Active Ingredient Member Webinar
Thursday 14 January 2021

Host A/Prof Chris Pearce (FACRRM)

Panel

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Australian College of Rural & Remote Medicine
WORLD LEADERS IN RURAL PRACTICE

ACRRM acknowledges Australian Aboriginal People and Torres Strait Islander People as the first inhabitants of the nation. We respect the traditional owners of lands across Australia in which our members and staff work and live, and pay respect to their elders past, present and future.

Active Ingredient Prescribing (AIP) Jenene Baker DoH

Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS) legislation has been changed to require the inclusion of active ingredient name(s) on new PBS and RPBS prescriptions from 1 February 2021, except for:

- handwritten prescriptions;
- Prescriptions generated using a 'free-text' function within software;
- paper-based medication charts in residential aged care; and
- a small number of PBS and RPBS items which should be prescribed by brand name only for safety or practicality reasons (i.e. medicinal foods, multivitamins, wound dressings, etc.)

AIP conformant versions of prescribing software are now available, which automatically include active ingredients on prescriptions. Prescribers need to update their prescribing software by 1 February 2021.

Preserving Clinical Decision Making

Preserving prescribers' and consumers' choice of medicine has been a major consideration throughout the development of the implementation strategy for Active Ingredient Prescribing (AIP).

- Prescribers can still choose a specific brand of medicine for their patient.
- Prescribers can still include a brand name on the prescription wherever clinically necessary for the treatment of their patient. Where a brand name is included on a prescription, the active ingredient name(s) will appear first.

Where brand substitution is allowed, consumers can still choose their preferred brand at time of supply.

What Prescribers need to do

- Update prescribing software before 1 February 2021, to ensure you are using a version which supports active ingredient prescribing.
- Capability has been built into your clinical information system. Contact your software provider directly to find out about how to upgrade your software to the latest version that has AIP capability.
- Subscribe to your software provider newsletters and correspondence.
- Stay up to date with communication from clinical peak organisations.

Where can I get more information?

A range of educational and communication materials have also been developed to assist prescribers, pharmacists and consumers to understand the changes to prescribing. These are available:

- On the PBS website
- On the NPS MedicineWise website
- On the Royal Australian College of General Practitioners website
- On the Australian College of Rural and Remote Medicine website
- On the Australian Medical Association website

Australian Commission on Safety and Quality in Healthcare Active ingredient prescribing resources

- Resources developed by the Australian Commission for Safety and Quality in Health Care:
  - *The Active ingredient prescribing – User guide for Australian prescribers*
  - *The List of Medicines for Brand Consideration* *(LMBC)*
  - *The List of Excluded Medicinal Items* *(LEMI)*
  - *Fact Sheet: Active ingredient prescribing*

Fact sheet – Principles for prescribing by active ingredient plus brand name

Box 1: Prescribing by brand in addition to active ingredient 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; or
10. Medicines not approved for use in Australia can be accessed by consumers and prescribers. This includes Special Access Scheme medicines.

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Fact sheet – Circumstances where prescribing should be by brand name only

Box 2: Prescribe by brand 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)

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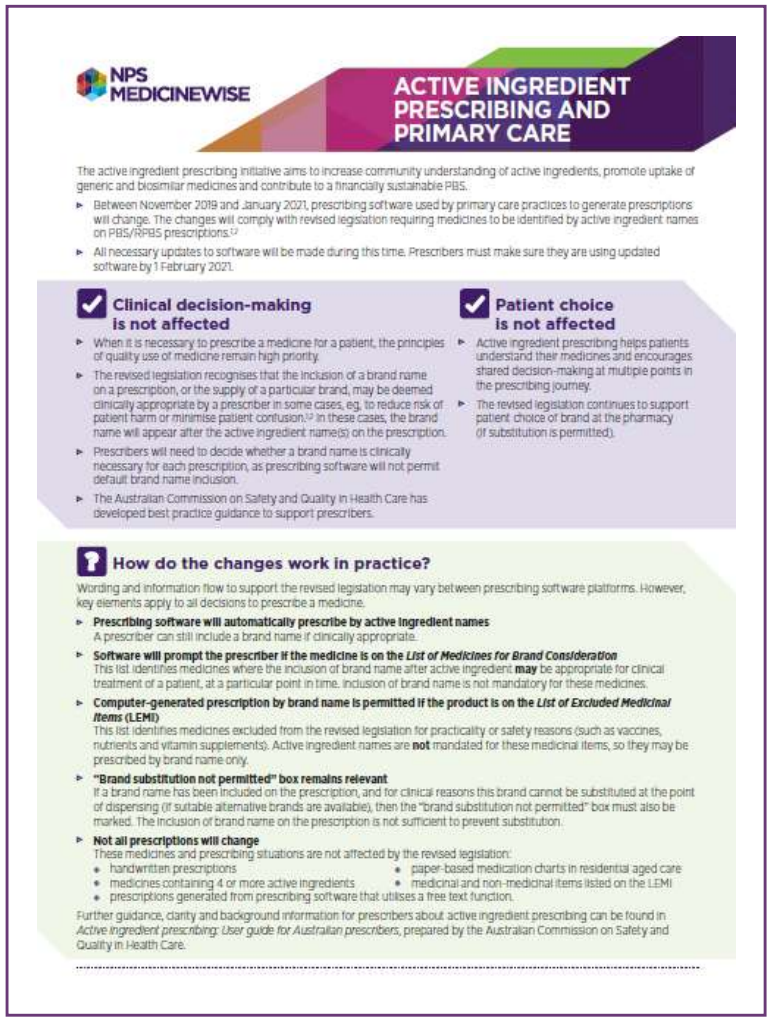
NPS MedicineWise Support Resources

