# **EXPLANATORY STATEMENT**

# REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (AUSTRALIAN PARTICIPANTS IN BRITISH NUCLEAR TESTS) 2006

#### **EMPOWERING PROVISION**

Section 18(5) of the Australian Participants in British Nuclear Tests (Treatment) Act 2006 (the Act).

#### PURPOSE

The attached instrument (2013 No. R45) (the Scheme) replaces the *Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests)* 2006 (2006 No.R33) (the revoked Scheme).

The Scheme is a legislative instrument made under section 18 of the Act. It applies, with modifications, the *Repatriation Pharmaceutical Benefits Scheme* (RPBS) made under section 91 of the *Veterans' Entitlements Act 1986* to the situation of eligible persons requiring pharmaceutical benefits in connection with their treatment for malignant neoplasia.

An eligible person is an Australian participant in british nuclear tests who is eligible for treatment of malignant neoplasia under the Act.

The application of the modified RPBS to an eligible person means the person receives pharmaceutical benefits for malignant neoplasia at the concessional rate.

The Scheme retains most of the revoked Scheme but applies new measures in the RPBS:

- prescribing by authorised nurse practitioners and authorised midwives of pharmaceutical benefits on the Pharmaceutical Benefits Scheme (but not pharmaceutical benefits solely on the <u>Repatriation</u> Pharmaceutical Benefits Scheme ) (nurse/midwife prescribing measure)
- prescribing by medication chart/continued dispensing (medication chart/continued dispensing measure)

#### THE NURSE/MIDWIFE PRESCRIBING MEASURE

Under the *National Health Act 1953* an "authorised midwife" or an "authorised nurse" may prescribe pharmaceutical benefits under the Pharmaceutical Benefits Scheme (PBS). The application of the modified RPBS to an eligible person will enable an authorised midwife or an authorised nurse to prescribe benefits under the RPBS that are listed on the PBS but not benefits that are <u>only</u> listed on the Repatriation Pharmaceutical Benefits Scheme (RPBS) i.e. not also listed on the PBS. The reason for the latter situation is that at the time the attached instrument was made DVA had not determined which RPBS medicines would be suitable for an authorised midwife or an authorised nurse to prescribe. It should be noted that under the *National Health Act 1953* an authorised midwife and an authorised nurse are only permitted to prescribe certain PBS medicines.

#### THE MEDICATION CHART/CONTINUED DISPENSING MEASURE

#### Medication Chart Prescribing

Medication Chart prescribing is only relevant to the prescription of pharmaceuticals for residents of aged care facilities. Residents receiving medication currently have a medication chart showing the medicines the person receives. A medical practitioner or authorised nurse practitioner (prescriber) inserts relevant information in an item in the chart. Essentially the attached Scheme makes an item in the Medication Chart, that is completed in accordance with the Scheme, a prescription for the purposes of the Scheme.

Medication chart prescribing will enable a prescriber to write a prescription for a patient in residential care by writing details of the medicine for the patient in an item in the chart. A copy of the chart is provided to a pharmacist i.e. it is the prescription. Ultimately it is proposed that medication charts be electronically transmitted to pharmacists.

The advantages of this method of prescribing is that "transcription errors" may be reduced, as there will be one medication management resource for residents for most of their medicines. Further the prescriber will not need to write prescriptions at a later time once they have returned from their visit to the facility, which may prevent transcription error due to recall error. This would not only reduce the administrative burden for pharmacists in following up discrepancies, but would also improve resident medication safety.

By the pharmacist having access to the prescriber's ongoing order for supply from the medication chart, the risk of disruption to the resident's ongoing therapy is reduced.

There was a trial of medication chart prescribing in 20 or so selected residential care facilities in NSW. The Department of Health & Ageing managed the trial and obtained relevant amendments to the legislation it administers in order for medication charts to be recognised as prescriptions. The trial was for the period August 2012-January 2013.

From 19 March 2013, medication chart prescribing will be implemented in a phased approach.

The Scheme needed to provide for medication chart prescribing because a resident of a residential care facility may be an eligible person (member etc) and a prescriber may seek to prescribe a medicine for the person via a medication chart but the medicine is only available under the Scheme and is not available under the Pharmaceutical Benefits Scheme.

Medication chart prescribing can be confined to residential care facilities in particular States or Territories because in order for a prescription to be valid under the Scheme it must be recognised by State/Territory law. Accordingly if a State/Territory law does not permit medication chart prescribing then a medication chart prescription in that State or Territory would not be a prescription under the Scheme.

continued dispensing (dispensing without a prescription)

This initiative enables certain medicines to be supplied without a prescription, in certain situations.

