



**Australian Government**  

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**Department of Veterans' Affairs**

**Reference Manual  
for Submissions to the  
Repatriation Pharmaceutical  
Reference Committee**

**October 2013**

Department of Veterans' Affairs  
The RPRC  
Pharmacy Programs and Operations

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Edition 5, October 2013

## CONTENTS

<b>CONTENTS</b> .....	<b>I</b>
<b>INTRODUCTION</b> .....	<b>III</b>
<b>PART 1: ROLE AND RESPONSIBILITIES OF THE REPATRIATION PHARMACEUTICAL REFERENCE COMMITTEE</b> .....	<b>5</b>
<b>REPATRIATION PHARMACEUTICAL BENEFITS SCHEME</b> .....	<b>5</b>
<b>THE REPATRIATION PHARMACEUTICAL REFERENCE COMMITTEE (RPRC)</b> .....	<b>6</b>
<b>GUIDELINES FOLLOWED BY THE RPRC</b> .....	<b>6</b>
<b>LISTING</b> .....	<b>7</b>
RPRC DECISION.....	7
RESTRICTED OR AUTHORITY REQUIRED LISTING.....	8
LISTED MAXIMUM QUANTITIES AND REPEATS.....	8
DELISTING.....	8
RE-SUBMISSIONS.....	9
REVIEW OF LISTINGS.....	9
<b>RPRC SECRETARIAT</b> .....	<b>9</b>
<b>PART 2 INFORMATION ON PREPARING A SUBMISSION TO THE REPATRIATION PHARMACEUTICAL REFERENCE COMMITTEE</b> .....	<b>10</b>
<b>PROCESSING OF SUBMISSIONS</b> .....	<b>10</b>
TIMING OF IMPLEMENTATION OF RECOMMENDATIONS.....	10
<b>MAJOR SUBMISSIONS</b> .....	<b>11</b>
<b>WOUND CARE PRODUCT SUBMISSIONS</b> .....	<b>11</b>
<b>MINOR SUBMISSIONS</b> .....	<b>12</b>
<b>REQUESTS FOR PRICE MODIFICATION</b> .....	<b>14</b>
<b>REQUESTS FOR CHANGES TO MANUFACTURER CODE, PACK SIZE OR PROPRIETY NAME</b> .....	<b>14</b>
<b>PART 3 GUIDELINES FOR PREPARING A MAJOR SUBMISSION</b> .....	<b>15</b>
<b>GUIDELINES</b> .....	<b>15</b>
INTRODUCTION.....	15
SUBMISSION FORMAT.....	15
COMMUNICATION WITH RPRC SECRETARIAT.....	16
<b>PRODUCT INFORMATION</b> .....	<b>17</b>
PHARMACOLOGICAL CLASS AND ACTION.....	17
TGA REGISTRATION/LISTING NOTICE.....	17
APPROVED PRODUCT INFORMATION (PI).....	17
PROPOSED INDICATION/S FOR RPBS LISTING.....	17
PHARMACEUTICAL BENEFITS SCHEME (PBS) STATUS.....	17
PATIENT SUPPORT PROGRAMS.....	17
PROPOSED PRICING.....	17

