

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020

Authority

Section 140 of the *National Health Act 1953* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

This instrument makes minor amendments to the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). This instrument changes the date that applies in relation to a prescription supply of a pharmaceutical benefit that is written before 1 November 2020 under subsection 102(1) of the Principal Regulation, by changing the date to 1 February 2021.

Background

The Pharmaceutical Benefits Scheme (PBS) is established under the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Paragraph 89(a) of the Act relevantly provides that a person is not entitled to receive a pharmaceutical benefit supplied by an approved pharmacist unless the supply is made on presentation of a prescription written by a PBS prescriber in accordance with the Act and the Principal Regulations. PBS prescribers include approved medical practitioners, dentists, optometrists, midwives and nurse practitioners.

Section 105 of the Act provides that the regulations may specify terms and conditions relating to the supply of pharmaceutical benefits and provides rules about writing prescriptions for the purposes of the PBS.

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 Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

The Principal 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) from 1 February 2021.
- 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 a brand name.

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 (the Department) 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 commence the day after registration and will extend the original start date of 1 November 2020 by three months to the new start date of 1 February 2021. This will allow software vendors and prescribers sufficient time to update prescribing software to versions which meet the new active ingredient prescribing requirements.

The AIP 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.

Consultation

The Department has consulted with: State and Territory Governments; the Australian Commission on Safety and Quality in Health Care; prescriber, pharmacy, pharmaceutical industry and consumer peak bodies; Services Australia; the Therapeutic Goods Administration; the Australian Digital Health Agency; the Medical Software Industry Association and the clinical software industry concerning the proposed extension to the implementation timeframe for AIP.

Stakeholders support the extension to the implementation timeframe, and agree it is necessary given environmental pressures, including responses to the bushfires and COVID-19 pandemic. It is also agreed that this change would benefit prescribers who are under significant pressure at present. The Department has also consulted with the Department of Veterans Affairs, which has amended its legislative requirements for AIP relating to Repatriation Pharmaceutical Benefits Scheme medicinal items accordingly.

The Department developed the active ingredient prescribing implementation strategy through a co-design approach with industry, including peak clinical and industry bodies, 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, state and territory government representatives and the ACSQHC which are

supportive of this initiative.

Commencement

The Regulations commence the day after registration.

Details of the Regulations are set out in the [Attachment](#).

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020*

Section 1 – Name

This section provides that the name of this instrument is the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020*.

Section 2 – Commencement

This section provides that the instrument commences the day after registration.

Section 3 – Authority

This section provides that the instrument is made under section 140 of the *National Health Act 1953*.

Section 4 – Schedule(s)

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceutical Benefits) Regulations 2017 (the Principal Regulations)

Item [1] Section 102(1)

Subsection 102(1) of the Principal Regulations provides that section 102(1) applies in relation to a prescription supply of a pharmaceutical benefit that is written before 1 November 2020. This item replaces this date with 1 February 2021.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020* (the Regulations) amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). The Regulations changes the date that applies in relation to a prescription supply of a pharmaceutical benefit that is written before 1 November 2020 under subsection 102(1) of the Principal Regulation, by changing the date to 1 February 2021.

The Principal Regulations require the inclusion of Active Ingredients on all eligible Pharmaceutical Benefit Scheme (PBS) prescriptions. The Regulations make adjustments to require PBS prescribers to include 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, from 1 February 2021. The regulatory amendments also require active ingredients to appear before brand where a prescriber determines that the inclusion of a brand name is necessary for the clinical treatment of their patient.

The PBS provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the *National Health Act 1953* which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

Human rights implications

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it assists in the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Regulations are compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The Regulations improve patient safety and medicines safety by requiring the inclusion of active ingredients on PBS prescriptions. Presentation of the active ingredient in all places where the consumer accesses medicines information is central to medication safety. It will also improve the long-term financial sustainability of the PBS as a viable medicines subsidy scheme.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms.