Australian Government

Repatriation Medical Authority

Member Handbook

February 2022

Contents

INTRODUCTION

1. The Repatriation Medical Authority (RMA) is an expert medical body established as an independent statutory authority, responsible for determining the medical-scientific framework within which decisions about claims for compensation for injuries, diseases and deaths attributed to military service are decided.

2. Members of the RMA are medical practitioners and scientists, appointed by the Minister for Veterans' Affairs on a part-time basis. The purpose of this manual is to provide an introduction, background and context to the role and operations of the RMA for RMA Members on their appointment, and for reference and guidance thereafter in their role.

3. The manual contains a number of chapters, covering an introduction to the Statements of Principles (SOPs) system, sound medical-scientific evidence, and standards of proof. It includes a number of detailed appendices, including a history of the Australian Repatriation system, those Parts of the *Veterans' Entitlements Act 1986* (VEA) which directly relate to the RMA and the Specialist Medical Review Council (SMRC - the body established to review RMA decisions on application), a number of policy documents providing a detailed description of the RMA's operations, and a description of the operations of the SMRC.

4. Members wishing to obtain additional information about any aspect of the RMA, SOPs, disability compensation or the Repatriation system should discuss their specific needs or interests with the RMA Registrar and/or Principal Medical Officer. The RMA Secretariat holds a range of books, case-law and reference material which may assist in providing a more detailed understanding of the issue of interest.

THE STATEMENTS OF PRINCIPLES SYSTEM

Background

5. Compensation for the incapacity or death of members of the Australian Defence Force, as part of a wider 'repatriation' system, has its genesis in World War One. The establishment of the Repatriation Commission and the Repatriation Department (now known as the Department of Veterans' Affairs) and passage of the *Repatriation Act* in 1920 created a national system designed to deliver on behalf of Australia obligations owed to volunteers who had "heroically fought and suffered in its defence".[1] The system has been organised around five principal areas – war pensions and other compensatory assistance; general assistance to war veterans; medical and hospital benefits; housing; and war graves[2].

6. Other programs have ceased or been developed over time as circumstances and expectations have changed. Pensions and assistance provided to veterans with tuberculosis, for example, disappeared in the 1970s. A national network of prostheses factories (the Repatriation Artificial Limb and Appliance Centres) were closed in the early 1990s, and general and psychiatric hospitals were similarly closed, transferred to State Governements or sold between 1988 and 1994. Compensation pensions for 'peacetime' service commenced in 1972, and expanded greatly in 1999. Commemoration activities grew rapidly from the late 1990s.

7. Compensation, in the form of a pension (payable at a variety of levels commensurate with the level of severity of the associated impairment), and medical treatment for injuries or diseases causally related to war service were introduced as an integral part of the original repatriation system. The provisions and basis for determining whether a claimed condition, whether it be an injury or disease, is in fact due to war service – or other types of 'eligible' service after World War Two – have varied over time, as a result of changes to the legislation, decisions by the courts or the understanding of medical causation. The area of veterans' entitlements law is one of the most extensively contested areas of administrative law, with more cases each year than any other area other than taxation law.

8. A formal review of the compensation program was prompted by the 1992 Auditor-General's report on the compensation provided by the Department of Veterans' Affairs (DVA) to veterans and their dependants for injuries, diseases and death attributable to service. That review, together with a number of High Court decisions which allowed successful claims by veterans and the outcome of an inquiry by the Senate Committee on Legal and Constitutional Affairs, led to the establishment in 1993 of the Veterans' Compensation Review Committee, chaired by Professor Peter Baume. That Committee took evidence from the veteran community and issued a report entitled 'A Fair Go' in March 1994.

9. The RMA arose from the recommendation of the Baume Committee that an expert medical committee should be formed. It was considered that such a committee would assist in providing a more equitable and consistent system of determining claims for disability pensions for veterans and their dependants.

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[1] Lloyd, C & Rees J (1994) *The Last Shilling: A History of Repatriation in Australia*, MUP, Melbourne, p 1
[2] Ibid p 3

10. The Government announced the establishment of the RMA in the 1994/95 Federal Budget. The role of the RMA was to issue binding SOPs based on sound medical-scientific evidence (SMSE) stating what factors must exist to establish a causal connection between service and 'particular kinds of injury, disease or death' (conditions). The *Veterans' Entitlements Act 1986* (VEA) was amended to reflect this announcement on 30 June 1994. The passage of the *Military Rehabilitation and Compensation Act 2004* (MRCA) extended the application of SOPs to the consideration of claims to have injury, disease or death accepted as service-related under that Act for all service on or after 1 July 2004.

11. A more detailed overview of the Repatriation system can be found in **Appendix 1**. The overview, 'History of Repatriation System', is chapter 3 of the *2003 Report of the Review of Veterans' Entitlements* (the Clarke Report)[3]. An overview with a focus on military compensation arrangements which is chapter 2 of the DVA's *2011 Review of Military Compensation Arrangements*, can be found at **Appendix 2**[4].

12. Further reading could include Lloyd and Rees's *The Last Shilling* or Creyke and Sutherland's *Veterans' Entitlements Law*[5].

The Legislation

13. The VEA was amended in 1994 to establish the RMA (s196A). A new Part XIA was inserted in the Act which set out the constitution, functions and powers of the organisation and, broadly, how it should operate. Its functions are specified as undertaking investigations and determining SOPs (s196B). The VEA specifies how investigations are commenced (s196B), who may request an investigation or review (s196E), make a submission (s196F), and how investigations must be notified (s196G).

14. The number (s196L), qualifications (s196M) and tenure of office (s196N) of RMA Members are also specified in Part XIA, as well as reference to the meetings of the RMA (s196R), payments to Members (s196S) and staff to support the RMA (s196T).

15. A new Part XIB of the VEA provided for the establishment and operation of the SMRC.

16. Part XIA and Part XIB of the VEA are included as **Appendix 3**.

17. These changes were introduced in the *Veterans' Affairs (1994-95 Budget Measures) Legislation Amendment Act 1994*. In doing so, the Minister for Veterans' Affairs said:

> *The Bill will, in effect define by reference to such statements of principles the concept of "reasonable hypothesis", as it appears in subsection 120(3) of the Veterans' Entitlements Act. The result will be that a medical hypothesis linking particular kinds of injury, disease or death with war service that does not have a sound medical-scientific basis will no longer be sufficient to constitute a*

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[3] http://www.dva.gov.au/consultation-and-grants/reviews/clarke-review#report

[4] https://www.dva.gov.au/sites/default/files/files/consultation%20and%20grants/reviews/mrca/mrcareport/vol1-full18032011.pdf

[5] Clem LLoyd and Jacqui Rees, *The last shilling : a history of Repatriation in Australia*, Carlton : Melbourne University Press, 1994; Creyke, RC & Sutherland, *Veterans' Entitlements Law*, 3rd Edition, Federation Press, Sydney, 2016.

