EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 72 OF 2018

NATIONAL HEALTH ACT 1953

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination 2018 (No. 3)

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* (as amended) (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 (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 (eg. 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 = Clozapine, form Oral liquid 50 mg per mL, 100 mL, manner of administration = oral) is no longer determined to be an exempt item because it no longer meets subsection 84AH(d)(iii). This is due to the temporary listing of another pharmaceutical item and brand that would be suitable for use by the same patient population.

In addition, this instrument also changes the form description for two drugs – levodopa with carbidopa and mercaptopurine. The form description is changing for levodopa with carbidopa from tablet 200 mg-50 mg (anhydrous) (modified release) to tablet (modified release) 200 mg-50 mg (as monohydrate). The form description is changing for mercaptopurine from oral suspension 20 mg per mL, 100 mL to oral suspension containing mercaptopurine monohydrate 20 mg per mL, 100 mL. These changes are due to the International Harmonisation of Ingredient Names reform.

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

The Amending Determination affects pharmaceutical companies with medicines listed on the PBS. Before drugs are determined to be exempt, there are detailed consultations about the drug with the responsible person, and a recommendation is received from the Pharmaceutical Benefits Advisory Committee (PBAC). Any PBAC recommendation is made following receipt of submissions by affected pharmaceutical companies. For all pharmaceutical items that are determined to be exempt, 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. Further consultation on the Amending Determination was deemed unnecessary for both the removal of exempt status on clozapine and the administrative changes due to the International Harmonisation of Ingredient Names (IHIN) reform. Consultation had already taken place regarding determining exempt status with the affected pharmaceutical company, in addition, to the administrative nature of the changes due to the IHIN reform. Both IHIN changes in this instrument are amendments to the description

of the two forms in column two consistent with the naming conventions adopted by the IHIN reform.

General

The instrument commences on 1 August 2018.

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

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination 2018 (No. 3) (PB 72 of 2018)

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. This instrument (the Amending Determination) amends the principal instrument which provides for the allocation of drugs to the exempt list if the pharmaceutical item satisfies the criteria in section 84AH of the Act.

This instrument amends the principal determination by removing the specified form of the drug clozapine from the exempt list because it no longer meets the criteria for exempt status given that a second temporary brand of the same pharmaceutical item is listing on the PBS. In addition, this instrument also amends the principal determination by changing the form description for two drugs – levodopa with carbidopa and mercaptopurine. These changes are due to the International Harmonisation of Ingredient Names reform.

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.

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