- The NPS MedicineWise active ingredient prescribing website hub has:
  - Information and links to further reading about active ingredient prescribing
  - A consumer article, ‘Active ingredient prescribing: All you need to know’
  - Leave-behinds (A4 fact sheets) for prescribers and for pharmacists (also attached to this email)
  - https://www.nps.org.au/active-ingredient-prescribing



NPS MEDICINEWISE

ACTIVE INGREDIENT PRESCRIBING AND PRIMARY CARE

The active ingredient prescribing initiative aims to increase community understanding of active ingredients, promote uptake of generic and biosimilar medicines and contribute to a financially sustainable PBS.

- Between November 2019 and January 2021, prescribing software used by primary care practices to generate prescriptions will change. The changes will comply with revised legislation requiring medicines to be identified by active ingredient names on PBS/RPBS prescriptions.[2]
- All necessary updates to software will be made during this time. Prescribers must make sure they are using updated software by 1 February 2021.

Clinical decision-making is not affected

- When it is necessary to prescribe a medicine for a patient, the principles of quality use of medicine remain high priority.
- The revised legislation recognises that the inclusion of a brand name on a prescription, or the supply of a particular brand, may be deemed clinically appropriate by a prescriber in some cases, eg, to reduce risk of patient harm or minimise patient confusion.[2] In these cases, the brand name will appear after the active ingredient name(s) on the prescription.
- Prescribers will need to decide whether a brand name is clinically necessary for each prescription, as prescribing software will not permit default brand name inclusion.
- The Australian Commission on Safety and Quality in Health Care has developed best practice guidance to support prescribers.

Patient choice is not affected

- Active ingredient prescribing helps patients understand their medicines and encourages shared decision-making at multiple points in the prescribing journey.
- The revised legislation continues to support patient choice of brand at the pharmacy (if substitution is permitted).

How do the changes work in practice?

Wording and information flow to support the revised legislation may vary between prescribing software platforms. However, key elements apply to all decisions to prescribe a medicine.

- **Prescribing software will automatically prescribe by active ingredient names**
  A prescriber can still include a brand name if clinically appropriate.
- **Software will prompt the prescriber if the medicine is on the *List of Medicines for Brand Consideration***
  This list identifies medicines where the inclusion of brand name after active ingredient **may** be appropriate for clinical treatment of a patient, at a particular point in time. Inclusion of brand name is not mandatory for these medicines.
- **Computer-generated prescription by brand name is permitted if the product is on the *List of Excluded Medicinal Items* (LEMI)**
  This list identifies medicines excluded from the revised legislation for practicality or safety reasons (such as vaccines, nutrients and vitamin supplements). Active ingredient names are **not** mandated for these medicinal items, so they may be prescribed by brand name only.
- **"Brand substitution not permitted" box remains relevant**
  If a brand name has been included on the prescription, and for clinical reasons this brand cannot be substituted at the point of dispensing (if suitable alternative brands are available), then the "brand substitution not permitted" box must also be marked. The inclusion of brand name on the prescription is not sufficient to prevent substitution.
- **Not all prescriptions will change**
  These medicines and prescribing situations are not affected by the revised legislation:
  - handwritten prescriptions
  - medicines containing 4 or more active ingredients
  - prescriptions generated from prescribing software that utilises a free text function.
  - paper-based medication charts in residential aged care
  - medicinal and non-medicinal items listed on the LEMI

Further guidance, clarity and background information for prescribers about active ingredient prescribing can be found in *Active ingredient prescribing: User guide for Australian prescribers*, prepared by the Australian Commission on Safety and Quality in Health Care.