EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 81 OF 2017

NATIONAL HEALTH ACT 1953

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Determination 2017

Authority and operation

This legislative instrument is made pursuant to section 84AH of the *National Health Act 1953* (the Act) to determine those pharmaceutical items that are 'exempt items' for the purposes of statutory price reductions and price disclosure requirements under Division 3A and 3B of Part VII of the Act.

This Instrument revokes and replaces the *National Health Act 1953 – Determination under section 84AH- Exempt items* (PB 58 of 2007).

This Instrument commences on the day of registration on the Federal Register of Legislation.

Purpose

Section 84AH empowers the Minister, or the Minister's delegate, 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 (PBAC)) 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 statutory price reductions and price disclosure requirements under Division 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 (for example, children or geriatric patients) for whom other formulations of the drug are not suitable.

Consultation

No consultation was required.

Affected pharmaceutical companies have previously sought exempt item status and the Pharmaceutical Benefits Advisory Committee (PBAC) has previously provided advice (where appropriate) to the Minister or the Minister's Delegate under subsection 101(4AB) of the Act.

General

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

Statement of Compatibility with Human Rights

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

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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* determines exempt pharmaceutical items. That is, the Minister identifies a specific drug on the Pharmaceutical Benefits Scheme (PBS) in a specific form and with a particular manner of administration as exempt from the operation of statutory pricing mechanisms under the *National Health Act 1953* (the Act).

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 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. 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.

Lisa La Rance
Assistant Secretary
Pricing and Policy Branch
Technology Assessment and Access Division
Department of Health