EXPLANATORY STATEMENT

Veterans' Affairs Pharmaceutical Benefits Schemes Amendment Instrument 2017 (Instrument 2017 No. R7/MRCC7)

EMPOWERING PROVISIONS

Section 91 of the *Veterans' Entitlements Act 1986* (VEA) and section 286 of the *Military Rehabilitation and Compensation Act 2004* (MRCA).

PURPOSE

The attached instrument (2017 No. R7/MRCC7) varies, respectively:

- the *Repatriation Pharmaceutical Benefits Scheme* under the VEA;
- the *MRCA Pharmaceutical Benefits Scheme* under the MRCA

(collectively referred to as "the Schemes").

The Schemes are legislative instruments that set out the circumstances in which the Repatriation Commission and the Military Rehabilitation and Compensation Commission (the Commissions) may arrange for pharmaceutical benefits to be provided to veterans, members and former members of the Defence Force, or their dependants at a concessional rate.

The *Repatriation Pharmaceutical Benefits Scheme* also applies, subject to modifications, to people entitled to treatment under the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006* (see s.18 of that Act).

The attached instrument varies the Schemes to give effect to the following measures:

- updating the "as-in-force" date to 1 January 2018 for documents incorporated-by-reference into the Schemes. This will give effect to the price variations and new listings to be included in the Repatriation Pharmaceutical Benefits Scheme Schedule (RPBS Schedule) from 1 January 2018.

- consequential amendments to the Schemes on the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960.*

Incorporated Documents measure (changes to the RPBS Schedule)

The attached instrument updates the "as-in-force" date for documents that are incorporated-by-reference into the Schemes from 1 July 2017 to 1 January 2018.

The Schemes incorporate-by-reference a number of documents. These documents are set out in Schedule 1 of the Schemes. One particular document, the Repatriation Pharmaceutical Benefits Scheme Schedule (or RPBS Schedule) will be changed on 1 January 2018 to include additional listings for generic brand items and price variations for 14 currently listed items.

The RPBS Schedule is part of the Schemes and enables eligible clients of the Department of Veterans' Affairs (DVA clients) to access pharmacy items at a concessional rate. The RPBS Schedule includes all items available to the general community under the Pharmaceutical Benefits Scheme (PBS) as well as separate listings that are exclusive to DVA clients at a concessional rate.

Specifically, from 1 January 2018, the RPBS Schedule will be updated to include:

- an additional listing for a generic brand item relating to medication for the treatment of upper and lower respiratory tract infections;
- an additional listing for a generic brand item relating to medication for use in patients' pre and post angioplasty; and
- price increases for 14 currently listed items for various wound dressings.

The addition of the two generic brand items will ensure eligible DVA clients have the benefit of further generic brand medications at a subsidised cost.

The price increases for the 14 listed items will not affect the amount DVA clients pay for these items. They will continue to pay the specified co-payment for pharmaceuticals (currently $6.30). This co-payment may be discounted at the pharmacist's discretion in line with arrangements in place since 1 January 2016.

The attached instrument amends the Schemes to ensure that the updated version of the RPBS Schedule as it exists on the relevant date (1 January 2018) is the version of the document that is incorporated into, and made part of, the Schemes.

Under current legislation, non-legislative material may only be incorporated by reference into the Schemes in the version in which it exists on a specific date, and not as it may exist "from time to time".

As the references in the Schemes to the RPBS Schedule are being updated, the opportunity has been taken to update the references to other incorporated documents (included in the Schedules to the Schemes) so that any later version of these documents in existence on 1 January 2018 is the version that is recognised by the Schemes.

Additionally, the opportunity has been taken to review the list of incorporated documents listed in Schedule 1 to the Schemes to remove references to redundant documents.

