency.
AHPRA	Australian Health Practitioner Regulation Agency.
AIP	Active Ingredient Prescribing.
AMA	Australian Medical Association.
AMT	Australian Medicines Terminology.
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. For example, a reference set could contain the AMT concept IDs applying to medicinal items for identifying drugs for the prescriber to consider if the brand name on the prescription is necessary for the clinical treatment of their patient.
APF	Australian Pharmaceutical Formulary
ARTG	Australian Register of Therapeutic Goods. The Australian Register of Therapeutic Goods is a computer database of therapeutic goods maintained by the Therapeutic Goods Administration (TGA). ¹
Biosimilar	A biosimilar is a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original "innovator" products and can be manufactured when the original product's patent expires.
Brand Name	The trade name given to the drug by the company which manufactures it, protected by patent.
Computer Generated Prescription	A prescription generated by prescribing software, whether printed and hand signed or an electronic prescription (once electronic prescribing is enabled in October 2019). This includes computer generated and electronic medication charts in hospitals and the residential aged care setting.
Department of Health	Australian Government Department of Health.

¹ <http://www.tga.gov.au/industry/artg.htm>

Acronym/Term	Description
Drug	Within the context of this document "drug" is used to refer to prescribable items listed under the Schedule of Pharmaceutical Benefits being the terminology consistent with references under the PBS/RPBS regulations.
DVA	Department of Veteran's Affairs
ETP	Electronic Transfer of Prescriptions This facility allows a copy of the prescription to be uploaded by the prescribing software to a Prescription Exchange Service available for downloading by the pharmacy of choice of the patient.
Eligible Approved Supplier	A Pharmacist or Medical Practitioner approved under the <i>National Health Act 1953</i> to supply pharmaceutical benefits.
Free text facility	Free text facility allows a prescriber to simply type the drug details for a prescription as if from a typewriter, <u>without reference</u> to a drug lookup.
Electronic prescription	An electronic prescription is a legal PBS prescription in an electronic format that is electronically created and made available for dispensing (rather than in a paper format).
GBMA	The Generic and Biosimilar Medicines Association.
Generic Brand/Generic Medicine	A generic brand is a drug product that is comparable to the originator drug as registered with the registration authority (in this case the TGA) which has its dosage form, strength, route of administration, quality and performance characteristics, and intended use therapeutically identical to the originator drug.
INN	International Non-Proprietary Name.
LEMI	List of Excluded Medicinal Items.
LMBC	List of Medicines for Brand Consideration. (Previously known as Recommended List of Drugs for Brand Inclusion)
MA	Medicines Australia.
Medicinal items	Drugs within the scope of this initiative excluding bandages, dressings, diagnostic tools, food supplements and vitamin supplements.
MPP	Medicinal Product Pack refers to a medicine's active ingredient, dose, form, strength and pack size.
MSIA	Medical Software Industry Association Inc.
NCTS	The National Clinical Terminology Service.
NPS MedicineWise	National Prescribing Service MedicineWise.
Originator Pharmaceutical Product	The product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety, and quality according to requirements at the time of authorization. Known also as "F1 Medicine".

Acronym/Term	Description
PBS	The Pharmaceutical Benefits Scheme ² .
PDS	Pharmacy Dispensing Software.
PES	Prescription Exchange Service.
PGA	Pharmacy Guild of Australia.
Pharmacist	A person who is registered as a pharmacist under the AHPRA, which in association with the Pharmacy Board of Australia has deemed that person to be a pharmacist.
PBAC	Pharmaceutical Benefits Advisory Committee.
PBS Prescriber	Doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS/RPBS medicines under the <i>National Health Act 1953</i> .
PSA	Pharmaceutical Society of Australia.
RACGP	Royal Australian College of General Practitioners.
RPBS	Repatriation Pharmaceutical Benefits Scheme.
SHPA	Society of Hospital Pharmacists of Australia.
TGA	Therapeutic Goods Administration.
VRD	Vendor Resource Document.

