EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 116 OF 2025

NATIONAL HEALTH ACT 1953

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination (No. 3) 2025

Purpose

The purpose of this legislative instrument, made under section 84AH of the *National Health Act 1953* (the Act), is to amend the legislative instrument titled *National Health (Pharmaceutical Benefits Scheme-Exempt items – Section 84 AH) Determination 2017* (PB 81 of 2017) to make changes to the pharmaceutical items that are determined to be exempt items.

Background

Part VII of 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.

Drugs and medicinal preparations to which Part VII applies are declared as such by the Minister, by legislative instrument under subsection 85(2) of the Act. These are listed drugs (as defined in subsection 84(1)). The Minister may also determine by legislative instrument the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3)) and the manner of administration of the form of the listed drug so determined (subsection 85(5)). If a drug has a declaration under subsection 85(2) in force in respect of it and determinations under subsections 85(3) and 85(5) in force in respect of it, then that declared drug in that determined form with that determined manner of administration is a pharmaceutical item. The Minister may also determine, by legislative instrument, brands of pharmaceutical items (subsection 85(6)).

Section 84AH empowers the Minister to determine, by legislative instrument, that a pharmaceutical item is an 'exempt item' if the pharmaceutical item satisfies the criteria in section 84AH. The criteria in section 84AH are as follows:

(a) that there is only one listed brand of the relevant pharmaceutical item; and
(b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the one listed brand of the relevant pharmaceutical item; and
(c) there is at least one other pharmaceutical item that has the same listed drug as the relevant pharmaceutical item; and
(d) the Minister is satisfied (having regard to advice, if any, from the Pharmaceutical Benefits Advisory Committee that:
    i. the listed drug in the relevant pharmaceutical item represents suitable therapy for a particular patient population; and
    ii. the relevant pharmaceutical item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration; and

iii. no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

The effect of a pharmaceutical item being determined to be an exempt item is that the listed brand of that pharmaceutical item is excluded from certain statutory price reductions and price disclosure requirements under Divisions 3A and 3B of Part VII of the Act. The intention is to encourage the availability of certain pharmaceutical items with particular formulations of drugs that are used by a demographic subgroup (e.g. children or geriatric patients) for whom other formulations of the drug are not suitable.

Changes to PB 81 of 2017 made by this instrument

This instrument makes the following changes to PB 81 of 2017:

One pharmaceutical item (listed drug = Paracetamol, form = Oral liquid 120 mg per 5 mL, 100 mL, manner of administration = Oral) is no longer determined to be an exempt item because it is delisting from the PBS as requested by the responsible person.

Variation and revocation

Unless there is an express power to revoke or vary PB 81 of 2017 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 81 of 2017.

Consultation

Consultation on the Amending Determination has taken place with the relevant pharmaceutical company regarding the removal of exempt status on the specified form of paracetamol. Advice from the Pharmaceutical Benefits Advisory Committee (PBAC) was requested regarding the delisting of the specified form of paracetamol. Two-thirds of the PBAC membership is from the following interests or professions: consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and medical specialists. The PBAC considered that the deletion of paracetamol oral liquid in the 100 mL form would not result in an unmet clinical need. No additional consultations with experts was undertaken regarding this determination because consultation with the affected company drew on the knowledge of persons with relevant expertise.

General

This instrument commences on 1 October 2025.

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

Authorised Version Explanatory Statement registered 30/09/2025 to F2025L01206

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination (No. 3) 2025 (PB 116 of 2025)

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

This *National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Determination 2017* (the Principal Determination) determines exempt pharmaceutical items. This instrument (the Amending Determination) amends the principal determination which provides for the allocation of drugs to the exempt list if the pharmaceutical item satisfies the criteria in section 84AH of the *National Health Act 1953* (the Act).

This instrument amends the principal determination by removing the specified form of the drug paracetamol from the exempt list because it is delisting from the Pharmaceutical Benefits Scheme (PBS) as requested by the responsible person.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights 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 providing subsidised access to medicines for people. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Determining exempt items under section 84AH of the Act encourages the availability of certain pharmaceutical items with particular formulations of drugs that are used by a demographic subgroup (e.g. children or geriatric patients) for whom other formulations of the drug are not suitable. The recommendatory role of the Pharmaceutical Benefits Advisory Committee ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This legislative instrument is compatible with human rights. Human rights continue to be protected by retaining on the PBS clinically important medicines and maintaining exemptions from pricing reductions only where appropriate under the legislation.

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Authorised Version Explanatory Statement registered 30/09/2025 to F2025L01206