Specifically, the attached instrument removes references to the following documents from Schedule 1 and other provisions of the Schemes:

- the British Pharmacopoeia
- the United States Pharmacopoeia
- the European Pharmacopoeia

- the Australian Pharmaceutical Formulary
- a prescribed pharmacology text of international standing
- the Pharmaceutical Codex as amended and authorised by regulations under the *Therapeutic Goods Act 1989*.

These documents are no longer used as tools when considering whether a medication conforms with certain standards before it can be prescribed. They are no longer relevant on the basis that prior approval of "non-Scheduled items" under the Schemes are not predicated on the drug or therapeutic substance being listed in any of the relevant documents, but rather on the information provided by the medical practitioner.

Consequential amendments on the remaking of the National Health (Pharmaceutical Benefits) Regulations 1960

The attached instrument also updates the Schemes consequentially as a result of the recent sunset review and remake of the *National Health (Pharmaceutical Benefits) Regulations 1960* (former Regulations).

The provisions of the *National Health (Pharmaceutical Benefits) Regulations 2017* (new Regulations) have been reordered and renumbered during the sunset review and remake process.

The purpose of the attached instrument is to update the various provisions of the Schemes that refer to sections of the *National Health (Pharmaceutical Benefits) Regulations* to refer to the renumbered sections and name of the new Regulations.

This measure updates the provisions of the Schemes to ensure alignment with the *National Health (Pharmaceutical Benefits) Regulations 2017* following its sunset remake.

Further details of the attached instrument are set out in Attachment A.

CONSULTATION

Section 17 of the *Legislation Act 2003* requires a rule-maker to be satisfied, before making a legislative instrument that any consultation the rule-maker considered appropriate and reasonably practicable, has been undertaken.

In respect of the new listings and price variations to the RPBS Schedule, the Department of Health, the Department of Finance and the Repatriation Pharmaceutical Reference Committee (RPRC) were consulted.

The RPRC is an expert committee operating under the governance of the Department of Veterans' Affairs and comprised of members of various medical, pharmacy and ex-servicemen's organisations and clinical specialty members. The RPRC advises the Commissions and the Minister on potential new listings for the RPBS Schedule and associated matters.

The nature of the consultation included meetings and correspondence with the Department of Health and Department of Finance to identify any potential issues or concerns with the listings and agree the financial implications. The changes to the RPBS Schedule were endorsed by the Commissions on the recommendation of the RPRC.

For the consequential measures, consultation took place with the Department of Health in the course of remaking the *National Health (Pharmaceutical Benefits) Regulations 1960.*

Consultation was by way of email correspondence. No further consultation was undertaken in relation to these amendments to the Schemes as they are consequential in nature and flow from the re-making of the *National Health (Pharmaceutical Benefits) Regulations 1960.*

No external consultation was considered necessary or appropriate for the amendments relating to the removal of references relating to redundant documents in the Schemes.

Accordingly, it is considered the requirements of section 17 of the *Legislation Act 2003* have been met.

RETROSPECTIVITY

None.

DOCUMENTS INCORPORATED BY REFERENCE

Yes. The documents in the revised Schedule 1 are incorporated into the Schemes in the form in which they exist on 1 January 2018 and not in the form in which they may later change or exist "from time to time".

The RPBS Schedule and other incorporated documents are available for inspection at: Department of Veterans' Affairs (ACT Office), Level 5, Gnabra Building, Corner Bunda and Genge Streets, Civic, Canberra. Phone: (02) 6289 6243.

The RPBS Schedule (also known as the Repatriation Schedule of Pharmaceutical Benefits) is accessible on the Department of Health website at: https://www.pbs.gov.au/browse/rpbs.

HUMAN RIGHTS STATEMENT

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

The attached legislative instrument engages an applicable right of freedom – specifically, the Right to Health contained in article 12(1) of the International Covenant on Economic Social and Cultural Rights.

The Right to Health is the right to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights has stated that health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.

