AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

FACT SHEET
for clinicians

Active ingredient prescribing

Guidance for Australian prescribers

What is active ingredient prescribing?

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.

Active ingredient prescribing uses standardised International Non-proprietary Names (INN) for medicines and will apply for most Pharmaceutical Benefits Scheme (PBS)/Repatriation Pharmaceutical Benefits Scheme (RPBS) items. There are exceptions including handwritten prescriptions, paper-based medication charts in the residential aged care sector, and medicinal items with four or more active ingredients.

The principles for active ingredient prescribing mandated for PBS items extend to private prescriptions.

When will it be implemented?

From 1 February 2021 most prescriptions generated for supply under the PBS and the RPBS must meet the revised arrangements to be eligible for subsidy.

Why did it happen?

Active ingredient prescribing will:

- Increase consumer health literacy around their medicines and make communication clearer and unambiguous
- Improve safe and quality use of medicines with consistent and standardised descriptions of medicines
- Empower and equip prescribers and consumers to better understand the active ingredients in medicines
- Assist conversations between pharmacists and consumers concerning generic and biosimilar alternatives
- Promote the appropriate uptake of generic and biosimilar medicines, with a decrease of out-of-pocket expenses for some consumers
- Improve financial sustainability of the PBS and RPBS
- Enhance prescribers' stewardship role of the PBS, and encourage more sustainable prescribing practices
- Align Australian prescribing with international practices.

Who is affected?

All health professionals with prescribing rights to PBS and RPBS medicines, including medical practitioners and nurse practitioners, are required to follow the principles of active ingredient prescribing.

Changes to prescribing software will facilitate prescription preparation with the active ingredient name. The brand name should be included after the active ingredient on prescriptions where clinically necessary.

The Medical Software Industry Association has developed a vendor resource document for prescribing software developers to ensure appropriate changes to software products are implemented. Clinical software systems will enable prescribing by active ingredient with or without the inclusion of the brand name on the prescription as deemed appropriate by the prescriber.

12/2020

How will it be implemented?

The Australian Commission on Safety and Quality in Health Care (the Commission) has been engaged by the Australian Government Department of Health to generate and maintain the following active ingredient prescribing clinical support documents:

- ***Active ingredient prescribing – User guide for Australian prescribers*** (user guide)[1]
- **List of Medicines for Brand Consideration** (LMBC)[2]
- **List of Excluded Medicinal Items** (LEMI)[3].

The user guide describes principles for active ingredient prescribing and identifies some situations and/or medicines where prescribers should consider if specifying the brand name is clinically necessary for the safe treatment of their patient. For example, in situations where formulations are not interchangeable due to variations in delivery of the active ingredient, prescribers should consider specifying brand names to prevent the risk of medication-related harm. To facilitate this, clinical software systems will alert prescribers when a prescribed medicine is on the LMBC. The alert will advise the prescriber to consider what should be included on the prescription for patient safety.

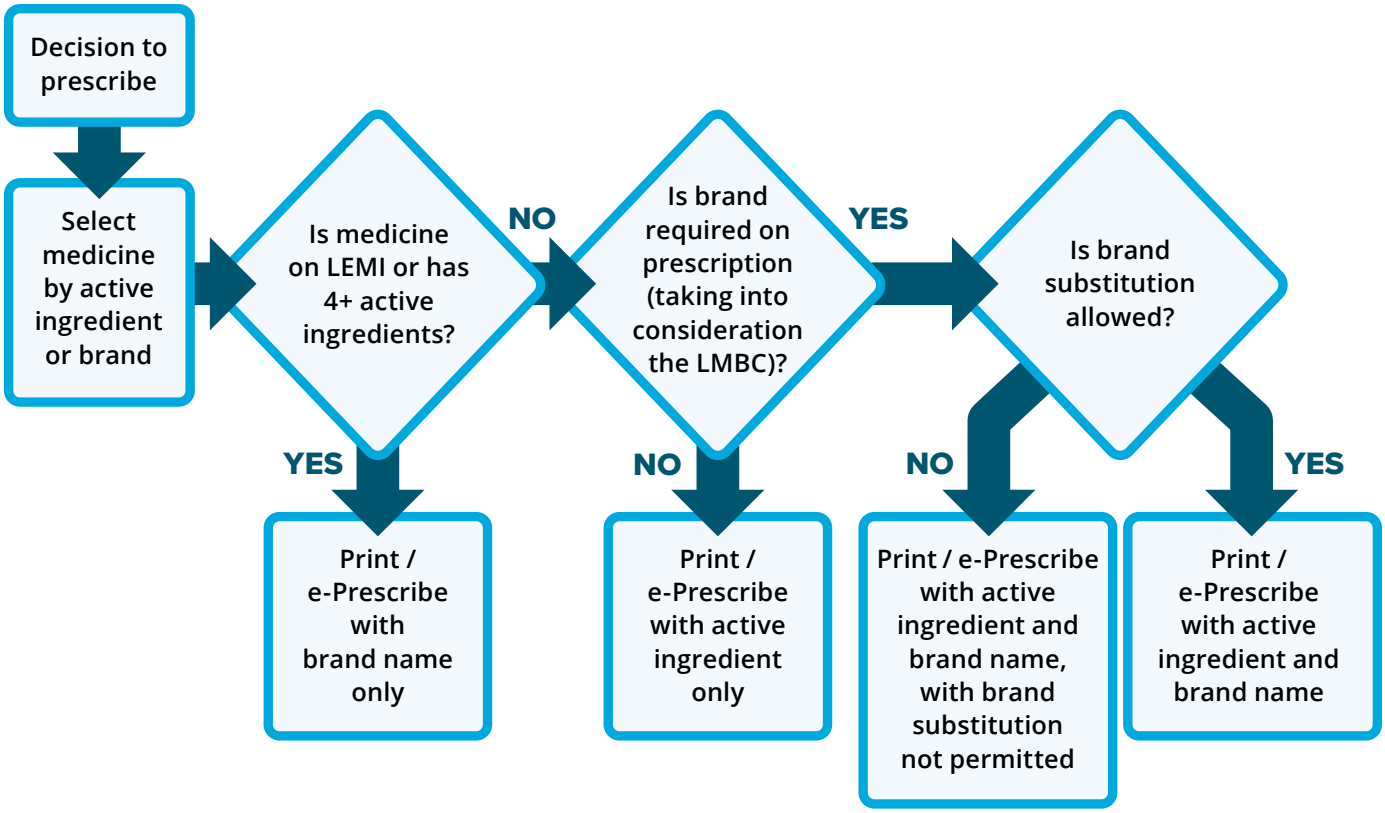
How are prescribing decisions affected?

