EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listed drugs on F1 or F2) Amendment Determination 2012 (No. 6)

PB 67 of 2012

Authority

This instrument, made under subsection 85AB(1) of the *National Health Act 1953* (the Act), amends the *National Health (Listed drugs on F1 or F2) Determination 2010* (PB 93 of 2010) (the Principal Determination).

The Principal Determination provides for the allocation of drugs to the F1 and F2 formularies of the Pharmaceutical Benefits Scheme (PBS).

Purpose

The Act provides that listed drugs may be assigned to formularies identified as F1 and F2. F1 is intended for single brand drugs and F2 for drugs that have multiple brands, or are in a therapeutic group with other drugs with multiple brands. Drugs on F2 are subject to the provisions of the Act relating to statutory price reductions, price disclosure and guarantee of supply.

Section 84AC of the Act provides that a drug is on F1 or F2 if there is a determination in force under section 85AB that the drug is on F1 or F2.

Subsection 85AB(1) of the Act empowers the Minister to determine by legislative instrument that a listed drug is on F1 or F2. For a drug to be on F1, it must satisfy the criteria in subsection 85AB(4). This requires that there are no listed brands of pharmaceutical items that have the drug that are bioequivalent or biosimilar, and no listed brands of pharmaceutical items that have another drug in the same therapeutic group as the first drug that are bioequivalent or biosimilar. It also requires that the drug was not on F2 the day before the determination comes into effect. A drug may only be determined to be on F2 if it does not satisfy one or more of the criteria for F1 (subsection 85AB(3)).

When subsection 85AB(5) of the Act applies, which relates to listed drugs with a single brand combination item on the PBS, the listed drug is not placed on F1 or F2, but on the administrative combination drug list.

This instrument (the Amending Determination) amends the Principal Determination by removing two listed drugs dihydroergotamine and etidronic acid from F1.

Consultation

The Amending Determination affects pharmaceutical companies with medicines listed on the PBS. Before drugs are listed and allocated to formularies, there are detailed consultations about the drug with the intended 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. 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 Amending Determination instrument commences on 1 September 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

National Health (Listed Drugs on F1 or F2) Amendment Determination 2012 (No. 6)

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 subsection 85AB(1) of the *National Health Act 1953* (the Act), which relates to listed drugs on F1 or F2. This instrument amends the principle instrument which provides for the allocation of drugs to the F1 and F2 formularies of the Pharmaceutical Benefits Scheme (PBS).

This instrument (the Amending Determination) amends the Principal Determination by: removing two drugs dihydroergotamine and etidronic acid from F1.

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.

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