Overview

The legislative instrument engages the Right to Health by:

- making two new generic brands of medicines available to DVA clients at a concessionary price;
- ensuring certain medicines remain on the RPBS by increasing the subsidy DVA will pay for those medicines. But for that increase, the manufacturers of the medicines might have had their medicines de-listed thereby denying their availability to DVA clients at a concessionary price.

Other measures contained in the attached instrument do not engage applicable rights or freedoms, as they are consequential in nature.

The instrument makes a number of technical consequential amendments to the Schemes. It updates various section numbers and name references as a consequence of the remake of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Similarly, the amendments relating to the removal of references to redundant documents are updating measures.

Conclusion

The attached legislative instrument is considered to be compatible with the right to health because it provides new medicines at a concessionary price to the veteran community and ensures certain medicines continue to be available to that section of the community.

Dan Tehan
Minister for Veterans' Affairs

Rule-Maker

FURTHER EXPLANATION OF PROVISIONS

See: Attachment A

Attachment A

Veterans' Affairs Pharmaceutical Benefits Schemes Amendment Instrument 2017

Section 1
This section sets out the name of the instrument – the *Veterans' Affairs Pharmaceutical Benefits Schemes Amendment Instrument 2017*.

Section 2
This section provides that the instrument commences on 1 January 2018.

Section 3
This section sets out the primary legislation that authorises the making of the instrument, namely subsection 91(2) of the *Veterans' Entitlements Act 1986* in respect of the variations to the *Repatriation Pharmaceutical Benefits Scheme* in Schedule 1, and subsection 286(2) of the *Military Rehabilitation and Compensation Act 2004* in respect of the variations to the *MRCA Pharmaceutical Benefits Scheme* in Schedule 2.

Section 4
This section provides for the variations to the Schemes outlined in the Schedules to the instrument to have effect.

Schedule 1 - Variations to the Repatriation Pharmaceutical Benefits Scheme (the RPBS or the Scheme)

Part 1 – Updating of incorporated documents and other amendments

Item 1
This item replaces Schedule 1 to the *Repatriation Pharmaceutical Benefits Scheme*. Schedule 1 lists the documents that are incorporated by reference into the Scheme.

This amendment changes Schedule 1 to revise the "as-in-force" date for the documents included in Schedule 1 from 1 July 2017 to 1 January 2018. The effect of this amendment is to ensure that the updated version of the RPBS Schedule as it exists on 1 January 2018 is the version that is incorporated into and forms part of the Scheme. The amendment will also ensure that any other documents listed in Schedule 1 that have been updated since 1 July 2017 are incorporated into the Scheme in their more recent version.

References to some documents (redundant documents) in Schedule 1 have been omitted. The omitted documents are:

- the British Pharmacopoeia
- the United States Pharmacopoeia
- the European Pharmacopoeia
- the Australian Pharmaceutical Formulary
- a prescribed pharmacology text of international standing

- the Pharmaceutical Codex as amended and authorised by regulations under the *Therapeutic Goods Act 1989*.

Item 2 is a consequential amendment. It amends subparagraph 7(d) of the Scheme by omitting references to certain redundant documents. These references are no longer required as the publications are no longer used when a delegate considers whether a drug or therapeutic substance conforms with certain standards before it can be prescribed.

Following this amendment subparagraph 7(d) will provide that no drug or therapeutic substance shall be prescribed unless it conforms with the specific or general standards as determined by the relevant Minister under the *Therapeutic Goods Act 1980*.

Item 3 is a consequential amendment. It amends section 41 by omitting references to the redundant documents. The minimum acceptable standard for a pharmaceutical benefit will now be as described in the regulations under the *Therapeutic Goods Act 1989*.

Items 4 and 5 are consequential amendments as a result of the omission of the redundant documents.

Part 2 – Consequential amendments

Items 6 to 11 update various sections in the Scheme to reflect the new section numbers and name references as a result of the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Item 12 inserts a definition of 'Minister for Health' in the interpretation section of the Scheme. This is as a result of the amendments to the definition of "approval number" (item 6) which includes the Minister for Health as a person who is authorised to allot numbers to various health providers for approvals to prescribe or supply pharmaceutical benefits.

