EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 54 OF 2012

NATIONAL HEALTH ACT 1953

AMENDMENT DETERMINATION UNDER SECTION 84AH OF THE NATIONAL HEALTH ACT 1953 (2012) (No. 2)

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 *Determination under section 84AH of the National Health Act 1953* (as amended) (PB 58 of 2007) 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 the 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 58 of 2007 made by this instrument

This instrument makes the following changes to PB 58 of 2007:

- One pharmaceutical item (listed drug = Cefuroxime, form = Powder for oral suspension 125 mg (as axetil) per 5 mL, 70mL, manner of administration = Oral) is determined to be an exempt item.

- One pharmaceutical item (listed drug = Tipranavir, form = Oral liquid 100 mg per mL, 95 mL, manner of administration = Oral) is no longer determined to be an exempt item.

Consultation

This instrument affects pharmaceutical companies with medicines listed on the PBS. In relation to the introduction of the exempt items measure, which commenced on 1 August 2007, pharmaceutical companies have been consulted during both the policy development and implementation phases.

The Pharmaceutical Benefits Advisory Committee (PBAC) was also consulted in relation to issues relevant to this determination. The Pharmaceutical Benefits Advisory Committee (PBAC) is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister for Health about which drugs and medicinal preparations should be available as pharmaceutical benefits and about other matters as required under the Act. Under subsection 101(4AB) of the Act PBAC provides advice to the Minister if it is satisfied of certain matters concerning suitability of pharmaceutical items for use by particular sub-groups. Consideration given by PBAC, under section 101(4AB), to the pharmaceutical items affected by the instrument, was considered by the delegate of the Minister who made the instrument.

General

The instrument commences on 1 August 2012.

This instrument constitutes a legislative instrument for the purpose of the *Legislative Instruments Act 2003*.

Statement of Compatibility with Human Rights

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

Amendment Determination – Exempt items (PB 58 of 2007)

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 Legislative Instrument is made pursuant to section 84AH of the *National Health Act 1953* (the Act), which determines when a pharmaceutical is exempt. This instrument amends the principle 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 (the Amending Determination) amends the Principal Determination by: removing the drug tipranavir from the exempt list and determining the drug cefuroxime to be an exempt item.

Human rights implications

This legislative instrument engages Article 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.

Adriana Platona

Assistant Secretary, Pharmaceutical Evaluation Branch

Pharmaceutical Benefits Division, Department of Health and Ageing