<b>PLACE OF PRODUCT IN VETERAN AND WAR WIDOW(ER)S THERAPY .....</b>	<b>18</b>
DISEASE AND PATIENT CHARACTERISTICS FOR GENERAL POPULATION .....	18
EPIDEMIOLOGY AND RISK FACTORS FOR DVA POPULATION .....	18
CURRENT APPROACHES TO TREATMENT .....	18
PROPOSED USE OF SUBMITTED PRODUCT .....	18
CO-ADMINISTERED THERAPIES .....	18
SUBSTITUTED THERAPIES .....	18
CONDITIONS FOR THERAPY CONTINUATION .....	18
<b>REVIEW OF EVIDENCE FOR PROPOSED INDICATION WITHIN THE DVA POPULATION .....</b>	<b>19</b>
SYNOPSIS .....	19
OBJECTIVE OF REVIEW .....	19
SELECTION CRITERIA .....	19
SEARCH STRATEGY .....	19
METHODS OF REVIEW .....	19
DESCRIPTION OF ALL IDENTIFIED STUDIES .....	19
RESULTS .....	19
REFERENCES .....	19
<b>COST-EFFECTIVENESS ANALYSIS FOR PROPOSED INDICATION WITHIN THE DVA POPULATION .....</b>	<b>20</b>
CHOICE OF COMPARATOR .....	20
PERSPECTIVE OF ANALYSIS .....	20
METHODS AND DATA .....	20
RESULTS .....	20
<i>Costs and effectiveness</i> .....	21
RELEVANCE OF RESULTS TO DVA POPULATION .....	21
REFERENCES .....	21
<b>UTILISATION AND COST PROJECTIONS WITHIN THE DVA POPULATION .....</b>	<b>21</b>
POPULATION PROJECTIONS FOR PROPOSED INDICATION .....	21
UTILISATION OF PROPOSED PRODUCT AND COMPARATOR(S) .....	21
EXPENDITURE OF PROPOSED PRODUCT AND COMPARATOR(S) .....	21
DVA HEALTH-RELATED EXPENDITURE .....	21
<b>SUBMISSION APPENDICES .....</b>	<b>22</b>
APPENDIX 1: COPIES OF ALL REFERENCES .....	22
APPENDIX 2: COPIES OF ALL REFERENCES .....	22
<b>DVA POPULATION STATISTICS AND PROJECTIONS .....</b>	<b>22</b>
VETERAN AND WAR WIDOW(ER)S POPULATION .....	22
PHARMACEUTICAL UTILISATION .....	22
<b>APPENDIX A: INDEX OF DVA COSTS .....</b>	<b>22</b>
<b>APPENDIX B: PRICING AND SUPPLY AGREEMENT .....</b>	<b>23</b>
<b>APPENDIX C: RPRC DECISION TREE .....</b>	<b>23</b>

## **INTRODUCTION**

The Department of Veterans' Affairs (DVA) exists to serve Australia's veterans, their war widow(er)s and dependants through programs of care, compensation and commemoration.

The Repatriation Commission under the Veterans' Entitlements Act 1986 is responsible for the preparation and maintenance of the Repatriation Pharmaceutical Benefits Scheme (RPBS). The Repatriation Pharmaceutical Reference Committee (RPRC) which was established in 1982, advises the Commission and the Minister on pharmaceutical items to be made available to eligible recipients under RPBS arrangements.



**PART 1:**

**ROLE AND RESPONSIBILITIES OF THE REPATRIATION  
PHARMACEUTICAL REFERENCE COMMITTEE**

**REPATRIATION PHARMACEUTICAL BENEFITS SCHEME**

Under the provisions of section 91 of the *Veterans' Entitlements Act 1986 (VEA)*, the Repatriation Pharmaceutical Benefits Scheme (RPBS) authorises the prescribing and dispensing of pharmaceutical benefits by community pharmacists to eligible persons to address their specific clinical needs.

A comprehensive range of pharmaceuticals is available to entitled veteran beneficiaries through the RPBS. These include:

- items listed in the Pharmaceutical Benefits Scheme (PBS),
- items listed in the Repatriation Schedule of Pharmaceutical Benefits, and
- items available under Prior Approval arrangements, unscheduled items within their marketing approval when clinically justified by the prescriber. Additionally, increased quantities and/or repeats may also be provided with Departmental Prior Approval.

All medicines must be approved for marketing in Australia by the Therapeutic Goods Administration (TGA).

In defined cases, pharmaceuticals and other treatments may be limited to the treatment of injuries or conditions that are service-related and recognised by the Department as veterans' accepted disabilities.

## **THE REPATRIATION PHARMACEUTICAL REFERENCE COMMITTEE (RPRC)**

The *Veterans' Entitlements Act 1986 (VEA)* provides a “whole of life” health service for entitled veterans and war widow(er)s. Eligibility for treatment at Departmental expense is given at section 53D of the VEA, while “provision of treatment” and “veterans eligible to be provided with treatment” are given at sections 84 and 85, respectively.

The National Health Act 1953 philosophy of providing a government subsidy for all Australians allowing reasonable access to life-saving medicines at an affordable cost. This PBS list forms a major part of the RPBS. The remaining items available under RPBS arrangements are items targeted to the particular clinical needs of veterans and war widow(er)s. These needs may reflect:

- The entitlement of veterans to pharmaceuticals for treatment of conditions resulting from their service;
- The underlying beneficial nature of entitlements under the VEA; or
- Cost-benefit considerations taking account of the “whole of life” context of veterans’ health services and the age and health profile of the veteran and war widow(er)s’ community.

The RPRC’s primary purpose is to advise the Repatriation Commission and the Minister regarding the clinical appropriateness of a range of pharmaceutical items including wound dressings. The Committee ensures that the items listed on the RPBS, and their conditions of supply, are the most appropriate to meet the special and individual needs of entitled veterans and war widow(er)s.