² www.pbs.gov.au

3 Introduction

This document is one of the prescribing vendor support components developed by MSIA, as requested by the Australian Government Department of Health (the Department), associated with the implementation of Active Ingredient Prescribing (AIP) which had previously been referred to as the International Non-Proprietary Name Prescribing Measure.

As part of the 2018-19 *"Improving Access to Medicines - encouraging greater use of generic and biosimilar medicines"* measure³, the Department has implemented a group of initiatives designed to improve prescribing practices within Australia by improving the timely transfer and provision of medicine information between medical professionals and changes to prescribing software to increase medication safety.

These initiatives include the Electronic Prescribing Initiative, Active Ingredient Prescribing Initiative and the Electronic Recording and Reporting of Controlled Drugs.

While these initiatives were announced and are funded under a broader Budget measure with similar timeframes, implementation is occurring separately.

When the program was originally introduced to the prescribing vendors MSIA assisted the Department in facilitating several teleconferences and a face to face workshop on 2 August 2018.

Subsequently the program has undergone significant refinements as an outcome of the co-design and input from a variety of stakeholders.

3.1 Regulatory change overview

The legislative amendments are tabled under *"The National Health (Pharmaceutical Benefits) Amendment (Active ingredient Prescribing) Regulations 2019"*⁴ and *"The Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019"*⁵ and *"The National Health (Pharmaceutical Benefits) Amendment (Active ingredient Prescribing) Regulations 2020"*

These regulatory amendments require the inclusion of active ingredient name(s) on all RPBS/PBS prescriptions and allow for the identification of a brand if the prescriber deems this to be clinically appropriate for the treatment of their patient.

Where the brand name is included, the active ingredient(s) must appear first.

The Department of Veterans' Affairs has also amended RPBS legislation for RPBS items to include the same conditions as the PBS legislation for AIP.

3.1.1 Extension of transition period

A further regulatory amendment was made in August 2020 to extend the transition period from 1 November 2020 to 1 February 2021 to allow adequate time for the changes to be rolled out to prescribers to ensure that prescriptions shall comply with all legislative requirements from this date.

³ <https://www1.health.gov.au/internet/budget/publishing.nsf/Content/budget2018-factsheet13.htm>

⁴ <https://www.legislation.gov.au/Details/F2019L01312>

⁵ <https://www.legislation.gov.au/Details/F2019L01387>

3.1.2 Inclusion of the Brand as a Default is prohibited

The legislative changes also stipulate that computer programs used to generate PBS/RPBS prescriptions must not apply the brand to prescriptions by default.

The prescriber must make a clinical decision on the application of the brand name for prescriptions in various circumstances. Refer to section 10.2 for further details of the legislation.

3.1.3 Exemptions

The legislative amendments also enable the Secretary of the Department to determine some pharmaceutical benefits as exempt from active ingredient prescribing requirements.

These items will be determined by the Department in consultation with the ACSQHC as described in the Guidelines for Active Ingredient Prescribing (See references to "LMBC" and "LEMI" section 4.2.1).

3.1.4 Timetable for Implementation

The implementation of these amendments was originally scheduled to be released over a twelve month transitional period commencing 31 October 2019. However, in recognition of the impact of the Australian bushfires and COVID-19 on some vendors and their capacity to implement AIP changes by 1 November 2020, the Department has extended the implementation timeframe for AIP. Prescribing software are now required to comply by 1 February 2021. Vendors are still encouraged to deploy updated prescribing software to support AIP changes as soon as possible.

4 Project Background Details

The MSIA will provide support services to the software vendors to ensure that the appropriate changes to their software products are implemented to enable prescribing by *active ingredient* with or without the inclusion of brand name on the prescription as deemed appropriate by the prescriber (for medicinal items in scope).

