

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Continued Dispensing) Amendment Determination 2013 (No.1)

PB 45 of 2013

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply ('Continued Dispensing').

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the Act, is to amend the *National Health (Continued Dispensing) Determination 2012* (Principal Determination). The Principal Determination specifies the pharmaceutical benefits that may be supplied, and the conditions that must be satisfied when those pharmaceutical benefits are supplied, by an approved pharmacist without a current prescription, but on the basis of a previous prescription from a PBS prescriber.

This instrument:

- amends the conditions to provide that the requested supply and the previous supply may be for pharmaceutical benefits that are not the same but are 'a' flagged in the Schedule of Pharmaceutical Benefits as being substitutable; and
- amends the determination of pharmaceutical benefits covered by Continued Dispensing to provide that any listed brand of a pharmaceutical item mentioned in Schedule 1 is able to be supplied under Continued Dispensing. It is intended that any listed brand of a pharmaceutical item mentioned in Schedule 1 is able to be supplied under Continued Dispensing. In addition this will ensure that any change to the brands of a pharmaceutical item available on the PBS automatically changes the brands available under Continued Dispensing.

A provision by provision description of this Instrument is contained in the [Attachment](#).

Consultation

Broad consultation has been undertaken throughout the development of the initiative. A public written consultation process was undertaken in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiative. The Department has continued to engage with stakeholder groups as individual issues are identified. In particular, throughout the development of the

professional guidelines to support Continued Dispensing the Pharmaceutical Society of Australia established an expert reference group made up of key industry representatives. This group was integral to the development of the implementation models for this initiative.

In addition, the Department has also undertaken direct consultation with the Department of Human Services and has also engaged and consulted with state and territory Departments of Health to seek their input and support for the initiative, which is reliant on amendments to state and territory legislation.

These amendments are considered to be of a minor and mechanical nature.

This Instrument commences on the day after registration.

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

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2013 (No.1)*

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Continued Dispensing) Amendment Determination 2013 (No.1)* and that it may also be cited as PB 45 of 2013.

Section 2 Commencement

This section provides that this Instrument commences on the day after registration.

Section 3 Amendments to *National Health (Continued Dispensing) Determination 2012*

This section provides that Schedule 1 amends the *National Health (Continued Dispensing) Determination 2012* (Principal Determination).

Schedule 1 Amendments

Item [1] Subsection 1.03(2)

This item amends the list of terms that have the same meaning as in the Act in subsection 1.03(2) of the Principal Determination to add the defined term ‘Schedule equivalent’.

Item [2] after Paragraph 2.01(3)(b)

This item amends subsection 2.01(3) of the Principal Determination to provide that particular references to ‘the pharmaceutical benefit’ in Part 2 of the Principal Determination include pharmaceutical benefits that are ‘a’ flagged in the Schedule of Pharmaceutical Benefits as being substitutable (ie Schedule equivalent).

Item [3] Section 3.01

This item amends the determination of pharmaceutical benefits available under Continued Dispensing to cover all listed brands of the pharmaceutical items listed in Schedule 1 of the Principal Determination

Item [4] Schedule 1

This item replaces Schedule 1 of the Principal Determination and removes the names of the brands available under Continued Dispensing.

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing) Amendment Determination 2013 (No.1)

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

The purpose of this legislative instrument, made under subsection 89A(3) of the Act, is to amend the *National Health (Continued Dispensing) Determination 2012* (Principal Determination). This determination specifies the pharmaceutical benefits that may be supplied, and the conditions that must be satisfied when those pharmaceutical benefits are supplied, by an approved pharmacist without a current prescription, but on the basis of a previous prescription from a PBS prescriber.

This instrument:

- amends the conditions to provide that the requested supply and the previous supply may be for pharmaceutical benefits that are 'a' flagged in the Schedule of Pharmaceutical Benefits as being substitutable; and
- amends the determination of pharmaceutical benefits to provide that any listed brand of a pharmaceutical item mentioned in Schedule 1 is able to be supplied under Continued Dispensing.

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 for people to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

Conclusion

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

Steve Dunlop
Acting Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health and Ageing