Items 13 to 22 update various sections in the Scheme to reference the renumbered section numbers and name references consequential on the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Item 23 inserts a note to section 45. Section 45 sets out requirements for the keeping of documents by community pharmacists that are not continued dispensing or medication chart prescriptions.

The note clarifies that a document referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.

Item 24 inserts a note to section 45A. Section 45A sets out requirements for the keeping of information by community pharmacists relating to continued dispensing supplies.

The note clarifies that the information referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.

Item 25 inserts a note to section 45B. Section 45B sets out requirements for the keeping of documents by community pharmacists relating to medication chart prescriptions.

The note clarifies that the document referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.

Schedule 2 - Variations to the MRCA Pharmaceutical Benefits Scheme (the MRCA PBS or the Scheme)

Part 1 – Updating of incorporated documents and other amendments

Item 1
This item replaces Schedule 1 to the *MRCA Pharmaceutical Benefits Scheme*. Schedule 1 lists the documents that are incorporated by reference into the Scheme.

This amendment changes Schedule 1 to revise the "as-in-force" date for the documents included in Schedule 1 from 1 July 2017 to 1 January 2018. The effect of this amendment is to ensure that the updated version of the RPBS Schedule as it exists on 1 January 2018 is the version that is incorporated into and forms part of the Scheme. The amendment will also ensure that any other documents listed in Schedule 1 that have been updated since 1 July 2017 are incorporated into the Scheme in their more recent version.

References to some documents (redundant documents) in Schedule 1 have been omitted.

The omitted documents are:

- the British Pharmacopoeia
- the United States Pharmacopoeia
- the European Pharmacopoeia
- the Australian Pharmaceutical Formulary
- a prescribed pharmacology text of international standing
- the Pharmaceutical Codex as amended and authorised by regulations under the *Therapeutic Goods Act 1989*.

Item 2 is a consequential amendment. It amends subparagraph 7(d) of the Scheme by omitting references to certain redundant documents. These references are no longer required as the publications are no longer used when a delegate considers whether a drug or therapeutic substance conforms with certain standards before it can be prescribed.

Following this amendment subparagraph 7(d) will provide that no drug or therapeutic substance shall be prescribed unless it conforms with the specific or general standards as determined by the relevant Minister under the *Therapeutic Goods Act 1980*.

Item 3 is a consequential amendment. It amends section 41 by omitting references to the redundant documents. The minimum acceptable standard for a pharmaceutical benefit will now be as described in the regulations under the *Therapeutic Goods Act 1989*

Items 4 and 5 are consequential amendments as a result of the omission of the redundant documents.

Part 2 – Consequential amendments

Items 6 to 12 update various sections in the Scheme to reflect the new section numbers and name references as a result of the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Item 13 inserts a definition of 'Minister for Health' in the interpretation section of the Scheme. This is as a result of the amendments to the definition of "approval number" (item 6) which includes the Minister for Health as a person who is authorised to allot numbers to various health providers for approvals to prescribe or supply pharmaceutical benefits.

Items 14 to 23 update various sections in the Scheme to reference the renumbered section numbers and name references consequential on the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Item 24 inserts a note to section 45. Section 45 sets out requirements for the keeping of documents by community pharmacists that are not continued dispensing or medication chart prescriptions.

The note clarifies that a document referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.

Item 25 inserts a note to section 45A. Section 45A sets out requirements for the keeping of information by community pharmacists relating to continued dispensing supplies.

The note clarifies that the information referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.

Item 26 inserts a note to section 45B. Section 45B sets out requirements for the keeping of documents by community pharmacists relating to medication chart prescriptions.

The note clarifies that the document referred to for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transaction Act 1999*.