4.1 Universal Nature of this Program:

It is clearly understood that the AIP legislative amendments under the *National Health (Pharmaceutical Benefits) Regulations 2017* apply to PBS/RPBS drugs. As the ACSQHC, ADHA, TGA and jurisdictions are supportive of these principles extending to all prescriptions, prescribing vendors should not interpret the scope as being limited to the prescribing of PBS/RPBS items only.

4.2 ACSQHC Role

To support implementation, the ACSQHC was engaged by the Department in July 2019 to develop "Guidelines for Active Ingredient Prescribing". The guidelines will provide best practice recommendations to support prescribers' clinical decision making and patient safety relating to AIP.

Please also refer to section 5.7 relating to consistency of formatting of medicine names.

Guidelines for Active Ingredient Prescribing

These guidelines will align with existing recommendations for medicines information display such as the ACSQHC's *Recommendations for Terminology, Abbreviations and Symbols used in medicines documentation*⁶ and the electronic display of active ingredient and brand name as described in the *National Guidelines for On-Screen Display of Medicines Information*⁷.

These guidelines will assist prescribers in making appropriate clinical decisions regarding the specification of the brand name following the active ingredient.

Following extensive consultation with stakeholders, two Drug Lists have been developed to support prescribers:

- The List of Medicines for Brand Consideration (LMBC) to be distributed by ADHA as an AMT reference set; and
- The List of Excluded Medicinal Items (LEMI).

4.2.1 List of Medicines for Brand Consideration - (LMBC)

This list identifies medicines for which prescribers should consider if the inclusion of the brand name on the prescription is necessary for their patient.

A drug's inclusion on the LMBC is intended as a guide to support clinical decision making only and is not to be used as an absolute dictum which prescribers must follow.

The decision to include a brand name on a prescription for any drug will be made by the prescriber based on the appropriate clinical outcome for the patient.

Note:

- The LMBC list will be distributed by ADHA via an AMT Reference Set, such that items in the list are identified via their MPP AMT Id in the same format as the controlled drugs AMT reference set (developed for Real Time Prescription Monitoring - RTPM).
- The monthly PBS/RPBS data released by PharmCIS⁸ includes a text file "amt_ccyymm01.txt" containing the MPP AMT identifiers for all PBS/RPBS drugs.

⁶ <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/recommendations-terminology-abbreviations-and-symbols-used-medicines-documentation>

⁷ <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-guidelines-screen-display-medicines-information>

⁸ <https://dev.pbs.gov.au/embarqo/index.html>

4.2.2 Considerations for Prescribing LMBC Drugs

Where an LMBC item has been selected:

- and the prescriber has NOT intentionally nominated a brand
- and the prescriber has not been previously prompted during this prescribing event to consider including a brand;

the software should prompt the prescriber to consider if the inclusion of the brand name on the prescription is necessary for the clinical treatment of their patient.

4.2.3 Difference between RLDBI and LMBC

In prior versions of the VRD this concept was previously described by the acronym "RLDBI" (Recommended list of drugs for brand inclusion). It has since been determined that, as there are many scenarios in which it would be appropriate to prescribe these items by active ingredient without brand (particularly for treatment naïve patients). Any prompts should suggest a prescriber **consider** the inclusion of brand name on a prescription, if appropriate for their patient. There should **not** be any prompts that **recommend** the inclusion of a brand name.

4.2.4 List of Excluded Medicinal Items (LEMI)

The Department and the Commission are also identifying a List of Excluded Medicinal Items (LEMI).

The LEMI identifies drugs which are excluded under the AIP legislation from the mandated requirement to include the active ingredient names(s) on the prescription, and which therefore may be prescribed by the brand name only.

4.2.5 Clarification of Reference Set Status for LEMI:

As these drugs are specifically nominated by the legislation or identifiable by the classes, general terminology or the scenarios under which their prescribing occurs, the LEMI drugs are not subject to individual MPP identification via an AMT reference set.

