

## EXPLANATORY STATEMENT

### *Veterans' Entitlements Act 1986* *Military Rehabilitation and Compensation Act 2004*

#### **Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Continued Dispensing – Emergency Measures) Determination 2020**

##### **Authority**

Subsection 286(5) of the *Military Rehabilitation and Compensation Act 2004* (the MRCA) and subsection 91(4) provide that the Military Rehabilitation and Compensation Commission and the Repatriation Commission respectively may vary the *MRCA Pharmaceutical Benefits Scheme* (MRCA PBS) and the *Repatriation Pharmaceutical Benefits Scheme* (RPBS) (also referred to as the Schemes).

The proposed variations to the MRCA PBS and the RPBS implement the expansion of the existing 'continued dispensing' arrangements as an emergency measure for eligible Department of Veterans' Affairs (DVA) clients affected by the bushfires. The variations to the Schemes made by the Determination determine the pharmaceutical benefits that can be supplied by a community pharmacist under the Schemes without a prescription, and the conditions for such a supply.

##### **Purpose**

This instrument, made under both subsections 286(5) of the MRCA and 91(4) of the VEA, determines both the conditions under which 'continued dispensing' can occur and the eligible pharmaceutical benefits that can be supplied in that way.

On 10 January 2020 the Minister for Health announced the implementation of temporary, emergency measures to ensure people affected by the current bushfire situation would be able to continue to receive Pharmaceutical Benefits Scheme (PBS) subsidised medicines when a doctor's prescription was not immediately available.

Those changes to the provision of PBS subsidised medicines were implemented by a new legislative instrument made under subsection 89A(3) of the *National Health Act 1953*, the *National Health (Continued Dispensing—Emergency Measures) Determination 2020*.

The proposed instrument provides that DVA clients eligible for pharmaceutical benefits under the Schemes will also benefit from the implementation of the emergency measures by the incorporation (as modified by the amendments to the Schemes) of the instrument, the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* [F2020L00018] as in force at the time of commencement.

The incorporation of the legislative instrument on that basis is provided for under paragraph 14(1)(b) of the *Legislation Act 2003*.

This instrument expands the list of eligible medicines that can currently be obtained on the basis of 'continued dispensing' under both Schemes to include all of the PBS medicines listed in Schedule 1 of the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* and certain items which are only available for DVA clients eligible for pharmaceutical benefits under the Schemes.

The amendments to the Schemes ensure that eligible DVA clients will be able to obtain pharmaceutical benefits under the MRCA PBS or the PRBS if they are unable to attend their doctor during the bushfire crisis. No end date is specified in the instrument, however it is intended to be temporary.

Continued dispensing will enable the provision of a MRCA PBS or RPBS pharmaceutical benefit which is listed in new Schedule 2 of the RPBS (Pharmaceutical benefits not covered by the PBS—continued dispensing) at the maximum quantity or the same quantity that was previously supplied of an eligible medicine to an eligible DVA client by a community pharmacist, under specific circumstances, on the basis of a previous prescription, where a valid prescription is unavailable.

The eligible pharmaceutical benefits that can be provided as a continued dispensing supply will be limited to those contained in Schedule 1 of the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* and those items listed in new Schedule 2 of the RPBS.

This instrument will allow people to obtain any of the listed MRCA PBS and RPBS medicines without a prescription from their doctor, for the MRCA PBS or RPBS price.

In conducting a continued dispensing supply, pharmacists are required to consider the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists* (PSA Guidelines), prepared and issued by the Pharmaceutical Society of Australia. The PSA Guidelines are incorporated by reference into the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* (sections 2.01 and 2.10). The PSA Guidelines are freely available from the Pharmaceutical Society of Australia website at [www.psa.org.au/](http://www.psa.org.au/).

The PSA Guidelines provide advice and guidance to assist pharmacists to meet their professional responsibilities, exercise professional judgement in individual circumstances and manage risks associated with the continued dispensing of eligible prescribed medicines.

This instrument does not override state and territory poisons laws. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to the eligible medicines.

## **Consultation**

This instrument affects community pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit. The Department of Health has undertaken consultation with relevant peak bodies including the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia. The Department of Health has also consulted with state and territory Departments of Health about implementation. As this instrument provides for similar arrangements, DVA did not directly consult with these bodies. DVA has consulted with the Department of Health and Services Australia about implementation.

