

EXPLANATORY STATEMENT

Veterans' Entitlements (Dispensed Price for Repatriation Pharmaceutical Benefits/Updating Incorporated Documents) Amendment Instrument 2015 (Instrument 2015 No. R45)

Military Rehabilitation and Compensation (Dispensed Price for MRCA Pharmaceutical Benefits/Updating Incorporated Documents) Amendment Instrument 2015 (Instrument 2015 No. MRCC45)

EMPOWERING PROVISIONS

Subsection 91(3) of the *Veterans' Entitlements Act 1986* (the VEA) for Instrument 2015 No. R45.

Subsection 286(3) of the *Military Rehabilitation and Compensation Act 2004* (MRCA) for Instrument 2015 No. MRCC45.

PURPOSE

The attached instruments (2015 No. R45 and 2015 No. MRCC45) vary, 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 and 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 (including 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 (Treatment) Act 2006* (see s.18 of that Act).

The attached instruments implement two measures:

- the response by the Department of Veterans' Affairs (DVA) to a suggestion by the Australian National Audit Office (ANAO) that the Schemes clarify how the dispensed price of a pharmaceutical benefit provided under the Schemes is worked out. The dispensed price is the price DVA pays a Community Pharmacist for supplying a pharmaceutical benefit under the Schemes. The

ANAO noted in particular that the Schemes did not define “dispensed price” (ANAO Measure);

- updating of references in the Schemes to documents incorporated-by-reference into the Schemes (Incorporated Document Measure).

ANAO Measure

The ANAO suggestion that the Schemes clarify how the “dispensed price” is worked out for a pharmaceutical benefit supplied under the Schemes is contained in its Issues Paper in relation to the ANAO’s Performance Audit of the Administration of the Fifth Community Pharmacy Agreement 2014.

The Fifth Community Pharmacy Agreement (there is now a Sixth) was the agreement between the Australian Government and the Pharmacy Guild of Australia in relation to the delivery of medicines on the Pharmaceutical Benefits Scheme and related services.

The Schemes administered by DVA enable subsidised medicines to be provided to DVA clients at three levels. At the first level DVA clients may receive medicines that are also listed on the Pharmaceutical Benefits Scheme (PBS). These are the subsidised medicines DVA clients may obtain simply by being Australian citizens.

At the second level DVA clients may receive subsidised medicines that are not listed on the PBS and which are not available for members of the public generally. These medicines are listed on the Repatriation Schedule of Pharmaceutical Benefits (RSPB)(also called the RPBS Schedule in the Schemes) and are only available at a subsidised cost to DVA clients. The RSPB is contained in a part of the PBS.

At the third level, DVA clients may receive subsidised medicines that are not listed on either the PBS or RSPB.

The attached instruments are concerned with the second level at which DVA clients may receive medicines because at this level the bulk of the non-PBS medicines are supplied to DVA clients and it is for these medicines that there is no obvious pricing method in the Schemes.

The attached instruments, therefore, introduce a method for working out the price of a medicine listed on the RSPB. The price is the dispensed price of the medicine – the price DVA will pay a pharmacist less any co-payment by the client.

Under the attached instruments the Commissions will decide a price for a particular medicine. The price will be worked out as follows:

- (i) the Commission and a manufacturer of medicines (manufacturer) will agree on the “ex manufacturer price” for a medicine to be listed on the RSPB i.e. the price at which the manufacturer sells the medicine to a wholesaler.
- (ii) the wholesaler’s mark-up and the pharmacist’s mark-up (now known as the “administration, handling and infrastructure fee”) on the medicine is to be worked out as if the medicine is listed on the PBS. The method for working out the wholesaler’s mark-up and the administration, handling and

infrastructure fee for PBS items is contained in the Sixth Community Pharmacy Agreement.

- (iii) the pharmacist's dispensing fee for ready-prepared or extemporaneously-prepared items and any dangerous drug fee for ready-prepared items is also to be worked out as if the medicine is listed on the PBS. The method for working out the pharmacist's dispensing fee and any dangerous drug fee for PBS items is contained in the Sixth Community Pharmacy Agreement.
- (iv) the sum of the ex manufacturer price, the wholesaler's mark-up, the administration, handling and infrastructure fee, the pharmacist's dispensing fee and any dangerous drug fee is the dispensed price of the medicine.