Please refer to section 6 for an explanation of the prescribing rules and situations that are covered by these exclusions where the drug prescribed may be identified by the brand name only.

4.2.6 Incorporation of best practice guidelines and clinical decision making support within prescribing software

Prescribing software vendors should support clinical decision-making and patient safety by incorporating the Guidelines for Active Ingredient Prescribing, LMBC and LEMI.

4.3 Communications Support

The Department has committed to undertake communication and education activities with the medical industry and consumer awareness to support the implementation of AIP changes.

The Department has engaged NPS MedicineWise to facilitate communication and education activities for prescribers and consumers.

The Generic and Biosimilar Medicines Association (GBMA), Australian Medical Association (AMA), Medicines Australia (MA), Royal Australian College of General Practitioners, Consumers Health Forum of Australia, Pharmaceutical Society of Australia, Society of Hospital Pharmacies Australia and the Australian College of Rural and Remote Medicines have also agreed to facilitate communication to their members.

4.4 Pharmacy Dispensing Vendors

In addition to the support provided to prescribing software vendors, MSIA will be in communication with the dispensing vendors during the implementation. However, it is noted that pharmacy dispensing software generally supports the AIP requirements.

5 Guidelines for Implementation

This section re-iterates the implementation of the regulations associated with common prescribing situations.

5.1 Reminder of prescriber defaults supported by the software

Existing legislation specifically regulates that prescribing computer programs can not include a default to disallow brand substitution.

A similar provision is included in the regulatory amendments for AIP and prohibits prescribing software from automatically including brand names on prescriptions by default, to ensure doctors make a clinical decision regarding the inclusion of the brand. (Ref para 3.1.2)

5.2 Scenarios for On Screen Drug Selection

The recommendations are agnostic in terms of the process to be followed when the prescriber selects the drug.

Drugs may be selected either by brand name or by active ingredient name.

Several scenarios are explored below:

5.2.1 Prescriber selects the drug by Active Ingredient

As a specific brand has NOT been selected, the active ingredient name(s) only are to be included on the prescription.

However, as detailed in paragraph 4.2.1, if the medicine is on the LMBC, the prescribing software should prompt the prescriber "*to consider*" if the inclusion of the brand is clinically appropriate for their patient.

Where software vendors include a prompt in their software for medicines identified on the LMBC, the prompt should emphasise this distinction.

A recommendation is to include the wording 'Is brand name clinically necessary?', followed by 'yes' or 'no' options to indicate whether a brand name should be printed.

5.2.2 According to the presentation provided by the software vendor, the screen may display the originator brand and the generic brands if available. Prescriber selects the drug by Brand

The prescription must still include the active ingredient name(s) with the exception of the LEMI items as described in section 4.2.4.

The design of the workflow or screen presentation remains with the software vendor; however, the following updated regulation may impact this presentation.

5.2.3 The prescriber must make a clinical decision on the application of the brand name - Impact of this regulation

A prescriber selecting a brand name from a drop down menu is not equivalent to a decision to include a brand name on the prescription.

If the prescriber has not already been prompted during this prescribing event they should be prompted to consider if the inclusion of the brand is clinically appropriate for the treatment of their patient.

If a prescriber does not indicate that the prescription should include the brand name, the medicine should be prescribed by active ingredient name(s) only.

Alternatively, if the prescriber has indicated that inclusion of a brand name is suitable in this prescribing incidence, the active ingredient name(s) must still be included on the prescription, and before the brand name.

Note: Please refer to the discussion in para 5.3 associated with the "Brand Substitution not permitted" tick box for the exclusion which applies for that scenario.

A recommendation is to include a *tick box* or a *Yes/No prompt* that highlights the brand the prescriber used to select the drug including its active ingredient(s). The prompt should ask the prescriber if it is clinically appropriate for the brand selected to be included on the prescription with the active ingredient(s).

Reminder: Refer to para 3.1.2 prohibiting the use of a default in this situation.