## **Retrospectivity**

The determination will be taken to have commenced on 13 January 2020 in line with the commencement of the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* and will operate from that date.

The retrospective commencement is designed to support clients who have been impacted by the bushfire emergency and is intended to ensure that supplies of pharmaceutical benefits under the Schemes on or after that date are covered by the Determination.

The retrospective operation of the instrument will not infringe section 12 of the *Legislation Act 2003* because the retrospective operation would not disadvantage any person or impose a liability on a person other than the Commonwealth.

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

***VETERANS' AFFAIRS PHARMACEUTICAL BENEFITS SCHEMES  
AMENDMENT (CONTINUED DISPENSING – EMERGENCY MEASURES)  
DETERMINATION 2020 (Instrument 2020 No. R7/MRCC7)***

**1 Name**

This section provides that this Instrument is the *Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Continued Dispensing – Emergency Measures) Determination 2020*.

**2 Commencement**

This section states that this instrument commences on 13 January 2020.

A retrospective commencement is required to align the commencement of the amendments to the Schemes with the commencement of the *National Health (Continued Dispensing—Emergency Measures) Determination 2020*.

**3 Authority**

This section states that this instrument is made under section 286 of the *Military Rehabilitation and Compensation Act 2004* and section 91 of the *Veterans' Entitlements Act 1986*.

**4 Schedules**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

**Schedule 1 – Amendments**

**MRCA Pharmaceutical Benefits Scheme**

**Item 1** repeals and substitutes the definition of “Repatriation Pharmaceutical Benefits Scheme” in section 3. The repealed definition had contained a specific reference to the current instrument which would have required an amendment when the instrument was revoked and replaced.

The amended definition refers to the definition provided in the *Veterans' Entitlements Act 1986*.

**Items 2 to 6** amend section 16A of the MRCA Pharmaceutical Benefits Scheme (MRCA PBS).

Subsection 16A(1) is amended to include the heading “Pharmaceutical benefits covered by PBS and National Health Act section 89A instruments”.

Paragraph 16A(1)(a) is amended to replace the reference to Schedule 1 of the existing instrument made under subsection 89A(3) of the *National Health Act 1953* (National Health Act) that applies to the MRCA PBS for the purposes of providing certain pharmaceutical benefits without a current prescription.

The existing instrument is the *National Health (Continued Dispensing) Determination 2012* which will remain in place and the amended paragraph 16A(1)(a) refers to any instrument in force that has been made under subsection 89A(3) of the National Health Act.

The amended reference will ensure that paragraph 16A(1)(a) will also be referring to the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* or any other instrument that is subsequently made under subsection 89A(3) of the National Health Act.

Paragraph 16A(1)(b) is repealed and substituted. The repealed paragraph had referred to the supply of a pharmaceutical benefit under paragraph 16A(1)(a) as having been made in accordance with the conditions specified in the instrument referred to in that paragraph as if references in the instrument were references to certain terms that are specific to the MRCA PBS.

New paragraph 16A(1)(b) provides that the supply of a pharmaceutical benefit under paragraph 16A(1)(a) is to be made in accordance with the conditions specified in the instrument referred to in that paragraph and that the instrument has effect as set out in new subsection 16A(1B).

New subsection 16A(1A) provides that a community pharmacist may supply a pharmaceutical benefit at or from premises for which the pharmacist has approval under the National Health Act if:

- the pharmaceutical benefit is covered by the table in Schedule 2 to the RPBS (inserted by Item 12 of this Schedule); and
- the supply is in accordance with the conditions specified in the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* as if the supply under the MRCA PBS is a supply that was covered by that instrument; and
- the instrument has effect as amended by the provisions set out in new subsection 16A(1B) to the extent that those conditions are applicable to the supply; and
- the supply otherwise conforms with the requirements of section 16A as amended.

New subsection 16A(1B) modifies for the purposes of subparagraph 16A(1)(b)(ii) as amended and new subparagraph 16A(1A)(b)(ii), the effects of the instruments made under subsection 89A(3) of the National Health Act. Those instruments are the *National Health (Continued Dispensing) Determination 2012* and the *National Health (Continued Dispensing—Emergency Measures) Determination 2020*.