"reasonable hypothesis". This will be a matter solely for the expert medical authority to determine. I stress that the opinion of a single medical expert may still be sufficient to constitute a "reasonable hypothesis", provided that such opinion has a sound medical-scientific basis, as determined by the Authority. [6]

18. The Minister later said:

These changes maintain a beneficial repatriation system, including a "reasonable hypothesis" standard, modified as I have already outlined, for deciding compensation claims for death or disease relating to eligible war service. There has not been a return to a civil standard of proof, as recommended by the Baume Committee, which would have had the potential to reduce the success rate of claims, which currently stands at above 70%, to the pre-1977 rate of approximately 30%. The Government acknowledges the special status of veterans. It is hoped that these changes will be effective in overcoming the maverick and fringe claims that have interfered with the integrity of an extremely generous repatriation system, without having to return to a civil standard of proof for the determination of claims. [7]

19. The extrinsic material makes clear that the impetus for the setting up of the RMA and SMRC was to introduce scientific rigor into the repatriation compensation system and to stop poor quality or maverick medical evidence from being used as the basis for successful compensation claims.

20. To this end, the legislation also introduced sections 120A and 120B of the VEA that provided for the SOPs to be the point of reference in assessing whether any hypothesis connecting a medical condition to service is reasonable or whether a decision-maker can be reasonably satisfied about the connection between a condition and service. Sections 338 and 339 of the MRCA are to identical effect for all service on or after 1 July 2004.

21. For any given condition there are two SOPs, determined at either the RH or BOP standard of proof according to the legislation. For the RH standard, the sound medical-scientific evidence must indicate or point to a causal association between a risk factor and the disease in question. For the BOP standard the sound medical-scientific evidence must show that it is more probable than not that there is a causal association between a risk factor and the disease.

22. As a result, the military compensation system provides that claims for pension and the SOP factors used to determine claims are both assessed using two different standards of proof:

- The more generous (beneficial) standard, known as the reasonable hypothesis (RH) standard, applies to claims for conditions connected with operational (or equivalent) service. This includes peacekeeping, hazardous and British nuclear test defence service under the VEA), and warlike and non-warlike service under the MRCA; and
- The balance of probabilities (BOP) standard that is used for claims for conditions arising from non-operational service.

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[6] Hansard, 9 June 1994 at 1808
[7] at 1809

Statements of Principles

23. In summary, SOPs are instruments used to determine liability for claims made under the VEA and the MRCA.

24. The SOPs are 'templates' which set out all factors which can cause or permanently worsen a disease or injury (and potentially death). All claims for pensions are assessed against the relevant SOP. If an individual claimant's circumstances meet at least one of the causal factors listed in a SOP, the claim may be accepted provided that the provisions of the factor relied upon are related to service. If an individual claimant's circumstances do not meet one of the causal factors listed in a SOP, the claim must be refused.

25. Section 196B(13A) of the VEA provides that SOPs are legislative instruments and as such their operation is governed by the *Legislation Act 2003* (Cth) (Legislation Act). That Act provides for drafting standards for such instruments, their registration on the Federal Register of Legislation and importantly, Parliamentary scrutiny of their contents.

26. The SOPs are lodged for registration (with the instrument's explanatory statement) with the Office of Parliamentary Counsel which registers the instrument and delivers the instruments for laying before each House of the Parliament within 6 sitting days of that House after the instrument is registered. SOPs apply from the date of their registration on the Federal Register of Legislation or the date specified in them, whichever is the later.

27. A legislative instrument (or a provision) may be disallowed by either House within 15 sitting days after the instrument is tabled. During that time, any MP (or Senator) can move a motion of disallowance in relation to a SOP, which if passed (or if not defeated, withdrawn or otherwise disposed of within a further 15 sitting days) causes the SOP to be disallowed and repealed.

28. SOPs can also be amended by an amending instrument. To assist interested parties the Legislation Act provides for the lodgement and registration of a compilation SOP which shows the text of a SOP as amended and in force on the compilation date stated in that instrument.

29. As a result of the drafting standards the SOPs have a defined structure designed to enhance their use by claimants and decision makers. Information about the structure of the SOPs is to be found in the '*User Guide to the RMA's Statements of Principles'* at **Appendix 4**.

Military Compensation - Statutory Bodies

30. The system outlined above provides for the creation of are a number of statutory bodies with a role in the SOP system. Their details are set out below.

The Repatriation Medical Authority

31. The RMA is an independent statutory authority responsible to the Minister for Veterans' Affairs (s196A of the VEA). It consists of a panel of five practitioners eminent in their fields of medical science, who are appointed on a part-time basis for up to 5 years (with members being eligible for reappointment).

32. The VEA requires that at least one RMA Member must be a person having at least 5 years experience in the field of epidemiology. In practice, all Members have had extensive experience in epidemiology. Since its initial establishment in 1994, Ministers have ensured that all RMA members have expertise in epidemiology and evidence-based medicine, and collectively have a mix of research and clinical skills covering areas of particular relevance to veterans, including oncology, psychiatry, cardiovascular and respiratory diseases, and musculoskeletal conditions.

The Specialist Medical Review Council

33. The SMRC is an independent statutory authority established under s196V of the VEA. Its functions as set out in s196W of the VEA, are to review determinations of the RMA on request. The SMRC does not consider individual claims for pension.

34. Unlike the RMA, the membership of the SMRC changes with each review. As set out in s196ZE of the VEA, the SMRC consists of members appointed by the Minister according to the expertise necessary to deal with the matters under review. The structure of the SMRC reflects the Parliamentary intention that determinations of the RMA be reviewed by medical specialists or scientists who have expertise in the injury or disease under review.

35. For further details about the operations of the SMRC see **Appendix 8**.

The Commissions

36. The Repatriation Commission and the Military Rehabilitation and Compensation Commission (together, the Commissions) are responsible for granting pensions, allowances and other benefits, providing treatment and other services and generally administering the VEA and the MRCA. The Commissions are part of the Veterans' Affairs portfolio, and function in an executive management capacity. The Commissions are responsible for considering and determining individual claims for pension, utilising the SOPs determined by the RMA. The Commissions have no staff of their own but delegate many of their powers to DVA staff.

37. The DVA Secretary chairs both Commissions. The Secretary and the 2 other members of the Repatriation Commission join with members nominated by the Defence Minister and Department of Employment to make up the membership of the Military Rehabilitation and Compensation Commission.

38. The Commissions may request the RMA to review a condition and make submissions to both the RMA and to the SMRC.

Determination of a Statement of Principles (SOP)

39. The RMA's primary function, as set out in s196B of the VEA, is to undertake investigations of particular conditions, and determine the contents of the SOPs for each condition based on the SMSE abiut that condition.

40. In order to make a SOP, the RMA assesses links between:

- service;
- the medical condition (injury or disease); and

- the medical causes of a condition (which are expressed as the factors in the SOP).

41. This assessment is a three-stage process.

42. Firstly, the RMA must be of the view that there is a link between service and a particular condition. This is the basis for the RMA's obligation to make a legislative instrument for a particular condition and the requirement to conduct an investigation concerning that condition[8] This consideration can also include whether a particular condition referred to it is properly "a disease or injury".[9]

43. Secondly, the RMA examines the link between a factor (or medical cause) and a disease having regard to the SMSE. This is the basis for the RMA's inclusion of a factor in a SOP. If there is no SMSE sufficient to determine a SOP, the RMA must declare it will not make a SOP.[10]

44. Finally, the link between a factor and service needs to be considered by the RMA but only to the extent of deciding whether the factor can be related to service for the condition to be said to be related to service.

45. The decision about whether that link between factor and service is established on the material in any given case is left for determination by the delegates of the Commissions.

Investigations

46. The RMA can determine a SOP of its' own volition or after an investigation.

47. Investigations of conditions and reviews of exisiting SOPs can be undertaken on request from eligible parties[11], at direction by the SMRC, or on the RMA's own initiative.