### **GUIDELINES FOLLOWED BY THE RPRC**

In formulating its recommendations, the RPRC refers to sponsor submissions, research and best practice guidelines. The RPRC frequently seeks expert opinion from relevant professional bodies and clinical experts in any relevant field.

In assessing the available data, the RPRC considers the following areas and it is recommended that submissions address these issues:

- Safety
- Quality
- Application to the general population
- Application to the veteran and war widow population
- Efficacy, particularly against accepted levels of evidence
- Comparative efficacy
- Economic evaluation
- Expenditure projections across all DVA health-related areas

More detail is available from the RPRC Decision Tree (Appendix C)



## LISTING

### RPRC DECISION

The decision reached by the RPRC in considering a submission to list a product on the RPBS, will be one of the following:

- Unrestricted listing of the item on the RPBS approved;
- Restricted listing of the item on the RPBS approved;
- Prior Approval listing;<sup>1</sup>
  - Authority required;
  - Non-Scheduled item available for individual access through prior approval arrangements as specified by determination of the RPRC;
- Application deferred pending the availability of additional information;
- Application deferred pending appropriate pricing; and
- Application declined. Individual access through Prior Approval arrangements is not appropriate.

In making its decisions the RPRC will, as far as is possible, provide a brief justification in relation to :

- (i) particular clinical needs of veterans and war widow(er)s
- (ii) therapeutic efficacy
- (iii) safety
- (iv) cost-effectiveness
- (v) treatment entitlement as inferred from the *Veterans' Entitlement Act 1986*
- (vi) equity of access
- (vii) comparison to evidence-based guidelines.

All items listed on the Schedule will be subject to periodic review.

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<sup>1</sup> All RPBS benefits that do not have an unrestricted listing in the Schedule of Repatriation Pharmaceutical Benefits, require "Prior Approval" at the time of prescribing. In the case of Authority Required listings and requests for increased quantity or repeats, prior approval is provided either by phone call or in writing to the Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC). Items that are not listed on the PBS, RPBS or within Section 100 (of the *National Health Act 1953*), can be prescribed but require an extensive written application to be made to the RPRC and are considered on a case-by-case basis.

### **RESTRICTED OR AUTHORITY REQUIRED LISTING**

An item will be considered for Restricted Benefit or Authority Required listing:

- (i) to limit RPBS usage in accordance with the approval and registration granted by the TGA, or
- (ii) to allow the controlled introduction of an item in a new therapeutic class, or
- (iii) to limit RPBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons, or
- (iv) to monitor possible adverse effects, possible misuse, overuse or abuse; or
- (v) where discussion between the veteran's doctor and a departmental pharmacist at the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) is judged necessary to ensure best use.

### **LISTED MAXIMUM QUANTITIES AND REPEATS**

For acute conditions, the maximum quantity recommended by the RPRC is that which is usually appropriate for a normal course of treatment (bearing in mind the manufacturer's pack size).

For chronic conditions, the maximum quantity and repeats usually provide for up to six months therapy depending on the need for clinical review of the condition. For patients requiring higher than average doses, increases in the listed maximum quantities and repeats are generally available through the Authority system.

### **DELISTING**

Circumstances which may result in removal of an item from the list include the following:

- (i) A more or an equally effective, but less toxic, item becomes available;
- (ii) Evidence becomes available that the item is ineffective;
- (iii) Evidence becomes available that the toxicity or abuse potential of the item outweighs its therapeutic value;
- (iv) The item has fallen into disuse or is no longer available;
- (v) Treatment with an item is no longer deemed cost-effective relative to other therapies;
- (vi) The price rises compared with therapeutically similar items;
- (vii) The item is no longer approved for marketing in Australia;
- (viii) There is no longer a need for the item within the veteran or war widow(er)s community; or
- (ix) Listing of the item on the PBS with an identical restriction.

## **RE-SUBMISSIONS**

Re-submissions responding to a negative RPRC decision will be considered where the sponsor submits new information that addresses the reasons for the negative decision. This information should be provided to the RPRC Secretariat at least 6 weeks prior to the following RPRC meeting.

Information contained in the original submission will remain valid for a period of twelve months from the date of the original submission. Re-submissions presented more than twelve months following the original submission are required to be a complete and new submission.

## **REVIEW OF LISTINGS**

The Committee regularly reviews the RPBS Schedule including items available, restrictions, maximum quantities and number of repeats applied to these listed items. These reviews are undertaken in two ways:

- (i) where a new item is under review for listing, the listed comparators and similar items are also reviewed, and
- (ii) RPBS Scheduled item groups are included as agenda items for each meeting with the aim of completing a review of the Repatriation section over each five-year period. Some therapeutic groups may be reviewed more frequently at the discretion of the RPRC.

