

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Prescriber bag supplies) Amendment Determination 2015 (No. 5)

PB 115 of 2015

Authority

Subsections 93(1) and 93AB(1) of the *National Health Act 1953* (the Act) provide for the Minister to determine the pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners, respectively, directly to patients. Subsections 93(2) and 93AB(2) of the Act provide for the Minister to determine the maximum quantity or number of units of a pharmaceutical benefit which may be obtained during a specified period, by a medical practitioner and an authorised nurse practitioner, respectively. The *National Health (Prescriber bag supplies) Determination 2012* (PB 73 of 2012) (the Principal Determination) determines the pharmaceutical benefits and maximum quantities of those pharmaceutical benefits for this purpose.

Purpose

This Amendment Determination amends the Schedule to the Principal Determination by: adding to Group 3, benzotropine in the form injection containing benzotropine mesylate 2 mg in 2 mL vial.

Variation and revocation

Unless there is an express power to revoke or vary PB 73 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 73 of 2012.

Background

Part VII of the *National Health Act 1953* (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.

Subsection 85(1) of the Act provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Drugs and medicinal preparations to which Part VII applies are declared by the Minister by legislative instrument to be so under subsections 85(2) and (2AA) of the Act. These are listed drugs as defined in subsection 84(1) of the Act.

Sections 93 and 93AB of the Act provide for certain pharmaceutical benefits to be obtained by medical practitioners and authorised nurse practitioners for direct supply for patient treatment. These pharmaceutical benefits are obtained as ‘prescriber bag supplies’ and use is free of charge to the patient. Section 93AA of the Act provides for supply by authorised midwives, but that power is not exercised in the Principal Determination and has not been exercised to date. For each drug and form identified in the Schedule of the Principal Determination, the pharmaceutical benefits that may be obtained as prescriber bag supplies are all brands of pharmaceutical benefits, determined by legislative instrument under subsections 85(2), (3), and (6) of the Act, having that drug in that form.

For subsections 93(2) and 93AB(2) of the Act, the maximum quantity of each pharmaceutical benefit is the maximum quantity that a medical practitioner and an authorised nurse

practitioner, respectively, may obtain during a calendar month. Where there is more than one drug and form with the same Group Number, the maximum quantity may be obtained for a pharmaceutical benefit having only one drug and form with the Group Number.

A quantity up to the maximum quantity may be obtained during a month, only if the total quantity of pharmaceutical benefits of any drug and form having the same Group Number in the possession of the prescriber bag supplier is less than the maximum quantity for the drug and form. Several Groups have two or more drugs and forms.

Consultation

This determination gives effect to recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body, established by section 100A of the Act, to make recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

Under subsection 101(4) of the Act, a drug or medicinal preparation may not be declared to be a drug or medicinal preparation to which Part VII of the Act applies unless the PBAC has recommended that it be so declared. When recommending the listing of a medicine on the PBS, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Consultation regarding implementation of arrangements for nurse practitioners as PBS prescribers occurred via advisory groups established to advise on specific issues and technical aspects. The advisory groups included practitioners from medical and allied health professions, with experience in midwifery, nursing, general practice, obstetrics, and representatives from registration bodies, state and territory health services, regional and remote health services, Indigenous populations, and consumers. Advice was provided on Medicare eligibility, collaborative arrangements with other health professionals, authorisation as PBS prescribers, and medicines for PBS prescribing.

The PBAC provided advice on pharmaceutical benefits suitable for listing for nurse practitioners.

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation.

This Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

This Determination commences on 1 December 2015.

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 Determination, made under sections 93 and 93AB of the *National Health Act 1953* (the Act), provides for certain pharmaceutical benefits to be obtained, and supplied, by medical practitioners and authorised nurse practitioners directly to patients for treatment. These pharmaceutical benefits are obtained for use for patient treatment as prescriber bag supplies and are free of charge to patients. This Determination adds one pharmaceutical item to a Group in the Schedule to the *National Health (Prescriber bag supplies) Determination 2012*.

Human rights implications

This legislative instrument engages Articles 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. An expert advisory committee provides advice regarding the medicines which should be included on the scheme and the circumstances in which they should be available.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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