Normally a pharmacist is not permitted to supply a medicine to a person without the person presenting a prescription for the medicine.

Situations arise where it is not practical for a person to obtain a prescription and in order to facilitate patient adherence to therapy and prevent treatment interruption, the attached Scheme enables pharmacists to supply certain medicines to the person in those situations (continued dispensing).

The medicine must be a standard Pharmaceutical Benefits Scheme/MRCA Pharmaceutical Benefits Scheme supply of a chronic therapy medicine to a patient by a pharmacist on the basis of a previous prescription.

Chronic therapy medicines are considered to be those medicines which are taken as treatment for a medical condition over a long period of time.

Initially, a Continued Dispensing supply will be limited to two therapeutic categories:

- Oral Hormonal Contraceptives (OHC) for systemic use.
- Lipid Modifying Agents (LMA), specifically the HMG CoA reductase inhibitors.

#### CONSULTATION

<u>The nurse/midwife prescribing measure</u> — "no", because the measure has been implemented for prescribing under the Pharmaceutical Benefits Scheme under the *National Health Act 1953* and consulting interested parties would have been unlikely to have been productive.

<u>The medication chart/continued dispensing measure</u> — "yes", direct consultation occurred with the Department of Health & Ageing (DoHA) which introduced a virtually identical measure.

The nature of the consultation was e-mail correspondence, telephone conversations and meetings.

In preparing its "medication chart/continued dispensing measure" DoHA undertook a public written consultation process in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists, aged care and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiative.

DoHA has continued to engage with stakeholder groups as individual issues are identified. In particular, throughout the development of the Residential Medication Chart the Australian Commission on Safety and Quality and Healthcare established an expert reference group made up of key industry representatives. This group was integral to the development of the implementation model for this initiative.

In addition, DoHA 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.

## STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

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

The attached legislative instrument does engage an applicable right or freedom. It relates to 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 attached legislative instrument engages with, and promotes, the Right to Health. The new health initiatives introduced by the instrument could benefit the health of the relevant members or dependents by ensuring that:

- (a) they could receive certain medications more quickly because the range of prescribers has been broadened to include authorised nurse practitioners and authorised midwives and because prescriptions are not needed for certain medicines e.g. contraceptives.
- (b) they are more likely to receive the correct medications (better medication management).

The UN Committee on Economic Social and Cultural Rights has stated that qualifying conditions for benefits must be reasonable, proportionate and transparent.

The conditions that apply to prescriptions written by authorised nurse practitioners or authorised midwives and to medication chart prescribing and continued dispensing fall into the category of "supervisory regulation" and are necessary to ensure the public safety and protect the public revenue. Further, the conditions are identical to those under the *National Health Act 1953* in relation to similar matters.

While authorised nurse practitioners and authorised midwives will be permitted to prescribe medicines under the Repatriation Pharmaceutical Benefits Scheme where those benefits are also listed on the Pharmaceutical Benefits Scheme, they will not be permitted to prescribe medicines under the <u>Repatriation</u> Pharmaceutical Benefits Scheme (RPBS) where those benefits are only listed on the Repatriation Pharmaceutical Benefits Scheme Schedule (incorporated-by-reference into the RPBS) i.e. the schedule referring to the pharmaceutical benefits that are available to veterans, members of the Defence Force and their dependants but not to the community generally.

The reason for this limitation is that at the time the attached instrument was made, DVA had not determined which RPBS Schedule medicines would be suitable for an authorised midwife or an authorised nurse to prescribe. It should be noted that under the *National Health Act 1953* an authorised midwife and an authorised nurse are only permitted to prescribe certain PBS medicines.

Conclusion

The attached legislative instrument is considered to be compatible with the human right to health because it promotes that right (e.g. creates a new type of prescription that aids the medication management of people/enables certain medicines to be supplied more quickly) and the conditions it imposes on the relevant initiatives are considered necessary to maintain the integrity of the measures and therefore would seem reasonable in the circumstances.

Minister for Veterans' Affairs Rule-Maker

### FURTHER EXPLANATION

Attachment A.

#### Attachment A

This is an explanation of the modifications to the RPBS. Apart form these modifications the RPBS applies to eligible persons, including with the new measures of nurse/midwife prescribing, medication chart prescribing and continued dispensing. Clause by clause explanations of these new measures are contained in the Explanatory Statement for the RPBS that commenced on the day after it was registered on the Federal Register of Legislative Instruments.