48. The Legislation Act requires the RMA to review and reissue each SOP at least every 10 years, failing which a SOP ceases to have legal effect.

49. After completing an investigation of a condition, the RMA determines SOPs in respect of that condition which specify the various factors which can cause (or aggravate) a condition and must exist in order to be able to relate the condition to military service.

50. Depending on the strength of the evidence supporting a causal association, a proposed medical cause may be a factor in both the RH and BOP SOPs (stronger evidence), a factor in the RH SOP only (weaker evidence), or neither (inadequate or insufficient evidence, or evidence of no association). Sometimes a factor may be in both SOPs, but described in a way that is easier to meet in the RH SOP in accordance with the more generous standard of proof. For example, the required exposure dose may be lower or the time to clinical onset longer in the RH SOP.

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[8] S196B(4) of the VEA.
[9] S 5D of the VEA provides for the defintions of 'disease' and 'injury'. See also *Comcare v Paul Mooi [1996] FCA 1587*.
[10] S196B(6) of the VEA.
[11] S196E(1) of the VEA specifies the persons and organisations eligible to request an investigation or review.

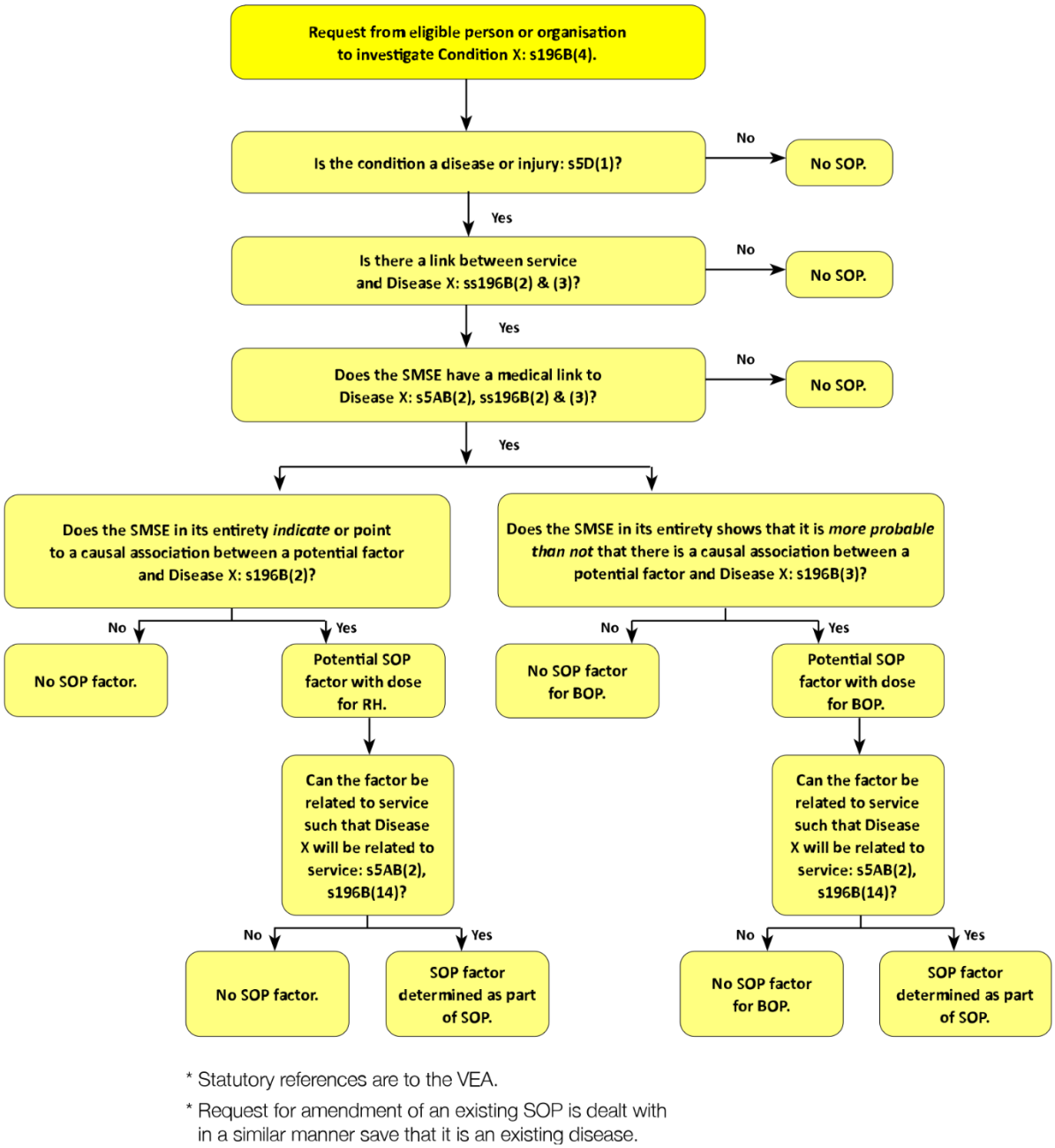
51. For factors that can be described in terms of levels of exposure, the dose may be quantified in various ways. Examples include pack-years for smoking, sieverts for ionising radiation, numbers of hours or days within a specified time period for certain chemicals or activities, and body mass index for overweight or obesity.

52. Some factors are not quantifiable. Examples include having a specified disease or injury or being exposed to a particular virus or other kind of infectious agent.

53. The amount and quality of available evidence may affect the RMA's ability to differentiate the dose between the two SOPs. Where a causal relationship is well-established for a quantifiable factor, and there is detailed information concerning the relationship between the exposure dose and the condition, it may be possible to accurately determine a dose consistent with the RH standard, i.e., which is associated with a small but measurable increase in risk. When such information is absent, the lower dose in the range can be applied to the RH standard. For risk factors with less information, a reliable distinction between the doses for the two standards is harder to make based on empirical evidence.

54. The following diagram summarises the process of SOP determination for a new condition. The process is the same for a review of an existing condition, except that consideration of whether the condition is a disease or injury is not usually necessary..

Figure 1 - Determination of Statements of Principles for new condition – Disease X



* Statutory references are to the VEA.
* Request for amendment of an existing SOP is dealt with in a similar manner save that it is an existing disease.

For further details about the operations of the RMA see *The Repatriation Medical Authority Practices and Procedures* at **Appendix 5**.

SOUND MEDICAL-SCIENTIFIC EVIDENCE (SMSE)

55. Central to the SOPs regime is the concept of SMSE. Both the RMA (and the SMRC) must base their decisions on SMSE as defined in the s5AB(2) of the VEA which states:

> 2. *Information about a particular kind of injury, disease or death is taken to be sound medical-scientific evidence if:*
>
> *(a) the information:*
>
> *i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or*
>
> *ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and*
>
> *(b) in the case of information about how that kind of injury, disease or death may be caused—meets the applicable criteria for assessing causation currently applied in the field of epidemiology.*

56. The RMA's process for sourcing evidence is based on standard practices for systematic reviews and is set out in its paper titled Guidelines for RMA Researchers at **Appendix 6**.

Evaluation of sound medical-scientific evidence

57. The RMA can only make a SOP about a particular kind of injury, disease or death where there is sufficient SMSE to justify the making of the SOP. The SMRC when reviewing a decision made by the RMA, must base its decision on the SMSE available to and obtained by the RMA[12].

58. The RMA and the SMRC are required to assess material against certain epidemiological criteria. The criteria set out below are not exhaustive and may not be relevant in all cases. They are a guide to the material that is acceptable to the RMA and the SMRC.

Quality of evidence

59. In assessing studies, both the RMA and the SMRC look for SMSE that:

- is well-designed;
- provides enough information;
- is not merely hypothesis generating exercises from large databases;
- has adequate outcome measurements; and
- has no major faults in the methodology.

Assessing Combined Epidemiological Evidence

60. The RMA and the SMRC examine the body of evidence against these criteria:

- strength of association;
- consistency;

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[12] The SMRC does not conduct new literature searches and cannot rely upon 'new' information that has not been considered by the RMA.

- specificity;
- temporality;
- biological gradient;
- plausibility;
- experimental evidence; and
- analogy.

Websites

61. Website articles are not SMSE if they are opinion based, not subject to peer review, or do not meet the applicable criteria for assessing causation currently applied in the field of epidemiology.

Animal Studies

62. Animal studies may sometimes support the biological plausibility of an association. However, results from animal studies may not be generalisable to humans and are at best used as initial research that may indicate a need for further studies on human subjects or to demonstrate possible biological mechanisms.

Laboratory Studies

63. Laboratory-based studies of human cells are used in medical research for exploring potential pathological mechanisms, such as examining inflammatory responses to toxins. Processes occurring at the cellular level can be misleading as many other processes contribute to human health effects. While such studies may demonstrate biological mechanisms or generate further research, only some would lead to further discoveries, and they can often produce a range of conflicting results.

64. Such studies can be material that epidemiologists would consider appropriate to take into account, but the weight attached to their results when considering causes of diseases varies, and is generally relatively low compared to human studies.

STANDARDS OF PROOF

65. Under the VEA and the MRCA, there are two legislated standards of proof that are applied to SOPs. Based on these, the RMA creates two SOPs for each kind of injury, disease or death.

66. The two SOPs are known generically as the RH and BOP SOPs.

Applying Standards of Proof

Beneficial legislation

67. Both the RMA and the SMRC are required to apply these standards of proof in arriving at their decisions. The VEA and the MRCA are sometimes referred to as 'beneficial legislation'. The proper effect of it being so classified has been clarified. The insertion of particular factors

associated with service arises from the nature of the legislative provisions, not because of the application or concept of 'beneficial legislation' (see **Appendix 7** for the full legal advice).

Overall evidence - not one study

68. Whether a reasonable hypothesis is 'indicated' is explicitly a matter for consideration and assessment by the RMA (or the SMRC) as part of the overall evaluative exercise it is carrying out. The evaluation addresses all the relevant SMSE, recognising that there may be contradictory evidence.

69. The overall evaluation function of the RMA and the SMRC is to determine whether the relevant SMSE, considered as a whole, indicates a reasonable hypothesis.

70. In short, the mere fact that one study (or even more than one study) is supportive of the existence of a reasonable hypothesis does not ordain the outcome on its own, but such a study (or studies) may be regarded as sufficient.

71. For the BOP SOPs, the consideration of 'more likely than not' applies a similar process where all the relevant SMSE is considered.

How the RMA interprets and applies the two Standards of Proof

72. The main role of the RMA is to determine SOPs. The RMA determines SOPs at the two standards of proof identified above, reflecting the legal tests set out in ss 196B(2) and 196B(3) of the VEA.

Legal tests

73. The legal tests for the identification of a factor and determination of a SOP are as follows:

Reasonable Hypothesis (RH) Standard

74. For a factor to be included at the reasonable hypothesis standard, the SMSE has to indicate or point to a reasonable hypothesis of a causal association between the factor and disease, as per section 196B(2) of the VEA.

> *196B(2) If the Authority is of the view that there is sound medical-scientific evidence that indicates that a particular kind of injury, disease or death can be related to:*
>
> *(a) operational service rendered by veterans; or*
> *(b) peacekeeping service rendered by members of Peacekeeping Forces; or*
> *(c) hazardous service rendered by members of the Forces; or*
> *(caa) British nuclear test defence service rendered by members of the Forces; or*
> *(ca) warlike or non-warlike service rendered by members;*
>
> *the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:*
>
> *(d) the factors that must as a minimum exist; and*

(e) which of those factors must be related to service rendered by a person;

before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

Balance of Probabilities (BOP) Standard

75. For a factor to be included at the balance of probabilities standard, the SMSE has to show that it is more probable than not that the factor is causally related to the disease, as per section 196B(3) of the VEA.

196(3) If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:

(a) eligible war service (other than operational service) rendered by veterans; or
(b) defence service (other than hazardous service and British nuclear test defence service) rendered by members of the Forces; or
(ba) peacetime service rendered by members;

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:

(c) the factors that must exist; and
(d) which of those factors must be related to service rendered by a person;

before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

RH v BOP

76. In considering what is meant by the term "reasonable hypothesis", the RMA is guided by relevant judicial decisions prior to its establishment, particularly the deliberations of the High Court of Australia in the cases of *Bushell* (1992)[13] and Byrnes (1993)[14]. The definition of reasonable hypothesis given in *Bushell* is as follows:

To be reasonable, a hypothesis must possess some degree of acceptability or credibility - it must not be obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous. For a reasonable hypothesis to be 'raised' by material …, we think it must find some support in that material - that is, the material must point to, and not merely leave open, a hypothesis as a reasonable hypothesis.

77. On the other hand, the BOP SOP test of “more probable than not” was the subject of consideration by the High Court in *Bradshaw v McEwans Pty Limited (1951)*[15] as follows:

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[13] Bushell vs Repatriation Commission (1992) 175 CLR 408
[14] Byrnes vs Repatration Commission (1993) 177 CLR 564
[15] Unreported, 27 April 1951: cited with approval in *Holloway v McFeeters* (1956) 94 CLR 470 at 480-1.

By more probable than not is meant no more than that upon a balance of probabilities such an inference might reasonably be considered to have some greater degree of likelihood.

Grading Criteria

78. The legal tests are very broadly framed. To give effect to these tests, the Authority has developed grading criteria which set out a standard and consistent approach to assessing the available SMSE. There are five grades, indicating decreasing levels of certainty about the likelihood that a factor is a cause of the condition under investigation (see detailed description below).

79. These grades are assigned to the body of SMSE concerning a particular risk factor for the disease or injury under investigation, not to individual studies. They are assigned by an RMA medical researcher in discussion with an allocated supervising member of the Authority prior to being considered at an RMA meeting.

80. The grades serve as a tool for communication and discussion and are indicative only. The final decision as to what factors are included in a SOP, as well as the wording of those factors, depends upon further consideration and discussion at a minimum of two RMA meetings. Grades 2, 3 and 4 generally signal the most uncertainty about the evidence, and therefore the greatest need for discussion.

81. In documenting these criteria, the RMA acknowledges that it has drawn upon and adapted grading criteria produced by the Institute of Medicine, the International Agency for Research on Cancer and the World Cancer Research Fund/American Institute for Cancer Research.

82. While there are logical propositions which guide the RMA in its deliberations, it is the expertise and experience of its Members which enables sound judgement to be made about the factors pertinent to each disease or injury. This approach also informs the formulation of factors.

83. For further detail about the standards of proof, the evidence gathering, assessment process and assessment of causation, and grading criteria please refer to the relevant sections of the *RMA Practices and Procedures* document at **Appendix 5**.

GLOSSARY

BOP	balance of probabilities
CI	confidence interval
DVA	Department of Veterans' Affairs
ESO	Ex-Service Organisation
ICD	International Classification of Diseases
MRCA	*Military Rehabilitation and Compensation Act 2004*
OR	odds ratio
RH	reasonable hypothesis
RMA	Repatriation Medical Authority
RR	relative risk
SMRC	Specialist Medical Review Council
SMSE	sound medical-scientific evidence
SOP	Statement of Principles
VEA	*Veterans' Entitlements Act 1986*

APPENDIX 1 - History of the SOP system

This overview entitled 'History of Repatriation System', is chapter 3 of the report of the Review of Veterans' Entitlements (also known as the Clarke Report). The review was commissioned by the Minister for Veterans' Affairs in early 2002, and the three-person committee chaired by retired Supreme Court Judge the Honourable John Clarke QC submitted its detailed report in January 2003.

CHAPTER THREE

HISTORY OF REPATRIATION SYSTEM 3

ANTECEDENTS

3.1 The obligation of the state to recompense the soldiery for service in its defence is an ancient one, dating at least from the Assyrian empire *circa* 1200 BC (Lloyd and Rees 1994, p. 7). Resettling veterans on land taken from vanquished barbarians or rival senatorial families was popular in ancient Rome and a linkage between land and resettlement appears frequently in the ensuing centuries, across a number of cultures. In Britain, pensions granted by statute began during the reign of Elizabeth I, with an Act of 1603 conferring the right of pension to a veteran 'maimed in the Queen's service' (Toose 1975, p. 19).

3.2 In 1681 under Charles II, the Chelsea Hospital system was established to provide treatment and convalescence for 'war damaged' or 'time-expired' soldiers. These men were known as 'in-pensioners'. Four years later an 'out- pensioner' scheme was established, with a gratuity for disablement payable at a flat rate for all ranks. In 1806, the amount of pension was made proportionate to the extent of the injury incurred (Toose 1975, p. 19). The debilitating effects of tropical disease were also recognised, in acknowled gment of the role of the military in forging and preserving the empire.

3.3 Widows and children of veterans were first provided for in Britain during the Crimean War (1854-56) through the Royal Patriotic Fund Corporation, a body reliant on public subscription with some support from the War Office. Similar funds were established in the Australian colonies in response to the sending of contingents to the Sudan Campaign, the Boxer Rebellion and the Boer War. While those organisations were assiduous in raising funds from the public, they were far less so in the actual distribution of money to veterans, and tended to be derelict in attending to the needs of those for whom they had been established.

EARLY DEVELOPMENT

3.4 The *Defence Act 1903* made provision for members of the Defence Force or their widows in the event of incapacity or death resulting from wounds or disease acquired while on active service. However, members of the Defence Force employed on active service were specifically excluded from the Commonwealth *Workmen's Compensation Act 1912,* apparently out of concern about the extent of the probable liabilities that would be incurred in time of war (Toose 1975, p. 20).

3.5 Nevertheless, Australia's commitment to the imperial war effort in 1914 necessitated the Commonwealth providing more fully for returned servicemen. Accordingly, in November 1914, the War Pensions Bill was introduced into the Parliament and received bipartisan support. The resulting Act granted pensions to Defence Force members killed or incapacitated as a result of service in warlike operations. Beneficiaries included those who enlisted or were appointed to active service outside Australia, or who served on a ship of war. Home service did not qualify. Disease was also included, with the proviso that it was contracted on active service. In 1915, the Act was amended to include members of the Army Medical Corps Nursing Service accepted or appointed for service outside Australia, and the following year it was extended to members on home service (Toose 1975, pp. 20-21).

3.6 Another significant early piece of legislation was the Australian *Soldiers' Repatriation Fund Act 1916,* although not for the reasons originally envisaged by its authors. The fund was in principle virtually identical to the failed patriotic funds of the 19th century, reliant on public subscriptions, with some augmentation from the Government, but established by statute rather than by the citizenry. It failed most singularly to achieve anything by way of fundraising, largely because of the prevailing political climate. Nevertheless, it did help shape the early model of the Australian repatriation system.

3.7 In early 1917, an executive committee of the trustees of the fund made a series of recommendations to the Prime Minister. They were:

- that the entire question of the re-establishment of discharged soldiers and the care of the dependants of soldiers generally should be made the concern of a Commonwealth authority; and
- that the Commonwealth authority should devise a substantially uniform system of dealing with returned soldiers and the dependants of soldiers on service or soldiers who died as a result of service in respect of:
  1. immediate amelioration;
  2. care of the totally incapacitated;
  3. vocational training of the partially incapacitated;
  4. employment generally;
  5. assistance towards permanent re-establishment;
  6. care of dependants;
  7. coordination of governmental and private efforts for the expansion of existing industries and promotion of new industries to meet the demand for employment; and

8 assembling and administration of funds (Toose 1975, pp. 24-5).

3.8 The recommendations were debated at an interstate conference shortly thereafter, at which it was decided that the Commonwealth should have definite control over all matters relating to repatriation, and that states should administer land settlement in conjunction with the Commonwealth through the Soldiers' Settlement Board of Australia (Toose 1975, p. 24).

3.9 Itis worthwhile to note the burgeoning activities of ex-service organisations (ES0s) in this period as more and more Australians returned from Europe. Pre-eminent among those ESOs was the Returned Sailors' and Soldiers' Imperial League of Australia (RSSILA), now known as the Returned & Services League of Australia (RSL). Through exceptionally skilful organisation, building on public sentiment in favour of the returned diggers, the League was able to exert considerable pressure on the Commonwealth Government. In particular, it achieved recognition of compensation as a right, rather than as an act of gratuity, which in turn signalled the end of the voluntary system exemplified by the patriotic funds.

THE AUSTRALIAN SOLDIERS' REPATRIATION ACT 1917

3.10 In response to the recommendations of the Trustees, the Vice-President of the Executive Council and soon to be first Minister for Repatriation, Senator Edward Millen, introduced the Australian Soldiers' Repatriation Bill into the Parliament on 18 July 1917. Among other things, the legislation provided for benefits and assistance to discharged servicemen, children under 18 of the deceased or incapacitated, and to widows in special circumstances.3

3.11 The Act was proclaimed on 8 April 1918 and the new Department of Repatriation began operations on the same date. The Minister was given overall responsibility for the administration of the Act, and a part-time honorary Repatriation Commission of seven was appointed with power to make recommendations to the Government for regulations granting benefits and assistance.

3.12 Millen introduced amendments to the Act shortly afterwards, saying that the Repatriation Department accepts 'as the minimum obligation the responsibility of providing the returned soldier with an opportunity of earning at least a living wage, and that until such opportunity is forthcoming subsistence be granted' (Toose 1975, p. 26).

3.13 The Repatriation Commission considered that the achievement of the objectives would entail expenditure on:

1. sustenance while awaiting employment;
2. sustenance while undergoing training;
3. sustenance while undergoing treatment or care in hospitals or special institutions;
4. sustenance while awaiting the allotment of land, and during the initial period of land occupancy;
5. medical treatment after discharge, including the provision of artificial limbs and other surgical aids;
6. emergency grants to cover exceptional necessities;
7. fees to educational institutions;
8. tools of trade, professional instruments and personal equipment;

9. small business plant and livestock;
10. homes;
11. passages to and from the Commonwealth;
12. transportation within the Commonwealth;
13. allowances to dependants; and
14. funeral expenses (Toose 1975).

3.14 The practical working of the repatriation system was governed by regulation, rather than by the provisions of the Act, principally because there was no precedent for the scheme and policy was therefore unfolding and changing at a rate too rapid to be accommodated within a formal legislative framework.

THE AUSTRALIAN SOLDIERS' REPATRIATION ACT 1920

3.15 New legislation in the form of the *Australian Soldiers' Repatriation Act 1920* repealed the *War Pensions Act 1914* and the *Australian Soldiers' Repatriation Act 1917.* Administrative changes under the new legislation included the reform of the Repatriation Commission into an incorporated body of three members, with Repatriation Boards (also of three) constituted for each state. The boards were responsible for determining and assessing claims, with an appeal from their decisions available to the Commission. Commissioners were paid for their work for the first time. At the same time, the Repatriation Department assumed responsibility for the payment of pensions from the Treasury (Toose 1975, p. 27)

3.16 The new Act also expanded entitlement for pensions through the introduction of the so-called 'occurrence clause' . This gave cover in respect of death or incapacity resulting from any occurrence happening during the period of service. As a result, the death or injury need not have had any causal connection with the individual's service; it must merely have occurred during the period of service (Toose 1975, p. 27).

3.17 Perhaps most significantly, the *Repatriation Act 1920* introduced the concept of a 'special rate' pension for those totally and permanently incapacitated (TPI) or blinded as a result of war service. Often referred to as 'the TPI pension', its initial rate of payment was £4 per week.[4]

3.18 Amendments to the Act in 1921and 1922 saw the Department accept liability for medical and hospital treatment of servicemen upon their discharge and for the administration of artificial limb factories. Inaddition, a Fif th Schedule to the Act was inserted after representations were made to Minister Millen by the Limbless Soldiers Association. This provided for an extra allowance to this class of veteran that brought their overall benefit to substantially the same level as that of special rate recipients (Toose 1975, p. 29).

THE BLACKBURN ROYAL COMMISSION

3.19 On 27 August 1924, a Royal Com mission chaired by Dr C B Blackbu rn was established to inquire if :

> ... the present method of determining whether an ex-soldier's disability is due to or aggravated by war service [is] adequate to decide the degree to which it is

aggravated and what portion of his present incapacity can be regarded as having resulted from war service. (Toose 1975, p. 29)

3.20 After consideration, the Royal Commission found that:

> In the majority of cases the present machinery for determining disability and assessing pensions is sufficient. There are, however, certain types of disabilities that are, for various reasons, inadequately determined . The inadequacy, to some extent, has been due to defects in the *Australian Soldiers' Repatriation Act* ... (Toose 1975, p. 29)

3.21 The Royal Commission's deliberations and findings on the matter of the appeals system provide an excellent illustration of the evolutionary gulf that exists between accepted policy strictures then and now. For instance, it was accepted that there would be no final body of appeal, but rather that the Repatriation Commission could reconsider a case virtually *ad infinitum,* provided that the claimant could adduce new evidence on each occasion. Other

recommendations included that the Repatriation Commission should not have medical practitioners as members, but only as technical advisers or referees, and that it was proper for a veteran to discuss his file, but most improper for him to actually see it (Lloyd and Rees 1994, pp. 232-5).

THE TWENTIES AND THIRTIES

3.22 Throughout the span of the Bruce-Page Government (1923-29) there was no minister appointed with sole responsibility for repatriation. Rather, the job was passed among a number of ministers and attended to only on a part- time basis. The absence of any consistent political control of repatriation, in combination with the lack of an appeal mechanism from decisions of the Repatriation Commission, resulted in considerable disquiet among the veteran community. Itwas felt that there were insufficient checks on the freedom of action of both the Department and the Commission.

3.23 The Government eventually moved to assuage these concerns in 1929. The Health Minister, Sir Neville Howse, who had general responsibility for repatriation, introduced legislation to establish War Pensions Entitlement and War Pensions Assessment Tribunals. An important principle laid down in the legislation related to the onus of proof. Once the appellant had made out a prima facie case, the onus was on the Repatriation Commission to disprove it (Toose 1975, p. 31).

3.24 By the 1930s, a condition known as 'burnt-out digger syndrome' began to attract official attention. A report from the Commonwealth Statistician in 1934 found a 13 per cent excess mortality rate among veterans compared with similarly aged civilians. In response, the Government introduced a service pension payable to returned soldiers at age 60 rather than at 65 (Lloyd and Rees 1994, pp. 251-6). This was the first repatriation income support measure, all previous benefits having been compensatory in nature.

WORLD WAR II

3.25 The *Australian Soldiers' Repatriation Bill 1940* introduced separate pension bases for troops who served overseas and those who served entirely in Australia. In

the former case the 'occurrence clause' had application, but not in the latter. The *Seamen's War Pensions and Allowances Act 1940* also came into force that year, providing for compensation and other benefits to Australian mariners (Toose 1975, pp. 35-8).

3.26 Three events of significance occurred in 1943. The first was new legislation to pension those who had served in New Guinea on the same basis as those who served overseas. The second was a liberalisation of the standard of proof provisions in the Repatriation Act. This effectively enshrined the reverse criminal standard of proof in legislation. The third was the extension of the area in which the Citizens' Military Force could be used. Previously, the militia was confined to service within Australia. Now it could be used in the South-Western Pacific Zone within an area fixed by proclamation for a period up to six months after the end of the war (Toose 1975, pp. 37, 38).

THE FIFTIES AND SIXTIES

3.27 The *Repatriation Act* was extended through the 1950s to provide benefits, including the service pension, to those who served from 27 June 1950 to 19 April 1956 and were allotted for duty in the operational area in Korea, or from 29 June 1950 to 1September 1957 in Malaya. The Act was later amended in the 1960s to cover Australian armed services personnel serving in the Indonesian Conf rontation. In 1957, the Repatriation (Far East Strategic Reserve) Act 1956 brought members of the Far East Strategic Reserve within the purview of the repatriation system, although the nature of their service was considered not to be the same as that of personnel in World War II or Korea. As a consequence they did not, at that time, receive eligibility for the service pension.

3.28 Increasing Australian military involvement in South-East Asia led to the passage of the *Repatriation (Special Overseas Service) Act* 1962. This legislation

> ... extended repatriation benefits for [s]pecial service inprescribed areas overseas, where Australian forces were engaged in 'warlike operations'. This provision was instrumental in providing pensions and benefits for Vietnam War veterans. (Lloyd and Rees 1994, p. 319)

3.29 A major reform to the war (now disability) pension structure took place in 1965 with the introduction of the intermediate rate, midway between the 100 per cent general rate and the special rate. The intention was to provide a greater level of compensation to veterans who were quite severely disabled, but nonetheless capable of engaging in employment on a part-time or intermittent basis.

3.30 The last major reform of the 1960s was the extension of the service pension to those with 'special service' under the *Special Operations Act* in 1968.

THE SEVENTIES

3.31 During the 1970s, peacetime coverage under the *Repatriation Act 1920* (to be preserved in the *Veterans' Entitlements Act 1986* (VEA)), was extended to serving military personnel (including national servicemen). This created a dual entitlement, as those individuals were already covered by the normal Commonwealth employees' compensation legislation. The situation was intended to be a short-term bridging measure pending the implementation of a new, separate Military Compensation Scheme. Unfortunately,

that legislation did not eventuate for another 22 years. The *Military Compensation Act 1994* ended peacetime coverage under the VEA.

3.32 Between 1971 and 1975, Justice Paul Toose of the New South Wales Supreme Court undertook a wide-ranging inquiry into all aspects of the repatriation system. A principal recommendation was that the various pieces of legislation be consolidated into one Act. This eventually occurred in 1986 with the passage of the VEA. But Toose's most enduring legacy is the underlying principles of repatriation that he expounded in his report (see Chapter 4).

3.33 In 1973, the Commonwealth began to partially exempt the disability pension from the service pension means test. The initial amount was 25 per cent, followed by an increase to 50 per cent in 1975, 60 per cent in January 1982 and finally 100 per cent in November of the same year.

3.34 From 1974, virtually all the Commonwealth's training schemes were transferred to the Department of Labour and Immigration. The following year, British, Commonwealth and allied (BCAL) veterans became eligible for the service pension. Between 1976 and 1979, Consumer Price Index (CPI) indexation of the major pensions was introduced, linking them to changes in the CPI. In accordance with a recoμ1mendation of the Toose Report, the Department of Repatriation became the Department of Veterans' Affairs (DVA) on 5 October 1976.

3.35 The appeals and review structure changed in 1979 with the establishment of the Repatriation Review Tribunal, which replaced the Entitlements Appeals Tribunal and the Assessment Appeals Tribunal. There were also increased avenues of appeal to the Federal Court and High Court on matters of law.

VETERANS' HEALTH CARE

3.36 After World War I, the Repatriation Department assumed responsibility for providing medical treatment for discharged soldiers suffering service-related disabilities. The Department's facilities were limited, and medical treatment was usually provided by arrangement with institutions established during the war by the Defence Department.

3.37 With the cessation of hostilities and the return to civilian life of the majority of servicemen, control of the military hospitals, sanatoria and artificial limb factories thathad been built in each capital city was transferred

progressively to the Repatriation Department. This was completed by 1922. To supplement the centralised outpatient facilities, arrangements were made by the Department for general practitioner and pharmaceutical services in country areas.

3.38 Similarly, after World War II, the Repatriation Department took over the much larger and more modern Army hospitals built during the war to meet immediate and post-war needs. These institutions became repatriation general hospitals and certain of the older institutions were retained and used as auxiliary hospitals to provide for special inpatient and outpatient needs.

3.39 By the time of the Toose Enquiry in the early 1970s, the continuing relevance of the repatriation general hospitals had come into question, with some submissions arguing that they should be amalgamated with hospitals in the state health systems. They were ultimately transferred to state government or private enterprise control by 1995, and DVA now purchases almost all its medical services

from these and other agents.

THE EIGHTIES

3.40 Allied veterans were made eligible for the service pension in 1980. It was necessary that they had served in a theatre of war, had at no time been a member of enemy forces and had been resident in Australia for 10 years.

3.41 In the early 1980s there were two particularly significant court cases, *Law* and *Bowman,* both of which had far-reaching ramifications for the repatriation system. The *Law* case of 1981'effectively conceded cigarette smoking in war-time as a causative element in entitlement' (Lloyd and Rees 1994, p. 358). This decision led to a very significant increase in claims for compensation resulting from smoking-related illnesses.

3.42 In *Bowman,* also in 1981, the Federal Court held with respect to the TPI pension that 'the effect of incapacity on ability to earn could only be gauged by reference to the market in which the applicant might expect to earn'. Also, it was

> ... sufficient in testing whether an applicant's ability to earn is due to his war-related disability to consider whether he would be equally unable to earn if he were free of this disability. The only hypothesis involved in this would be the consideration of the applicant free of his disability. (Lloyd and Rees 1994, p. 391)

3.43 This case significantly broadened potential eligibility for the TPI payment.

3.44 In 1981, peacekeeping operations were given coverage under the VEA and in 1982 this was made retrospective to World War II. Also in 1982, Australian, Commonwealth and allied mariners became eligible for the service pension. In the following year, the Commonwealth Government established a royal commission into the effects of the herbicide 'Agent Orange' on Vietnam veterans. Headed by Mr Justice Evatt, the commission ultimately found there was no connection between the spraying of the herbicide and health problems in Vietnam veterans. Similarly, no link was found to account for birth defects in the children of Vietnam veterans. The Commission's findings engendered considerable controversy and the issue is still without final resolution nearly two decades later.

3.45 In 1984, an income and assets test was introduced for the service pension and social security income support payments, replacing the sole income test. In May 1985, the Treasurer brought down an economic statement that had a noticeable impact on veterans' benefits. Among other things, the war widow's income support supplement was frozen, grants of dependants' pensions were terminated, and changes to the standard of proof were announced in response to the *O'Brien* case, in which

> ... a majority of the High Court held that it was not necessary for the material in a particular case to 'provide some positive reference in favour of the requisite connection between death and incapacity and war service'. (Creyke and Sutherland 2000, p. 402)

3.46 Unsurprisingly, this decision led to a subsequent large increase in the number of claims for disability pension. Changes to the standard of proof provided that

> ... where the Repatriation Commission is reasonably satisfied that the material before it does not raise a *reasonable hypothesis* of a connection between the death and incapacity of a veteran and the veteran's war service ... a pension shall not be granted. (Lloyd and Rees 1994, p. 400)

3.47 In addition, the reasonable hypothesis standard was restricted to those who had 'engaged in combat, the civil standard [applying] in other cases' (Lloyd and Rees 1994, p. 400).

3.48 In 1986, Toose's recommendation for a single Act consolidating all repatriation legislation was finally implemented. The VEA left most of the law unaffected, but did attempt to make crucial changes in certain areas relating to the disability and war widow's pensions. In particular, the Minister emphatically restated in the second reading speech that the special or TPI rate of disability pension should not be granted to veterans over the age of 65, except in very rare cases.

3.49 To oversee the early years of the VEA, a committee of eminent persons chaired by Justice Toose and known as the Veterans' Entitlements Act Monitoring Committee (VEAMC) was established. While generally finding the operations of the new legislation to be satisfactory, the VEAMC nevertheless recommended increased compensation for frail, aged veterans with high levels of impairment and restricted lifestyles. The result of this was the introduction of the extreme disablement adjustment (EDA), payable to extremely disabled veterans over 65 at effectively 150 per cent of the general rate disability pension.

RECENT DEVELOPMENTS

3.50 Australian personnel were involved in several, mainly United Nations-sponsored, activities throughout the 1990s. These tended to be of a peacekeeping or peace-enforcement type, and included deployments to Namibia, the Gulf, Rwanda, Cambodia, Somalia, Bougainville and Timor. The level of access of veterans of these engagements to VEA benefits has primarily depended on whether the service was declared 'warlike' or 'non-warlike'.

3.51 In terms of the operation of the VEA, two events took place that directly challenged the way the repatriation scheme had been operating. These were the Auditor-General's Report 1992-93 (Auditor-General 1993), and the *Bushell* case, which was considered by the High Court in 1992 (Creyke and Sutherland 2000, p. 177). The first made a series of critical findings relating to what were seen as tenuous causal linkages between service and disability. The concerns of the Auditor-General were confirmed by the *Bushell* decision of 1992.

