Active Ingredient Prescribing Rules

Reading time:
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Date created: 28/07/2021

Tags: Medico-Legal | Medical Practitioner | Dental Practitioner | General Surgery



From 1 Feb 2021, under the National Health (Pharmaceutical Benefits) Regulations 2017 (the Principal Regulations) Active Ingredient legislation, it is mandatory for the prescription of medicines to be listed by their active ingredient. Healthcare practitioners must include the active ingredient names when preparing prescriptions for Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS) medicines. This will mean most medicines will be prescribed by their active ingredient, not the brand name. It is important to understand the key concepts of this initiative and the impact it will have on prescribing workflows.

What is Active Ingredient prescribing?

Active Ingredient prescribing announced by the Australian Government is an initiative that is aimed to ensure consistent and standardised medicines information, to support safe and appropriate use of medicines. It aims to promote better patient understanding of the medicines they take and to encourage the use of generic medicines.

What are the changes to the prescription of medicines?

The legislation mandates that prescriptions itemise active ingredients by default, rather than brand names.

What are the exceptions to Active Ingredient prescribing?

- · Handwritten prescriptions
- Prescriptions generated through a free text function within a prescribing software
- Custom preparations
- Paper-based medication charts in aged care facilities
- Over the counter medication
- · Nonmedicinal items, such as dressings and food supplements

- · Prescriptions for medications with four or more active ingredients
- Vaccines

How and where should I document my decision to specify a brand in my prescription?

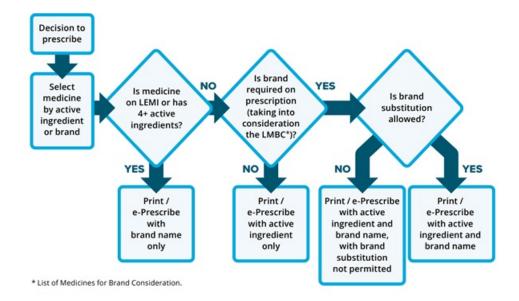
Decisions to specify a brand (either originator, branded generic or biosimilar) should be documented in the patient's health record, including My Health Record to ensure patient treatment continuity.

How will my prescribing workflows change under the new active ingredient prescribing rules?

The Australian Commission on Safety and Quality in Health Carerecommends these steps:

- 1. Search for and select the medicine according to your software. This may involve keying in the first letters of the active ingredient or the originator brand depending how the software is configured.
- 2. Once the medicine is selected, the prescription stating the active ingredient name of the medicine can be prepared. A prescriber may also consider if it is clinically necessary to specify the brand of the medicine. In this case, 'include brand name' is selected within the prescribing software.
- The prescription will then be generated to state the active ingredient (followed by a brand if indicated as necessary by the prescriber). Prescribers can also indicate if brand substitution is not permitted, taking into consideration the clinical needs of their patient.

Below is prescriber decision process diagram under the new changes, recommended by the Australian Commission on Safety and Quality in Health Care.



Where can I find a list of medicines that require a 'brand name plus active ingredient' or 'brand name only' prescription?

The Australian Commission on Safety and Quality in Health Care published a List of Medicines for Brand Consideration (LMBC) and a List of Excluded Medicinal Items (LEMI). The lists have been developed to assist prescribers in making good clinical prescribing decisions and meet the new legislative requirements for active ingredient prescribing.

The LMBC describes medicines recommended for consideration of brand specification to prevent serious incidents and consumer harm and exceptions where switching between brands is not recommended.

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