The modifications are set out in a Table in subsection 16A(1B) which lists certain references in those instruments and the terms which replace them for the purposes of the MRCA PBS.

Subsection 16A(2) is amended to include a reference to new subsection 16A(1A).

### **Repatriation Pharmaceutical Benefits Scheme**

**Items 7 to 11** amend section 16A of the Repatriation Pharmaceutical Benefits Scheme (RPBS).

Subsection 16A(1) is amended to include the heading “Pharmaceutical benefits covered by PBS and National Health Act section 89A instruments”.

Paragraph 16A(1)(a) is amended to replace the reference to Schedule 1 of the existing instrument made under subsection 89A(3) of the *National Health Act 1953* (National Health Act) that applies to the RPBS for the purposes of providing certain pharmaceutical benefits without a current prescription.

The existing instrument is the *National Health (Continued Dispensing) Determination 2012* which will remain in place and the amended paragraph 16A(1)(a) refers to any instrument in force that has been made under subsection 89A(3) of the National Health Act.

The amended reference will ensure that paragraph 16A(1)(a) will also be referring to the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* or any other instrument that is subsequently made under subsection 89A(3) of the National Health Act.

Paragraph 16A(1)(b) is repealed and substituted. The repealed paragraph had referred to the supply of a pharmaceutical benefit under paragraph 16A(1)(a) as having been made in accordance with the conditions specified in the instrument referred to in that paragraph as if references in the instrument were references to certain terms that are specific to the RPBS.

New paragraph 16A(1)(b) provides that the supply of a pharmaceutical benefit under paragraph 16A(1)(a) is to be made in accordance with the conditions specified in the instrument referred to in that paragraph and that the instrument has effect as set out in new subsection 16A(1B).

New subsection 16A(1A) provides that a community pharmacist may supply a pharmaceutical benefit at or from premises for which the pharmacist has approval under the National Health Act if:

- the pharmaceutical benefit is covered by the table in Schedule 2 to the RPBS (inserted by Item 12 of this Schedule); and
- the supply is in accordance with the conditions specified in the *National Health (Continued Dispensing—Emergency Measures) Determination 2020* as if the supply under the RPBS is a supply that was covered by that instrument; and
- the instrument has effect as amended by the provisions set out in new subsection 16A(1B) to the extent that those conditions are applicable to the supply; and
- the supply otherwise conforms with the requirements of section 16A as amended.

New subsection 16A(1B) modifies for the purposes of subparagraph 16A(1)(b)(ii) as amended and new subparagraph 16A(1A)(b)(ii), the effects of the instruments made under subsection 89A(3) of the National Health Act. Those instruments are the *National Health (Continued Dispensing) Determination 2012* and the *National Health (Continued Dispensing—Emergency Measures) Determination 2020*.

The modifications are set out in a Table in subsection 16A(1B) which lists certain references in those instruments and the terms which replace them for the purposes of the RPBS.

Subsection 16A(2) is amended to include a reference to new subsection 16A(1A).

**Item 12** inserts new Schedule 2 into the RPBS. Schedule 2 lists all of the pharmaceutical benefits (not listed under the PBS) which are only available for DVA clients eligible for pharmaceutical benefits under the MRCA PBS and the RPBS.

## **Statement of Compatibility with Human Rights**

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

### ***Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Continued Dispensing – Emergency Measures) Instrument 2020***

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 instrument provides for amendments to the legislative instruments, the *Repatriation Pharmaceutical Benefits Scheme* (RPBS) and the *MRCA Pharmaceutical Benefits Scheme* (MRCA PBS) and for the incorporation into both of those instruments of a determination made under the *National Health Act 1953* that 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 MRCA PBS or an RPBS prescriber.

This instrument specifies the conditions that must be met in order to undertake a continued dispensing supply and the eligible medicines that can be supplied on the basis of a previous prescription, where a valid prescription is unavailable.

#### **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 MRCA PBS and the RPBS are benefit schemes which assist with advancement of this human right by providing for subsidised access for veterans and their dependants to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the MRCA PBS and the RPBS support the effective administration of the Schemes.

#### **Conclusion**

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

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**Rule-Maker**