EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (COMMONWEALTH PRICE AND CONDITIONS FOR COMMONWEALTH PAYMENTS FOR SUPPLY OF PHARMACEUTICAL BENEFITS) AMENDMENT DETERMINATION 2025 (No. 5)

PB 57 of 2025

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 2024* (PB 26 of 2024), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), and amendments to that instrument, are made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

The amendments made by this Instrument provide for:

- the deletion of a form of the listed drug hydromorphone for the list of pharmaceutical benefits for which a dangerous drug fee applies (Schedule 3 to the Principal Determination); and
- the addition of a form of the listed drugs tiotropium and tiotropium with olodaterol for 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 Schedule, 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 Schedule 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.

General

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 June 2025.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (COMMONWEALTH PRICE AND CONDITIONS FOR COMMONWEALTH PAYMENTS FOR SUPPLY OF PHARMACEUTICAL BENEFITS) AMENDMENT DETERMINATION 2025 (No. 5)*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Amendment Determination 2025 (No. 5)* and may also be cited as PB 57 of 2025.

Section 2 Commencement

This section provides that the Instrument commences on 1 June 2025.

Section 3 Authority

This section states that this Instrument is made under subsection 98C(1) of the *National Health Act 1953*.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the deletion of a form of a listed drug for the list of pharmaceutical benefits for which a dangerous drug fee applies, and the addition of forms of listed drugs for 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

Form Deleted – Pharmaceutical benefits for which a dangerous drug fee applies

Listed Drug	*Form*
Hydromorphone	Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A) (Pharmascience)

Form Added – Pharmaceutical benefits to be supplied as complete packs only

Listed Drug	*Form*
Tiotropium	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations), pack of 2
Tiotropium with olodaterol	Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses, pack of 2

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 2025 (No. 5)

(PB 57 of 2025)

This 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 2025 (No. 5)* 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).

Human Rights Implications

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights (the Committee) reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

This Instrument advances the right to health and the right to social security by ensuring that amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (the Listing Instrument), that affect the pharmaceutical benefits for which a dangerous drug fee applies, and the pharmaceutical

benefits to be supplied as complete packs only, are made concurrently in this Instrument. The Department does not consider that it is appropriate to reimburse for a broken pack when a patient must be dispensed the full pack for the required clinical response, or when it is not considered safe or practical to divide the contents of a container.

The amendments in this Instrument involve the deletion of a form of the listed drug hydromorphone for the list of pharmaceutical benefits for which a dangerous drug fee applies (Schedule 3 to the Principal Determination), and the addition of a form of the listed drugs tiotropium and tiotropium with olodaterol for the list of pharmaceutical benefits to be supplied as complete packs only (Schedule 4 to the Principal Determination).

The Listing Instrument determines the pharmaceutical benefits that are on the Schedule through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which assists with advancement of these human rights 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 Schedule are evidence-based.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Listing Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the above-mentioned instrument would not result in an unmet clinical need, except where indicated for a particular form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period will be/has been instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are $31.60 for general patients and $7.70 for concession card holders.

The drug hydromorphone in the form oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A) (Pharmascience) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of hydromorphone in the form oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 March 2025. Patient access has not been affected as there are other section 19A products with the same form of the drug which remains PBS subsidised and accessible for patients.

Conclusion

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

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