#### EXPLANATORY STATEMENT

#### **INSTRUMENT NUMBER PB 82 OF 2017**

### NATIONAL HEALTH ACT 1953

National Health (Pharmaceutical Benefits Scheme- class of pharmaceutical items – Subsection 99ACA(3) Determination 2017

### **Authority and Operation**

This legislative instrument is made pursuant to section 99ACA(3) of the *National Health Act* 1953 (the Act) to determine a class of pharmaceutical items that are deemed to have been subjected to an administrative 12.5% price reduction.

This is to reflect those administrative price reductions that applied to certain pharmaceutical items prior to 1 August 2007, being the commencement of the *National Health Amendment* (*Pharmaceutical Benefits Scheme*) Act 2007, which codified the 12.5% reduction through the creation of section 99ACB of the Act.

This Instrument revokes and replaces the *Determination under subsection 99ACA(3) of the National Health Act 1953* (PB 59 of 2007).

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

# **Purpose**

Section 99ACA is a definitional section for the purposes of Division 3A of the Act. Division 3A is concerned with statutory price reductions for listed brands of pharmaceutical items.

A determination under section 99ACA(3) is needed to ensure that those pharmaceutical items that have previously taken a 12.5% administrative price reduction are not also subjected to a further price reduction under section 99ACB.

Section 99ACB(2) states that there are no further price reductions to those drugs identified as being "in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied".

This Instrument determines the classes of pharmaceutical items to which a 12.5% administrative price reduction has applied, defining the relevant class for the purpose of section 99ACB(2).

Schedule 1 sets out the determined classes of pharmaceutical items, by drug and manner of administration.

#### Consultation

Consultation was conducted when this Instrument was initially made. No further consultation was required.

#### 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

National Health (Pharmaceutical Benefits Scheme- class of pharmaceutical items – Subsection 99ACA(3) Determination 2017

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- class of pharmaceutical items – Subsection 99ACA(3) Determination 2017 determines classes of pharmaceutical items that have previously been subject to a 12.5% administrative price reduction prior to the implementation of a statutory price reduction of 12.5%. That is, the Minister identifies specific pharmaceutical items that have already taken a 12.5% reduction to ensure that these items do not take a duplicative reduction under section 99ACB of 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 Determination encourages PBS availability by making those pharmaceutical items more affordable and sustainable. It is promoting the right to an adequate standard of living, and the right to enjoyment of the highest attainable standard of physical and mental health.

#### 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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