## **RPRC SECRETARIAT**

The RPRC is serviced by the Commonwealth Department of Veterans' Affairs. The Secretariat is available for discussion about proposed submissions or related matters and as the point of contact concerning RPRC discussions and decisions. The RPRC Secretariat can be contacted by email: [rprc@dva.gov.au](mailto:rprc@dva.gov.au). All correspondence for the RPRC should be sent to:

Email: [rprc@dva.gov.au](mailto:rprc@dva.gov.au)

Or Postal Delivery:

The RPRC  
Pharmacy Programs and Operations  
Department of Veterans' Affairs  
GPO Box 9998  
BRISBANE QLD 4001

**PART 2****INFORMATION ON PREPARING A SUBMISSION TO  
THE REPATRIATION PHARMACEUTICAL  
REFERENCE COMMITTEE****PROCESSING OF SUBMISSIONS**

The Repatriation Pharmaceutical Reference Committee (RPRC) considers submissions not only from industry sponsors of medicine or therapeutic products and services, but also from medical bodies, health professionals, the Department of Veterans' Affairs, private individuals and their representatives.

The RPRC's meetings are generally held twice a year. The dates for the current year are available from the Secretariat and the DVA website at

<https://www.dva.gov.au/providers/pharmacists#repatpharmrefcom>

Copies of the submission should reach the committee secretary no later than six weeks prior to the meeting. Advice of an RPRC decision is provided to sponsors in writing after the Repatriation Commission and the Minister for Veterans' Affairs have responded to the RPRC recommendations.

**TIMING OF IMPLEMENTATION OF RECOMMENDATIONS**

<b>Action or event</b>	<b>Timing relative to RPRC meeting</b>
<b>TGA registration granted</b>	
Cut-off date for submissions	6 weeks prior
RPRC agenda to members	4 weeks prior
<b>RPRC meeting</b>	
Approval by Repatriation Commission and advice to Minister	Approx. 12 weeks post meeting
Written advice to sponsor	Approx. 2 weeks prior to listing on Schedule
Listing in the Schedule	Approx. 8 months post each RPRC meeting

## MAJOR SUBMISSIONS

A major submission is needed to apply to the Repatriation Pharmaceutical Reference Committee (RPRC) to:

- (i) list a new item on the Repatriation Pharmaceutical Benefits Schedule, or
- (ii) list a new presentation of a currently listed item, or
- (iii) request a significant change to the listing of a currently restricted item (including a new indication or a change to a restriction), or
- (iv) enable a review of the comparative cost-effectiveness of a currently listed item; or
- (v) list a new formulation (or strength) of a currently listed item for which a price premium is requested.

The sponsor should provide one electronic copy of the below documents to [rprc@dva.gov.au](mailto:rprc@dva.gov.au):

- one completed and signed original of the D9173 Form titled *Application to list or modify price of a product on the Repatriation Schedule of Pharmaceutical Benefits* (See Appendix B);
- one complete submission including executive summary and a complete cost-effectiveness analysis economic model including analysis against listed comparators, if possible; and

Part 3 of this document lists the requirements of a major submission to the RPRC.

## WOUND CARE PRODUCT SUBMISSIONS

Submissions for the listing of wound care products may be considered by the Advisory Wound Care Committee (AWCC), a sub-committee of the RPRC. The AWCC meet when required, depending on the number of wound care product submissions received by the Department of Veterans' Affairs. The submission should include a description of the wound product and studies that have been published, preferably in peer-reviewed journals and be of a level of evidence from one of the following:

- evidence obtained from a systematic review of all relevant randomised controlled trials.
- evidence obtained from at least one properly designed randomised controlled trial.
- evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

- evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.
- evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
- evidence obtained from case series, either post-test or pre-test and post-test.
- evidence obtained from technical publications ie studies in experimental biology (in vitro) and animal data on the dressing/product may be considered as acceptable supporting literature.

The sponsor should provide one electronic copy of the below documents to [rprc@dva.gov.au](mailto:rprc@dva.gov.au):

- one completed and signed original of the D9173 Form titled *Application to list or modify price of a product on the Repatriation Schedule of Pharmaceutical Benefits* (See Appendix B); and
- one complete submission including executive summary, case studies and a complete cost-effectiveness analysis economic model including analysis against listed comparators, if possible.

## MINOR SUBMISSIONS

A sponsor will make a minor submission to the RPRC for:

- (i) listing a new formulation, strength, brand or generic equivalent of a currently listed item for which a price premium is not requested, or
- (ii) a request to change the maximum quantity per prescription of a currently listed item, or
- (iii) a request to change the number of repeats per prescription of a currently listed item; or
- (iv) a request to change the agreed price of a currently listed item if the requested percentage increase since the most recent price change is greater than the Health Group CPI Index Number percentage change for the same period; or
- (v) clarification of the wording of a restriction (while not altering the intended use), or
- (vi) Any change to the reasons or conditions of listing.

A minor submission can be a letter explaining or justifying the change, clinical need and price involved.

The sponsor should provide one electronic copy of the below documents to [rprc@dva.gov.au](mailto:rprc@dva.gov.au):

- one completed and signed original of the D9173 form titled *Application to list or modify price or a product on the Repatriation Schedule of Pharmaceutical Benefits*  
(See Appendix B);
- one copy of the submission letter, the current TGA-approved certificate, TGA approved product information, the TGA Bio equivalence information if relevant and if possible, a cost-effectiveness analysis against listed comparators;
- If the submission is for a revised formulation, strength or brand of a currently listed item, one copy of the letter of registration with details of marketing approval and registration (if and when available, with the relevant Australian Drug Evaluation Committee (ADEC) resolution) should be provided.

## REQUESTS FOR PRICE MODIFICATION

All applications to modify a current price of a product currently listed on the Repatriation Schedule of Pharmaceutical Benefits must include:

- one completed and signed original of the D9173 form titled *Application to list or modify price or a product on the Repatriation Schedule of Pharmaceutical Benefits* (See Appendix B); and
- be forwarded to the RPRC Secretariat at [rprc@dva.gov.au](mailto:rprc@dva.gov.au)

The requested percentage price increase since the most recent price change is required to be less or equal to the Health Group CPI Index Number percentage change for the same period.

## REQUESTS FOR CHANGES TO MANUFACTURER CODE, PACK SIZE OR PROPRIETY NAME

In the cases detailed below, email your request to the RPRC Secretariat at: [rprc@dva.gov.au](mailto:rprc@dva.gov.au)

- transfer of manufacturer code;
- change in pack size or tablet numbers within packs without a corresponding price change; and
- change of propriety name of a listed product.



**GUIDELINES FOR PREPARING A MAJOR SUBMISSION****GUIDELINES****INTRODUCTION**

These Guidelines should be used by sponsors as a set of minimum requirements when preparing major submissions to the RPRC. They are not intended as a restrictive template, but rather to ensure the information and data provided is both sufficient and in a format that enables the RPRC to examine the evidence presented in a judicious and efficient manner. Furthermore, these Guidelines highlight particular issues that are specific to the veteran and war widow(er)s community and areas where the submission approach or presentation should differ from the PBS Submission Guidelines.

**SUBMISSION FORMAT**

- 1. Index**
- 2. Executive Summary**
- 3. Product Information**
  - 3.1 Pharmacological class and action
  - 3.2 TGA registration/listing notice
  - 3.3 Approved Product Information
  - 3.4 Proposed indication/s for RPBS listing
  - 3.5 PBS status
  - 3.6 Patient support programs
  - 3.7 Proposed pricing
- 4. Place of product in veteran and war widow(er)s therapy**
  - 4.1 Disease and patient characteristics for general population
  - 4.2 Epidemiology and risk factors for DVA population
  - 4.3 Current approaches to treatment
  - 4.4 Proposed use of submitted product
  - 4.5 Co-administered therapies
  - 4.6 Substituted therapies
  - 4.7 Conditions for therapy continuation

- 5. Review of evidence for proposed indication within the DVA population**
  - 5.1 Synopsis
  - 5.2 Objective of review
  - 5.3 Selection criteria
  - 5.4 Search strategy
  - 5.5 Methods of the review
  - 5.6 Description of all identified studies
  - 5.7 Results
  - 5.8 References
- 6. Cost-effectiveness analysis for proposed indication within the DVA population**
  - 6.1 Choice of comparator
  - 6.2 Perspective of analysis
  - 6.3 Methods and data
  - 6.4 Results
    - 6.4.1 Costs and effectiveness
  - 6.5 Relevance of results to DVA population
  - 6.6 References
- 7. Cost analysis for proposed indication within the DVA population**
  - 7.1. Utilisation of proposed product and comparator/s
  - 7.2. Expenditure of proposed product and comparator/s
- 8. Utilization and cost projections within the DVA population**
  - 8.1. Population projections and proposed indication
  - 8.2. Utilization of proposed product and comparator(s)
  - 8.3. Expenditure of proposed product and comparator(s)
  - 8.4. DVA health-related expenditure
- 9. Appendices**
  - 9.1 Appendix 1: Copies of all references from 5.8
  - 9.2 Appendix 2: Copies of all references from 6.6

#### **COMMUNICATION WITH RPRC SECRETARIAT**

The sponsor can consult with the RPRC Secretariat during the preparation of the submission.

The RPRC Secretariat can provide the sponsor with up-to-date projections of veteran and war widow(er)s populations for utilisation in the submission. It may also be possible to provide the sponsor with aggregate, de-identified data specifically addressing the prescription utilisation and incidence of specific diseases or conditions within the veteran and war widow(er)s community.

The Secretariat welcomes the opportunities to assist sponsors ensure submissions and models are appropriate.

## **PRODUCT INFORMATION**

### **PHARMACOLOGICAL CLASS AND ACTION**

### **TGA REGISTRATION/LISTING NOTICE**

Provide a copy of the current ARTG notice issued by the TGA.

### **APPROVED PRODUCT INFORMATION (PI)**

Provide a copy of the current, approved PI for the proposed product. If the PI has not received approval from the TGA by the time of submission to the RPRC, please provide the PI as submitted to the TGA and any subsequent correspondence between the sponsor and TGA relating to progress toward approval.

### **PROPOSED INDICATION/S FOR RPBS LISTING**

Specify the indication(s) proposed for RPBS listing.

If a restricted listing is sought, suggest a wording for the proposed restriction. If a general listing is sought, identify the proposed main indication(s).

### **PHARMACEUTICAL BENEFITS SCHEME (PBS) STATUS**

Note the presentation and strengths of the product already listed on the PBS.

If a prior submission for listing on the PBS of this product or presentation has been rejected by PBAC, provide specific discussion why the product should be considered for RPBS listing.

### **PATIENT SUPPORT PROGRAMS**

Include a comprehensive description of any non-pharmacological patient support programs that complement utilisation of the proposed product. Evidence of the changes in product effectiveness or patient outcomes due to the inclusion of the support program should be noted in Sections 5 of the submission. Alternatively, if the support program is an integral therapy component and has been included within the trials and economic evaluation, this should be highlighted.

Cost and consequence impacts should be included within Section 6. The funding source for the program must be clearly stated.

### **PROPOSED PRICING**

The proposed product will be listed on the RPBS at the Dispensed Price Maximum Quantity using the same formula as used to list on the PBS (refer PBS website pricing matters). The sponsor is required to enter into an agreement with DVA covering pricing at Agreed Ex-Manufacturers Price (AEMP) and Price to Pharmacy (PTP) (see Appendix B).

## **PLACE OF PRODUCT IN VETERAN AND WAR WIDOW(ER)S THERAPY**

### **DISEASE AND PATIENT CHARACTERISTICS FOR GENERAL POPULATION**

This may be excluded at the sponsor's discretion. However, this information may provide useful background against which the veteran characteristics can be compared. It may also be required to form the basis of, or justification for, a disease or treatment model.

### **EPIDEMIOLOGY AND RISK FACTORS FOR DVA POPULATION**

The sponsor should identify and detail information from the literature describing the condition(s) and patient characteristics.

The RPRC Secretariat will provide population projections for Gold and White entitlement cards. In many cases, it may also be possible to provide the sponsor with aggregate, de-identified data specifically addressing the incidence of specific diseases or conditions within the veteran and war widow(er)s community.

### **CURRENT APPROACHES TO TREATMENT**

The sponsor should detail current treatment practices and pathways for the proposed condition(s). Include practice guidelines, evidence-based practice, therapeutic guidelines and accepted practice.

### **PROPOSED USE OF SUBMITTED PRODUCT**

The sponsor will describe and justify the proposed place in current practice that the proposed product will occupy. The sponsor is required to enter into an agreement with DVA covering the proposed listing maximum quantity, packsize and number of repeats.

### **CO-ADMINISTERED THERAPIES**

The sponsor should note all therapies, including dosage, timing and frequency, that will be co-administered with the proposed product. Include pharmacological, physical, supportive and complementary therapies, and patient support programs.

### **SUBSTITUTED THERAPIES**

The sponsor should detail therapies that are likely to be reduced or eliminated due to the introduction of the proposed product.

### **CONDITIONS FOR THERAPY CONTINUATION**

The sponsor should identify appropriate therapy outcomes, or endpoints, that should be achieved by the patient to justify ongoing subsidised therapy with the proposed product. Proposed methodology for withdrawal of therapy from non-responsive patients should be discussed.

Alternatively, the case for ongoing subsidised therapy regardless of outcome should be justified.

## **REVIEW OF EVIDENCE FOR PROPOSED INDICATION WITHIN THE DVA POPULATION**

### **SYNOPSIS**

#### **OBJECTIVE OF REVIEW**

The review should provide a precise statement of the primary objective of the review.

#### **SELECTION CRITERIA**

To ensure the application of the review to the target population, describe and justify the criteria used to select studies included in this review.

#### **SEARCH STRATEGY**

Summarise the data sources utilised, dates searches were undertaken, search terms, and constraints.

#### **METHODS OF REVIEW**

The sponsor should provide a systematic review and meta-analysis. This component is of particular interest to ensure the validity of the analysis. The sponsor should describe the methods used to:

- Assess the quality of studies;
- Extract data from the studies;
- Synthesise data;
- Undertake statistical analyses; and
- Sensitivity analyses.

#### **DESCRIPTION OF ALL IDENTIFIED STUDIES**

Compile two tables:

- Included studies, and
- Excluded studies

Within each table, list study identifier (such as name of first author and year of publication), describe key characteristics of participants, number of cases and controls, study method, interventions, outcome measures, results (including statistical significance, p values and 95% CI) reason for exclusion (as applicable)

#### **RESULTS**

Results should be presented in both tabular and graphical presentations. All discussion should have particular application to the veteran and war widow(er)s population.

#### **REFERENCES**

Provide a complete list of all references, both published and unpublished studies. Copies of all these references must be provided in Appendix 1.

## **COST-EFFECTIVENESS ANALYSIS FOR PROPOSED INDICATION WITHIN THE DVA POPULATION**

Economic analysis has been introduced as a core component to Major Submissions to the RPRC in an effort to improve the relevance of information provided to the RPRC, to reduce the potential for value judgements, and to ensure that the care provided to veterans delivers the maximum possible health benefit for the limited DVA expenditure.

### **CHOICE OF COMPARATOR**

Justify the choice of the main comparator. The comparator may be pharmacological, surgical, supportive or other form of therapy.

### **PERSPECTIVE OF ANALYSIS**

The sponsor will utilise a limited societal perspective for all costs and outcomes.

The cost-effectiveness analysis should be undertaken in the true sense. Cost-minimisation will only be accepted when the effectiveness of the proposed product and comparator are equivalent. Cost-utility analyses are not necessary however, if the sponsor believes this is appropriate, it is recommended that it be discussed with the RPRC Secretariat before the analysis is undertaken.

### **METHODS AND DATA**

The conceptual model should be described, validated and accompanied by the decision tree, Markov model or event pathway.

Both traditional (frequentist) and Bayesian statistical models will be accepted.

All assumptions should be stated.

### **RESULTS**

Presentation of the results should include a discussion and tables including:

- total costs;
- total effectiveness;

and

- incremental costs;
- incremental effectiveness; and
- incremental cost effectiveness ratios.

Graphical representation of the results, as a plot of net cost and net effectiveness, would be considered valuable.

### ***Costs and effectiveness***

Intermediate, direct outcomes can be utilised, but they must be accompanied by a validation. Indirect costs and outcomes must be excluded.

All costs should be valued in Australian dollars and the reference year noted. Most direct costs will be provided by DVA and are presented later in this document (See Appendix A: Index of DVA Costs)

### **RELEVANCE OF RESULTS TO DVA POPULATION**

The results must be discussed as they apply to the veteran and war widow(er)s population. Any specific subgroup analysis undertaken that is particularly pertinent to this population, should be highlighted.

### **REFERENCES**

Provide a complete list of all references, both published and unpublished studies. Copies of all these references must be provided in Appendix 2.

## **UTILISATION AND COST PROJECTIONS WITHIN THE DVA POPULATION**

### **POPULATION PROJECTIONS FOR PROPOSED INDICATION**

Present the population projections for each of the proposed indication(s) for the proposed product and its comparators. Justify the projection model. Projections are required for Year 1 and the subsequent four out-years.

### **UTILISATION OF PROPOSED PRODUCT AND COMPARATOR(S)**

State the projected utilisation separately of the product and its comparator(s). These should be presented as one unit being equivalent to the proposed or existing Schedule Maximum Quantity. Projections are required for Year 1 and the subsequent four out-years.

### **EXPENDITURE OF PROPOSED PRODUCT AND COMPARATOR(S)**

State the projected expenditure separately of the product and its comparator(s). These should be calculated from the proposed (existing) dispensed price for maximum quantity. . Projections are required for Year 1 and the subsequent four out-years.

### **DVA HEALTH-RELATED EXPENDITURE**

The Department is responsible for all funded health services for eligible veterans and war widow(ers). The sponsor should provide projections for all health-related expenditures that are affected by the product and its utilisation and funded by DVA. Projections are required for Year 1 and the subsequent four out-years.

## SUBMISSION APPENDICES

### APPENDIX 1: COPIES OF ALL REFERENCES

Provide complete copies of all references and studies utilised. These must be accompanied by an index and presented in an easily searchable manner according to the index.

### APPENDIX 2: COPIES OF ALL REFERENCES

Provide complete copies of all references and studies utilised. These must be accompanied by an index and presented in an easily searchable manner according to the index.

## DVA POPULATION STATISTICS AND PROJECTIONS

Statistics provided will apply to the Australian Government Department of Veterans' Affairs during the preceding financial year.

### VETERAN AND WAR WIDOW(ER)S POPULATION

Please contact the RPRC Secretariat for the most recent population data.

### PHARMACEUTICAL UTILISATION

Please contact the RPRC Secretariat for prescription utilisation and condition incidence statistics applicable to the proposed indication. Utilization data is also available on the PBS website:  
[https://www.medicareaustralia.gov.au/statistics/pbs\\_item.shtml](https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml)

## APPENDIX A: INDEX OF DVA COSTS

Refer to the *Manual of Resource Items and their Associated Costs* published by the Department of Health and Ageing at  
<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pubs-manual-appendix1.htm>

Note that DVA incurs health costs associated with veteran care, including but not limited to:

- Pharmaceuticals;
- Hospital;
- Medical & Allied Health;
  - Local Medical Officers (LMO) (General Practitioners);
  - Specialist medical services;
  - Dental;
  - Hearing;
  - Chiropractic;
  - Optometrical;
  - Transport;
  - Dietetics;
  - Prostheses; and
- Community Nursing



**APPENDIX B: PRICING AND SUPPLY AGREEMENT**

A copy of the *Application to list or modify price of a product on the Repatriation Schedule of Pharmaceutical Benefits* can be found at:

<https://www.dva.gov.au/sites/default/files/dvaforms/D9173.pdf>

**APPENDIX C: RPRC DECISION TREE**

	Yes	No	??
1. Is the drug approved by ADEC for marketing in Australia?			
2. Has registration for the claimed indication been granted by TGA?			
3. Is the drug on the PBS or under consideration?			
4. Is there an Identified veteran need for this therapy?			
5. Is there proven efficacy: <ul style="list-style-type: none"> <li>- Verses placebo?</li> <li>- Verses other items?</li> <li>- Verses “gold standard”?</li> </ul>			
6. Is there a PBS/RPBS listed drug that is an appropriate comparator?			
7. Compared with the PBS/RPBS listed comparator, does the new item provide: <ul style="list-style-type: none"> <li>- Better efficacy?</li> <li>- Improved compliance?</li> <li>- A better safety profile?</li> <li>- Cost benefits?</li> </ul>			
8. Is there an efficacy/safety comparison with NON-DRUG treatment options? Eg. Surgery, watchful waiting.			
9. Is the evidence, submitted by the sponsor, of high quality?			
9.1 Have treatment endpoint’s been accurately identified?			
9.2 Have the trial subjects been clearly identified as being appropriate?			
9.3 What was the trial setting?			
9.4 How long did the trial last?			
9.5 How were the therapeutic benefits assessed? Was this valid?			
9.6 Were these effects clearly described?			
9.7 What measures were used to reduce variance and bias?			
9.8 Was the trial design satisfactory?			
9.9 Were sufficient trial subjects included?			
9.10 Was the dosage administered appropriate?			
9.11 Were there sufficient pre-trial wash out periods?			
9.12 What statistical tests were utilised? Were these appropriate?			
9.13 Are the trial conclusions justified?			
10. Will veterans be disadvantaged if the drug is not listed on the RBPS?			
11. Do best practice guidelines or expert clinical opinion support listing of the drug on the RBPS?			
12. Is the cost-minimisation analysis compared with existing, equivalent, listed therapy persuasive?			
13. Is the cost-effectiveness analysis persuasive?			
14. Can any other offset savings be identified?			
15. Does the proposal present “value for money”?			