The decision to prescribe and supply a particular brand of a medicine remains the choice of the prescriber as part of a shared decision-making process with the patient. Prescribers can also indicate if brand substitution is not permitted, taking into consideration the clinical needs of their patient. Where brand substitution is allowed the patient can then select the brand of medicine they would like, in consultation with their pharmacist.

Figure 1 sets out an example of a prescribing decision process under the active ingredient prescribing changes.

Prescribing using the active ingredient name is safe in the majority of prescribing situations where available brands are considered therapeutically equivalent. Exceptions to this approach are limited but important, and best practice guidance for active ingredient prescribing is provided to support safe and quality use of medicines.

Figure 1: Prescriber decision process following 1 February 2021



When and why should brand names be used?

In some circumstances, it is preferable to prescribe a medicine by brand name in addition to the active ingredient name for clinical reasons and/or patient safety[4]. This is particularly important for some high-risk medicines, for high-risk consumers and/or high risk situations. The LMBC lists medicines recommended for consideration of brand specification to prevent serious incidents and consumer harm.

From a safety perspective, it is also important to recognise that some 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.

Other circumstances where it may be preferable to prescribe by brand name in addition to the active ingredient include:

- Avoiding miscommunication between clinicians
- Preventing selection error
- Ensuring accuracy interpreting and dispensing the order.

Exceptions where switching between brands is not recommended are annotated within the LMBC. Intentional one-off switching from one brand to another for these products may still be achievable under controlled situations with dose titration, close monitoring, caution and the agreement of the consumer and/or carer. Principles for prescribing by active ingredient plus brand name are described in **Box 1**.

Box 1: Prescribing by brand name in addition to active ingredient name

Prescribing by brand name in addition to active ingredient name should be considered where:

1. Products are not therapeutically equivalent, or have not been assessed as being therapeutically equivalent. This includes active ingredients with multiple brand substitution groups (i.e. '■a' and '▲b' groupings)
2. Medicines have a narrow therapeutic index and minor changes in bioavailability may be clinically important. That is, small changes may result in toxicity or sub-therapeutic dosing which would have a clinically significant impact on outcome
3. Different formulations of the same active ingredient have different dosing and/or rates of administration
4. Different formulations of the same active ingredient have different release characteristics. This includes modified release formulations
5. Different brands have different dosing regimens for the same indications
6. Different brands have different dosing regimens for different approved indications
7. Similarity of active ingredient names will likely cause confusion
8. Administration 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 as Highly Specialised Drugs on the PBS/RPBS, require prescriptions that have been authorised in accordance with certain Authority Required procedures
10. Medicines not approved for use in Australia can be accessed by consumers and prescribers. This includes Special Access Scheme medicines.

Circumstances where prescribing should be by brand only are included in the LEMI, and are described in **Box 2**.

Box 2: Prescribing by brand name

Prescribe by brand name only where:

- Products contain four or more active ingredients (mandatory)
- Vaccines have varying strains, components or immunisation regimens (see LEMI)
- Items are non-medicinal items, listed under the 'Various' section of the General PBS Schedule or RPBS Schedule. These include items such as non-absorbed treatments, bandages tapes and dressings, allergens, diagnostic agents, oral rehydration salts, general nutrients, food supplements and vitamin supplements (see LEMI)
- Inclusion of active ingredients has been deemed impractical (for example, dermatologicals, ocular lubricants) or unsafe (for example, ophthalmologicals) or confusing (for example, triple therapy to treat H. pylori).

Further details on active ingredient prescribing are provided in the *Active ingredient prescribing – User guide for Australian prescribers*.

What needs to happen by 1 February 2021?

It is recommended that prescribers:

- Implement clinical software systems which conform with PBS/RPBS active ingredient prescribing legislative requirements by 1 February 2021
- Adopt the guidelines for active ingredient prescribing into their practice
- Become familiar with the active ingredient prescribing principles and LMBC to understand when prescribers should consider specifying the brand name on a prescription, depending on the clinical need of their patient
- Advise and counsel patients about the use of active ingredient terminology to enhance communication and health literacy
- Encourage the uptake of generic and biosimilar medicines when appropriate by providing assurances and information regarding their bioequivalence and suitability.

References

1. Australian Commission on Safety and Quality in Health Care. Active ingredient prescribing user guide. Sydney ACSQHC 2020.
2. Australian Commission on Safety and Quality in Health Care. List of Medicines for Brand Consideration (LMBC). Sydney, ACSQHC 2020.
3. Australian Commission on Safety and Quality in Health Care. List of Excluded Medicinal Items (LEMI). Sydney, ACSQHC 2020.
4. Straka RJ, Keohane DJ, Liu LZ. Potential clinical and economic impact of switching branded medications to generics. American J Therapeutics (2017); 24(3):e278–e289.

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