5.3 "Brand substitution not permitted"

Brand substitution by a pharmacist is valid between brands identified in the Schedule of Pharmaceutical Benefits that are equivalent for the purposes of substitution and may be interchanged without differences in clinical effect.

Therefore, it is only valid to tick the "brand substitution not permitted" box on the prescription if alternate brands are available to the one selected and the brand selected is the brand that must be dispensed for the patient.

If alternate brands are available and the box is ticked by the prescriber, the prescription must still include the active ingredient name(s) before the brand name with the exception of the LEMI items described in section 4.2.4.

But, as the prescriber has specifically nominated the brand, via the "brand substitution not permitted" box, a confirmation of the inclusion or otherwise of the selected brand as described in section 5.2.3 is NOT required.

5.4 Scenario where alternate brands are non-Bioequivalent

This section is best described by using the example of **warfarin** for which Coumadin and Marevan are listed and where it has been established that these brands are non-Bioequivalent.

The identical scenarios raised in this section apply equally to **clozapine**.

Section 5.4 has been included to specifically acknowledge the issues raised by PBAC, the practitioners and the jurisdictional Health Authorities relating to medicines such as **Warfarin** and **Clozapine** which specifically address the importance of maintaining the patient on a brand-specific version of the medicine.

5.4.1 Support information published by NPS MedicineWise®

Please refer to NPS MedicineWise® publication:

www.nps.org.au/australian-prescriber/articles/warfarin-tablets.

Brand substitution is only valid where identified in the Schedule of Pharmaceutical Benefits. Pharmacists should be well aware of this, particularly in relation to warfarin. The PBAC has recommended that a cautionary note be added to the PBS listing for all warfarin brands and strengths as follows:

'Caution: The listed brands have not been shown to be bioequivalent and should not be interchanged.'

The responsibility of the doctor is to prescribe by brand name (not generic name) to ensure patients continue to receive the same brand of warfarin.

It is noted that the PBAC recommended "Caution Statement" has been included for all listings of **warfarin** on the PBS.

Further, neither the "a" or "b" flags are included in the PBS listings, thereby indicating that brand substitution is NOT an option for these medicines.

In this example, all drugs containing the active ingredient *Warfarin* or *Clozapine* will be included on the LMBC list.

Please Note:

Unless specific jurisdictions regulate to the contrary, the active ingredient must still be included on the prescription for *Warfarin* (and *Clozapine*).

The following formatting example for Warfarin has been provided by the ACSQHC: **Warfarin sodium 2 mg (COUMADIN) – tablet Qty: 50**

5.4.2 Prescriber selects the drug by active ingredient name

If the prescriber had selected the item by ingredient name (*Warfarin in this example, also noting its inclusion on the LMBC*), the program MUST alert the prescriber to consider if the prescription should include the brand of *Warfarin* prescribed, the process of which is detailed in section 4.2.1.

5.4.3 Prescriber selects the drug by Brand

It is a requirement to include the active ingredient name prior to the brand.

5.5 F1 Medicines

Prescriptions for F1 medicines (i.e. Originator products for which no generic alternative is available) must also include the active ingredient(s) first with the requirement that the prescriber must specifically indicate if the brand name is to be included on the prescription - see section 5.2.3.

5.6 Practical issues associated with the formatting of printed prescriptions

PBS regulations specify that a single prescription form may include a maximum of up to three prescribed drugs unless the drug is an Authority Required or Section 100, or as otherwise nominated as "one prescription per page" by the jurisdiction.

The practical implementation of the "Brand substitution not permitted" tick box requires that where the prescriber has nominated this provision, it will require the "one prescription per page" scenario to be implemented.

Another practical scenario which may also limit the number of drugs included on a single prescription form will follow as a result of the increased space required to specify each drug prescribed, given that the active ingredients will normally be included.