The attached instrument modifies the application of the RPBS to eligible persons under the Act. The attached instrument cannot amend etc the RPBS. However for ease of drafting the language of making amendments etc has been used in some cases. Accordingly, in this attachment:

- a reference to a provision in the RPBS being substituted, means the provision no longer applies to an eligible person under the Act but the substituted provision does;
- a reference to a provision in the RPBS being amended means the provision applies to an eligible person under the Act as if it contained the amendment;
- a reference to a provision in the RPBS being omitted means the provision no longer applies to an eligible person under the Act.

#### Items Explanation

- [1] provides that the Scheme commences immediately after the new *Repatriation Pharmaceutical Benefits Scheme* (RPBS). This sequential commencement is necessary in order to have something (new RPBS) that may be modified.
- [2] specifies that a process commenced under the revoked Scheme that had not been completed under that Scheme when the attached instrument commenced is to be completed under the attached instrument as if it had commenced under the attached instrument.
- [3] is a definition section.

#### Schedule

- 1. modifies the title to the RPBS to make it clear the RPBS applies, in this context, to Australian participants in british nuclear tests.
- 2. modifies the Contents page of the RPBS to make it clear that the RPBS as modified applies to eligible persons and to omit references to matters that do not apply to eligible persons e.g. the pharmaceutical reimbursement.
- 3. modifies paragraph 1 of the RPBS so that it states that the modified RPBS is authorised by section 18 of the *Australian Participants in British Nuclear Tests (Treatment) Act 2006.*
- 4. modifies paragraph 2 of the RPBS so that it states that the purpose of the modified RPBS is to enable Community Pharmacists to supply pharmaceutical benefits to Australian participants in british nuclear tests who are eligible for treatment under the Act.

5. is a definition section.

The following definitions are definitions in the RPBS that have been modified:

*"Act"* means the Australian Participants in British Nuclear Tests (Treatment) Act 2006;

"accepted disability", in relation to a person eligible for treatment under the *Act*, means the malignant neoplasia of the person.

**"Eligible Person"** means a person who holds a *Repatriation Health Card* - *For Specific Conditions* and who is eligible for treatment of malignant neoplasia under the *Act*.

**"Repatriation Health Card - For Specific Conditions"** means an identification card, or written authorisation, provided to a person eligible under section 7 of the *Act* for treatment of malignant neoplasia.

Note: the specific condition covered by the card is malignant neoplasia.

**"RPBS"** means the *Repatriation Pharmaceutical Benefits Scheme* made under section 91 of the *Veterans' Entitlements Act 1986* as modified under section 18 of the *Australian Participants in British Nuclear Tests (Treatment) Act 2006.* 

**"revoked scheme**" means the *Repatriation Pharmaceutical Benefits Scheme* (Australian Participants in British Nuclear Tests) 2006 (2006 No.R33);

**"Scheme"** means the *Repatriation Pharmaceutical Benefits Scheme* made under section 91 of the *Veterans' Entitlements Act 1986* as modified under section 18 of the *Australian Participants in British Nuclear Tests (Treatment) Act 2006.* 

**"Treatment Principles"** means the *Treatment Principles* made under section 90 of the *Veterans' Entitlements Act 1986* as modified under section 16 of the *Australian Participants in British Nuclear Tests (Treatment) Act 2006*;

The RPBS has also been modified by omitting the following definitions (because they refer to matters that are not relevant to eligible persons):

"income support payment"
"income support payment under the Social Security Act 1991"
"MRCA supplement"
"pension supplement"
"pharmaceutical allowance"
"pharmaceutical reimbursement"
"Repatriation Health Card - For All Conditions"
"Repatriation Pharmaceutical Benefits Card" (and Note)
"social security pension supplement"
"SRCA disability"
"war widow/war widower pension"

6. substitutes paragraph 18 with the result that it does not mention "Repatriation Health Card – For All Conditions" and only mentions "Repatriation Health

Card - For Specific Conditions" because the Repatriation Health Card – For All Conditions is not relevant to eligible persons as they are only covered by a Repatriation Health Card - For Specific Conditions i.e. the specific condition of malignant neoplasia.

- 7. omits Note 2 to paragraph 21 because the note refers to matters associated with the pharmaceutical reimbursement and the pharmaceutical reimbursement is not relevant to eligible persons.
- 8. omits paragraph 23 because it relates to the pharmaceutical allowance under the *Veterans' Entitlements Act 1986* which is not relevant to eligible persons.
- 9. omits Part 5A because it relates to the pharmaceutical reimbursement which is not relevant to eligible persons.