Incorporated Documents Measure

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 Schedule (RPBS Schedule) (defined in the Schemes as the Repatriation Schedule of Pharmaceutical Benefits) has been changed to include a "new listing" (a new brand of anti-fungal nail treatment medicine available to DVA clients) and to increase the prices for a number of currently listed items (subsidy paid by DVA to pharmacists). The increasing of prices for a number of currently listed items on the RPBS will not affect the price the veterans have to pay for these items. The veteran co-payment for pharmaceuticals remains at \$6.10.

In order for the new listing/price increases to be authorised the Schemes need to be amended to refer to the RPBS Schedule in its changed state i.e. as the RPBS Schedule contains the new listing and price increases.

The attached instrument amended the Schemes to ensure that the changed version of the RPBS Schedule as it exists on the date chosen (1 January 2016) is the version of the document that is incorporated into, and made part of, the Schemes.

The RPBS Schedule is incorporated into the Schemes only in the version in which it exists on 1 January 2016 and not as it may exist "from time to time".

Other Incorporated Documents

As the references in the Schemes to the RPBS Schedule are being updated the opportunity was taken to update the references to other incorporated documents in the Schemes so that any later version of these documents in existence on 1 January 2016 is recognised by the Schemes.

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

CONSULTATION

For the ANAO Measure, "no" because existing arrangements are not being changed by the attached instrument merely clarified.

For the Incorporated Documents Measure, “yes”. In respect of the new listing/price increases in the RPBS Schedule the Department of Health, the Department of Finance and the Repatriation Pharmaceutical Reference Committee were consulted.

The Repatriation Pharmaceutical Reference Committee (RPRC) is a committee operating under the auspices of DVA and is comprised of officials and members of various relevant organisations. The RPRC advises the Repatriation Commission on potential new listings for the RPBS Schedule and associated matters.

Noting that paragraph 26(1A)(d) of the *Legislative Instruments Act 2003* requires an Explanatory Statement for a legislative instrument to contain a description of the nature of any consultation, the nature of the consultation for the instrument in respect of the Incorporated Documents Measure was e-mail correspondence, telephone conversations and meetings with the interested parties in question.

RETROSPECTIVITY

None, if the instruments are registered before 1 January 2016.

If registered after that date, the variations to the Schemes set out in Part B of the Schedule to each of the instruments (the Incorporated Documents Measure) will commence retrospectively on 1 January 2016.

Any such retrospective commencement will not contravene subsection 12(2) of the *Legislative Instruments Act 2003* (a legislative instrument is of no effect if it takes effect before registration and disadvantages a person or imposes liabilities on a person other than the Commonwealth) because it will not disadvantage any person or impose a liability on a person other than the Commonwealth.

DOCUMENTS INCORPORATED BY REFERENCE

Yes. The documents listed in the new Schedule 1 inserted into the Schemes by the attached instruments are incorporated into the Schemes in the form in which those documents were on 1 January 2016 and not in the form in which they may exist from time to time.

The incorporated documents are available for inspection at:

Department of Veterans’ Affairs (ACT Office), Lovett Tower, 13 Keltie St, Woden ACT 2606 / GPO Box 9998 Woden ACT 2606.

Tel.no:(02) 6289 6243 or any State or Territory Office of the Department of Veterans’ Affairs:Tel.no: 133 254.

HUMAN RIGHTS STATEMENT

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

In respect of the ANAO Measure the attached legislative instruments do not engage an applicable right or freedom, it merely clarifies an existing pricing structure.

In respect of the Incorporated Document Measure the attached legislative instruments engage 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.

The legislative instruments engage the Right to Health by:

- making a new brand of anti-fungal nail treatment medicine available to DVA clients at a concessionary price;
- ensuring certain medicines (wound dressings and drugs to treat erectile dysfunction and skin cancers) remain on the RPBS by increasing the subsidy DVA will pay on 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.

Conclusion

The attached legislative instruments are considered to be compatible with the human right to health because they provide a new medicine at a concessionary price to a section of the community and ensure certain medicines continue to be available to that section of the community.

