

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (COMMONWEALTH PRICE AND CONDITIONS FOR COMMONWEALTH PAYMENTS FOR SUPPLY OF PHARMACEUTICAL BENEFITS) AMENDMENT DETERMINATION 2021 (No. 1)

PB 15 of 2021

Purpose

The purpose of this legislative instrument, made under section 98C(1) of the *National Health Act 1953* (the Act), is to amend the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* (the Principal Determination) to make changes to the pharmaceutical benefits and ingredients in relation to which particular rules apply for ascertaining the Commonwealth price payable to an approved medical practitioner or an approved pharmacist for supply, and to make changes to the list of pharmaceutical benefits that must be supplied in complete packs.

The *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* sets out the manner in which the Commonwealth price for the supply of pharmaceutical benefits by approved medical practitioners will be ascertained, and the conditions subject to which payments will be made to approved pharmacists and approved medical practitioners for the supply of pharmaceutical benefits (including listing the pharmaceutical benefits to which certain conditions apply).

Authority

Paragraph 98C(1)(a) of the Act provides that the Minister may, from time to time, determine the manner in which the Commonwealth price for all or any pharmaceutical benefits is to be ascertained for the purpose of payments to approved medical practitioners for the supply of pharmaceutical benefits.

Paragraph 98C(1)(b) of the *National Health Act 1953* (the Act) provides that the Minister may determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

Variation and revocation

Unless there is an express power to revoke or vary the Principal Determination cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary the Principal Determination.

Changes to the Principal Determination made by this Instrument

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the addition of the drug ozanimod and a form of the listed drug desmopressin to the list of pharmaceutical benefits to be supplied as complete packs only (Schedule 4 to the Principal Determination). These changes are summarised, by subject matter, in the Attachment.

Background

Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Paragraph 98C(1)(a) of the Act provides that the Minister may, from time to time, determine the manner in which the Commonwealth price for all or any pharmaceutical benefits is to be calculated for the purpose of payments to approved medical practitioners for the supply of pharmaceutical benefits.

Paragraph 98C(1)(b) of the Act provides that the Minister may, from time to time, determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

Consultations

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

This Instrument commences on 1 March 2021.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (COMMONWEALTH PRICE AND CONDITIONS FOR COMMONWEALTH PAYMENTS FOR SUPPLY OF PHARMACEUTICAL BENEFITS) AMENDMENT DETERMINATION 2021 (No. 1)

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Amendment Determination 2021 (No. 1)* and may also be cited as PB 15 of 2021.

Section 2 Commencement

This section provides that the Instrument commences on 1 March 2021.

Section 3 Amendment of *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019*

This section provides that Schedule 1 amends the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019*.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of a drug and form of a listed drug to the list of Pharmaceutical Benefits to be supplied as complete packs only. These changes are summarised below.

SUMMARY OF CHANGES TO THE NATIONAL HEALTH (COMMONWEALTH PRICE AND CONDITIONS FOR COMMONWEALTH PAYMENTS FOR SUPPLY OF PHARMACEUTICAL BENEFITS) DETERMINATION 2019 MADE BY THIS INSTRUMENT

Drugs Added - Pharmaceutical Benefits to be Supplied as Complete Packs Only

Listed Drug

Ozanimod

Forms Added - Pharmaceutical Benefits to be Supplied as Complete Packs Only

Listed Drug Form

Desmopressin	Nasal spray (pump pack) containing desmopressin acetate 10 micrograms per actuation, 50 actuations, 5 mL
--------------	--

Statement of Compatibility with Human Rights

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

National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Amendment Determination 2021 (No. 1)

(PB 15 of 2021)

This 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 Legislative Instrument

The *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Amendment Determination 2021 (No. 1)* amends the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* which sets out the manner in which the Commonwealth price for the supply of pharmaceutical benefits by approved medical practitioners will be ascertained and the conditions under which payments will be made in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners (including listing the pharmaceutical benefits to which certain conditions apply).

The amendments in Schedule 1 involve the addition of a drug and form of a listed drug to the list of Pharmaceutical Benefits to be supplied as complete packs only.

Human Rights Implications

This Legislative Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with 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 PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

**Thea Connolly
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health**