5.7 Importance of Consistency

The ACSQHC *Guidelines for On-Screen Display of Medicines* highlights the importance of consistent presentation of medicines information wherever it is visible to consumers. It is recommended that vendors consider the formatting of prescriptions, and how pharmacy dispense labels will represent this information to ensure that active ingredient name(s) and the brand name utilise consistent formatting.

Where a medicine has multiple active ingredients or different salts vendors might consider having the brand name appear in capital letters as well as brackets (eg. "Warfarin sodium 2 mg (COUMADIN)"), or for the brand name to be bolded (eg. "Warfarin sodium 2 mg (**Coumadin**)").

This is a standard which can be consistently implemented between prescribing and dispensing prescription presentations for patients.

The evidence suggests that use of consistent presentation greatly increases consumer safety.

6 Situations excluded under the Active Ingredient Prescribing Legislations (LEMI)

This section describes the medicines and prescriptions excluded under the PBS and RPBS AIP legislation, and where the active ingredient name(s) are NOT mandated thereby allowing the medicinal item to be prescribed by the brand name only. These are:

- Handwritten prescriptions.
- Prescriptions with **four or more** active ingredients ⁹
- Items listed under the "VARIOUS" section of the General PBS Schedule including:
 - Allergens
 - Diagnostic Agents
 - General Nutrients, Food Supplements, Vitamin Supplements
 - Wound Assessment and Dressing Section
- DVA has included Items listed under the "VARIOUS" section of the RPBS Schedule including:
 - Allergens
 - Diagnostic Agents
 - General Nutrients, Food Supplements, Vitamin Supplements
 - Other Non-Therapeutic Products
 - Wound Assessment and Dressing Section
- Computer generated paper based National Residential Medication Charts.
- Prescriptions generated by a prescriber through a free text function within prescribing software as detailed in paragraph 6.1.
- These requirements do not apply where it would contravene State or Territory legislation.

6.1 Free Text Function

Prescribing systems may include a free text facility (refer to Glossary and Abbreviations) to type the drug details for the prescription without reference to a drug lookup via the drug data base or drug master file.

Some systems also support a facility whereby such details may be stored in the prescriber's private non-vendor supported data base.

Where these facilities are used to unambiguously identify the prescriber's intention, the software shall include an indicator such as "*(free text)*" to allow the prescription to be differentiated from a conventional computer generated prescription to ensure that compliance with PBS regulations is evident.

Example: **Lipitor tabs 10 mg; Qty:30** ***(free text)***

⁹ Paragraph 40(2A)(a) (ii) Paragraph 40(2A) (a) (ii) the prescription is for the supply of a pharmaceutical benefit that has 4 or more drugs.

6.2 Re-Prescribe or Duplicate Script Functions

This is another common facility provided by some prescribing software systems, whereby the prescriber accesses the patient history and selects a script in the history to create a new prescription identical to the one selected.

It is important to ensure that the re-prescribed item must follow the current AIP rules and not the rules as saved when previously prescribed.

6.3 Other prescribing situations where the inclusion of active ingredients is recommended but not mandatory

Prescribers are encouraged to include the active ingredients but the inclusion is not mandated under the following situations:¹⁰

- Products that have not been approved by TGA for use in Australia¹¹ including those accessed via:
 - The Special Access Scheme¹²
 - Medicinal cannabis products schemes¹³
 - Clinical Trials
 - Medicines accessed during a shortage

7 Guidelines on Recording Prescriptions

This section acknowledges the requirements for prescribers to keep accurate medical records.

These records need to accurately record medical events and information, including prescriptions, and therefore must reflect actual prescriptions generated and provided to patients. This includes active ingredients and brands where specified.

The requirement for accurate patient medical records is governed by state and territory legislation. Additionally, the A Medical Board of Australia's *Good Medical Practice: A Code of Conduct for Doctors in Australia*¹⁴ (the Code) provides specific guidance regarding making, storing and accessing medical records.

The Department expects vendors' products to assist prescribers in meeting their obligations under these laws and guidelines, and to ensure accurate records of prescriptions provided to patients are stored within prescribing software.

¹⁰ <https://www.humanservices.gov.au/organisations/health-professionals/topics/education-guide-prescribing-dispensing-and-claiming-hsd/32081>

¹¹ <https://www.tga.gov.au/accessing-unapproved-products>

¹² <https://www.tga.gov.au/form/special-access-scheme>

¹³ <https://www.tga.gov.au/access-medicinal-cannabis-products-using-access-schemes>

¹⁴ <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

7.1 Uploaded and Electronic Prescriptions

Where a healthcare provider uses conformant clinical software to either create an electronic prescription or uploads a copy of the prescription via ETP to a prescription exchange service, the electronic content must accurately record the prescriber's intention.

It follows that:

- If the prescription nominated the drug to be dispensed by the active ingredient(s) only, then the active ingredients only would be recorded in the electronic content.
- If the prescription included the active ingredient(s) followed by a nominated brand, then both the active ingredient(s) and the brand would be recorded in the electronic content.
- If the brand only was used to indicate the drug to be dispensed, then only the brand would be recorded in the electronic content.

There are no additional requirements for electronic prescriptions relating specifically to AIP. The Electronic Prescribing Solution Architecture and the Electronic Prescribing Participating Software Conformance Profile published by the ADHA¹⁵ details the prescription order items including the "*original text as presented*", the contents of which should be consistent with the above requirements.

8 References for Ingredient Medicinal Product Names

8.1 PharmCIS Electronic PBS/RPBS Data

For those vendors who obtain electronic drug PBS data directly from the monthly data published in the embargoed PharmCIS site "*Pharmaceutical Benefits Scheme for Software Developers*"¹⁶, there are several sources of the text for active ingredient names including the AMT MP "long numeric" concepts for PBS medicines linked via the PBS Item code.

- V3 PBS XML
- The Down-converted V2 PBS XML
- The Down-converted PBS TXT Extracts which and may be conveniently imported into Excel ¹⁷:
 - "amt_ccyymm01.txt" and
 - "drug_ccyymm01.txt"

¹⁵ <https://developer.digitalhealth.gov.au/user>

¹⁶ <https://dev.pbs.gov.au/embargo/index.html>

¹⁷ A publication is available to MSIA members which describes in detail how the above text files may be simply processed to allow the items to be imported.

8.2 The National Clinical Terminology Service (NCTS)

The AMT is released monthly as part of the SNOMED CT-AU releases. ¹⁸

This NCTS release includes the medicinal product names referenced by the AMT MP concepts for all prescribable Australian PBS and non-PBS drugs.

8.3 Other Sources

There are several alternative commercial and publicly available sources for this data available under subscription.

9 Recommendations for NON PBS Medicines

Communicating medicines information safely and consistently promotes quality use of medicines. Prescribing by active ingredient is best practice for all medicines. While the Department is only able to legislate and make recommendations concerning PBS/RPBS medicines, States and Territories have indicated guidelines should be expanded beyond PBS/RPBS items to all medicines.

Based on this premise, the NCTS AMT MP source for the ingredient name text referred to in para 8.2 is recommended.

10 Appendix

10.1 Brand substitution legislation in the *National Health (Pharmaceutical Benefits) Regulations 2017*:

For prescriptions:

Section 40(4):

For the purposes of paragraphs (2)(b), (c) and (d), a prescription must not be prepared using a computer program that operates, or may operate, to indicate on a prescription by default, for the purpose of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied.

For medication charts:

Section 41(2)(e)

using a computer program that operates, or may operate, to indicate on a prescription by default, for the purpose of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied.