Stuart Robert
Minister for Veterans' Affairs

Rule-Maker

FURTHER EXPLANATION OF PROVISIONS

See: Attachments A and B

Attachment A

**Veterans' Entitlements (Dispensed Price for Repatriation
Pharmaceutical Benefits/Updating Incorporated Documents)
Amendment Instrument 2015**

Section 1

This section sets out the name of the instrument - *Veterans' Entitlements (Dispensed Price for Repatriation Pharmaceutical Benefits/Updating Incorporated Documents) Amendment Instrument 2015*.

Section 2

This section provides that the instrument commences on 1 January 2016 (in respect of the variations in Part B of the Schedule (Incorporated Documents Measure) and on the day after registration in respect of the variations in Part A of the Schedule (ANAO Measure) and all other provisions of the instrument.

Section 3

This section sets out the primary legislation that authorises the making of the instrument, namely the *Veterans' Entitlements Act 1986*.

Section 4

This section defines "RPBS" for the purposes of the instrument.

Section 5

This section provides that an instrument specified in the Schedule to the instrument is varied in accordance with the applicable items in the Schedule.

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

PART A

Item 1

This item is a definitions section. An important new definition is the definition of "dispensed price".

Item 2

This item removes a redundant reference that should have been removed in a previous drafting exercise.

Item 3

This item inserts the steps for working out the dispensed price for a medicine listed on the Repatriation Schedule of Pharmaceutical Benefits (a writing contained in the Pharmaceutical Benefits Schedule and incorporated-by-reference into the RPBS as the "RPBS Schedule").

Item 4

This item rationalises provisions in the RPBS that relate to a component of a "dispensed price" namely the "dispensing fee". Most of the relevant former provisions are no longer necessary because the new definition of "dispensed price" covers the dispensing fee. The result of the rationalisation process is new section 26

that simply provides that the amount payable to a Community Pharmacist for the supply of a pharmaceutical benefit under the Scheme is the dispensed price.

Item 5

This item reflects the rationalisation process mentioned in item 4 and confines the direction about “non payment” in section 30 to non payment of the dispensed price as distinct from non-payment of the dispensing fee.

PART B

Item 1

This item updates references in the RPBS to documents that are incorporated-by-reference into the RPBS. The documents are incorporated in the version they are in on 1 January 2016 and not as they may change from time to time. The main document being updated is the RPBS Schedule.

Attachment B**Military Rehabilitation and Compensation (Dispensed Price for MRCA Pharmaceutical Benefits/Updating Incorporated Documents) Amendment Instrument 2015**

Section 1

This section sets out the name of the instrument - *Veterans' Affairs (Dispensed Price for MRCA Pharmaceutical Benefits/Updating Incorporated Documents) Amendment Instrument 2015*.

Section 2

This section provides that the instrument commences on 1 January 2016 (in respect of Part B of the Schedule (Incorporated Documents Measure) and on the day after registration in respect of Part A of the Schedule (ANAO Measure) and all other provisions of the instrument.

Section 3

This section sets out the primary legislation that authorises the making of the instrument, namely the *Military Rehabilitation and Compensation Act 2004*.

Section 4

This section defines "MRCA Pharmaceutical Benefits Scheme" for the purposes of the instrument.

Section 5

This section provides that an instrument specified in the Schedule to the instrument is varied in accordance with the applicable items in the Schedule.

Schedule - Variations to the MRCA Pharmaceutical Benefits Scheme (MPBS or the Scheme)**PART A**

Item 1

This item is a definitions section. An important new definition is the definition of "dispensed price".

Item 2

This item removes a redundant reference that should have been removed in a previous drafting exercise.

Item 3

This item rationalises provisions in the MPBS that relate to a component of a "dispensed price" namely the "dispensing fee". Most of the relevant former provisions are no longer necessary because the new definition of "dispensed price" covers the dispensing fee. The result of the rationalisation process is new section 26 that simply provides that the amount payable to a Community Pharmacist for the supply of a pharmaceutical benefit under the Scheme is the dispensed price.

Item 4

This item reflects the rationalisation process mentioned in item 3 and confines the direction about “non payment” in section 30 to non payment of the dispensed price as distinct from non payment of the dispensing fee.

PART B**Item 1**

This item updates references in the MPBS to documents that are incorporated-by-reference into the MPBS. The documents are incorporated in the version they are in on 1 January 2016 and not as they may change from time to time. The main document being updated is the RPBS Schedule.