10.2 Extract from regulations pertaining to this measure (Pharmaceutical Benefits) Regulations 2017:

The legislative amendments,
"*The National Health (Pharmaceutical Benefits) Amendment (Active ingredient Prescribing) Regulations 2019*"

¹⁸ <https://www.healthterminologies.gov.au/access>

"The Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019" and
The National Health (Pharmaceutical Benefits) Amendment (Active ingredient Prescribing) Regulations 2020".

are available on the Federal Register of Legislation's websites

<https://www.legislation.gov.au/Details/F2019L01312>

<https://www.legislation.gov.au/Details/F2019L01387> and

<https://www.legislation.gov.au/Details/F2020L01055>

[As these amendments have now been compiled \(i.e. incorporated\) into the relevant principal legislation, they are no longer in force. However, they provide a comprehensive summary of the changes made.](#)

An endorsed Explanatory Statement is also included to assist in interpreting the changes and provides additional background.

The following sections have been extracted from the PBS Explanatory Statement.

In the 2018-19 Budget, the Government announced the implementation of electronic prescribing from late 2019. This initiative included the implementation of active ingredient prescribing (AIP) to increase patient understanding of the medicines they are taking and promote the uptake of generic and biosimilar medicines, supporting a viable long term market for these medicines in Australia.

In order to increase understanding of active ingredients and support for generic and biosimilar medicines, the government committed to ensure the identification of active ingredient names on prescriptions, without impeding the professional and clinical judgment of prescribers.

The Regulations:

- require the inclusion of active ingredients on all PBS prescriptions (excluding handwritten prescriptions, paper-based medication charts in the residential aged care setting, prescriptions for medicines with four or more active ingredients and other items as determined by the Secretary for practicality and safety reasons);
- enable the inclusion of a brand on a prescription if deemed clinically necessary by the prescriber. This includes situations where the medication prescribed may pose a potential patient safety risk if the brand is not specified or to ensure medication continuance where a patient is familiar with a particular brand of their regular medicine;
- require active ingredients to appear first, where a prescriber makes a clinical decision to include a brand name on a prescriptions; and
- prohibit prescribing software from automatically including brand names on prescriptions by default, to ensure doctors make a clinical decision regarding the inclusion of brand.

These amendments do not interfere with patients' choice of medicines, or prescribers' ability to prescribe the medicine that best meets their patient's clinical need. To support prescribers' clinical decision regarding the inclusion of a brand, the Department of Health has engaged the Australian Commission on Safety and Quality in Healthcare (ACSQHC) to develop support documentation for prescribers, including Australian Guidelines for Active Ingredient Prescribing and a list of medicines where the inclusion of brand is recommended for patient safety.

The Regulations took effect from 31 October 2019; however, a transition period was provided to ensure prescribers had sufficient time to update prescribing software to versions which meet the new active ingredient prescribing requirements. Originally prescribing software was required to be compliant by 1 November 2020, however due to the significant additional workload within the clinical software industry due to the Australian Bushfires and COVID-19, this has been extended to 1 February 2021. The legislation was amended to reflect this change on 20 August 2020.

Active Ingredient Prescribing is part of a wider government strategy to ensure consistent and standardised medicines information. Presentation of the active ingredient name in all places where the consumer accesses medicines information is central to medication safety and this broader government strategy. The implementation of active ingredient prescribing is also identified as a joint commitment in the Department of Health's 2017 Strategic Agreements with the Generic and Biosimilar Medicines Association and Medicines Australia.

The Department of Health engaged in extensive consultation with peak clinical and industry bodies regarding the implementation of active ingredient prescribing. The Department developed the active ingredient prescribing implementation strategy through a co-design approach with industry, including clinicians, consumer groups, clinical software vendors and the pharmaceutical industry. The Department consulted directly with Services Australia, the Department of Veterans' Affairs, the Therapeutic Goods Administration and the ACSQHC which are supportive of this initiative. The Department also consulted with state and territory governments, which are also supportive.

Subsection 40(2C) ensures that these requirements do not apply where it would contravene State or Territory legislation.

10.3 Format of the RLDBI Reference Set

The specifications for the interpretation of this reference set and the distribution frequencies will be provided by ADHA.

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