3.52 Essentially, the High Court held that the establishment of a reasonable hypothesis – which the Commission must thereafter rebut beyond reasonable doubt to defeat certain claims – could be established if a specialist in a medical field found a causal link, nohvithstanding that every other specialist in that field did not. This decision had the potential to substantially widen the scope of successful compensation claims. In response, the Government appointed a committee of review headed by the Hon Professor Peter Baume, Head of Community Medicine at the University of New South Wales, to examine and make recommendations.

3.53 The Baume Report made a number of contentious recommendations on both points. The 'reasonable hypothesis' was considered too generous and the report recommended its replacement with the normal civil 'balance of probabilities' test. Regarding the Bushell decision, Baume recommended that an independent medical body be established to decide what factors caused particular disabilities. As a result, the Repatriation Medical Authority (RMA) and a Specialist Medical Review Council (SMRC) were established in 1994, the first body to formulate Statements of Principles (SOPs) on which medical conditions could be accepted as service related, and the second to hear appeals from decisions of the RMA. The recommendations on onus of proof were not taken up, but the RMA and SMRC were established despite opposition from some sections of the veteran community (Baume 1994).

3.54 Between 1995 and 2001, a number of studies were commissioned or undertaken by DVA into the health and mortality rates of Vietnam veterans. In part, these were in response to long-standing claims by Vietnam veterans of health problems and higher death rates peculiar to them. Many new programs targeting benefits and assistance to Vietnam veterans and their families were initiated as a result of these studies. A number of other studies for other veterans or service personnel have since commenced, including cancer and mortality studies for Korean veterans and British atomic test participants, and a health study for Gulf War veterans.

3.55 Rehabilitation of disabled veterans was given increased emphasis in 1997 with the introduction of the Veterans' Vocational Rehabilitation Scheme (VVRS), which allowed veterans to undertake training and subsequent employment without jeopardising their pension entitlements. The scheme has been generally well received, with a gradual increase in participation occurring in recent years.

3.56 The Military Compensation and Rehabilitation Service (MCRS) was transferred from Defence to DVA in 1999 under a service agreement between the two departments.

3.57 That year also saw the extension of the Repatriation Health Card – For All Conditions (Gold Card) to all World War II Australian veterans with qualifying service who were aged over 70. A subsequent extension effective from 1July 2002 granted the Gold Card to all post-World War II Australian veterans aged over 70 with qualifying service. In addition, a Repatriation Pharmaceutical Benefits Card (Orange Card), giving World War II BCAL veterans aged 70 years or more with qualifying service access to the Repatriation Pharmaceutical Benefits Scheme, came into effect on 1January 2002.

3.58 The last major review of repatriation legislation before the present one occurred in 2000. The report of Major General R F Mohr into service entitlement anomalies in respect of South-East Asian service between 1955 and 1975 recommended the extension of benefits to veterans of several conflicts not previously covered by the VEA.

CONCLUSION

3.59 Australia's repatriation system has often been described by successive governments as either the most, or one of the most, generous in the world. The Committee cannot comment on whether or not that statement is true without exhaustive analysis of other countries' systems and the context in which they

operate. However, the Australian repatriation system emerged in its own unique social, political and economic context. Furthermore, it has evolved considerably over the past eight decades or more. The *Repatriation Act 1920* was amended approximately 80 times before its replacement by the VEA, and there have been many changes to the latter. Nevertheless, the system's essential elements have remained in place and there can be no doubt that it has been a major institution of social justice in 20th century Australia, touching the lives of many Australians.

3.60 Repatriation is a fundamentally benevolent concept. The nation as a whole has always held that 'the right thing' should be done by our veterans. In keeping with this, the scheme has developed in a cautious and incremental fashion.

3.61 The Review has sought to maintain this tradition of generosity balanced by fairness.

APPENDIX 2 - Historical overview

This Historical Overview contains three elements:-

- Firstly, the background to the current military compensation arrangements outlined as part of a review of the 2004 *Military Rehabilitation and Compensation Act* undertaken in 2009, which followed concerns expressed by the veteran and ex-service community. A 6 member Steering Committee composed of high level senior officials handed down its findings in a 2011 report entitled *Review of Military Compensation Arrangements.* The extract is chapter 2 of that report[16].
- Secondly, the introduction of the *Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988* in 2017; and
- Thirdly, the report of the Productivity Commission, *A Better Way to Support Veterans, Report no. 93* delivered on 27 June 2019.

1. Review of Military Compensation Arrangements – 2011 – Chapter 2

Chapter summary

The Committee examined the evolution of military compensation arrangements in Australia. Since the First World War, successive governments have made it a high priority to provide compensation and related support to veterans and their dependants. Military compensation arrangements have evolved since that time in response to changing situations and a number of reviews. During the 1980s and early 1990s, significant changes were made in the standard of proof, pension eligibility, and compensation arrangements for peacetime service.

Legislation has included the *Australian Soldiers' Repatriation Act 1920* (later renamed the *Repatriation Act 1920*), *Veterans' Entitlements Act 1986* (VEA), *Safety, Rehabilitation and Compensation Act 1988* (SRCA), *Military Compensation Act 1994*, and the current *Military Rehabilitation and Compensation Act 2004* (MRCA). The MRCA covers defence service on or after 1 July 2004; the SRCA and VEA cover service before 1 July 2004. The MRCA is the first compensation legislation designed to cover the whole spectrum of military service, and it came into operation following an extensive examination of military compensation arrangements.

The current Review of Military Compensation Arrangements is the latest in a long line of reviews, inquiries and analyses of the compensation arrangements applying to military personnel and their dependants. Such attention demonstrates the sensitive and complex nature of this legislation and the importance given to it by governments.

Introduction

2.1 This chapter sets out some of the historical background to current military compensation arrangements. In what follows, the term 'military compensation arrangements' is used in a generic sense, covering the *Australian Soldiers' Repatriation Act 1920* (later renamed the *Repatriation Act 1920*) and subsidiary legislation; its successor, the *Veterans' Entitlements Act 1986* (VEA); the

[16] http://www.dva.gov.au/consultation-and-grants/reviews/review-military-compensation-arrangements/implementation-activities

Military Rehabilitation and Compensation Act 2004 (MRCA); and Commonwealth workers' compensation legislation as and when applied to military personnel (e.g. the *Safety, Rehabilitation and Compensation Act 1988* (SRCA) and its antecedent legislation).

Background to the repatriation system

2.2 Since 1914, Australian governments of all political persuasions have made it a high priority to provide compensation and related support to veterans and their dependants. The casualties and widespread social effects of the First World War made this an imperative for Australian governments. The repatriation system, as it was known, became both an important Australian institution and a key public policy issue.

2.3 Large-scale mobilisation in the Second World War led to significant growth of the repatriation system. The system remained in place throughout Australia's military involvement in Korea, Borneo, Malaya, and Vietnam. In a modified form, it played a role in operations in the First Gulf War, East Timor and the early stages of the Iraq and Afghanistan conflicts.

2.4 Veterans have a special status in Australian society. The compensatory benefits provided to veterans (or their dependants) can be seen as an expression of gratitude by the government of the day, and through it the nation, for their war service.

Legacy of the repatriation system

2.5 The more beneficial aspects of military compensation arrangements have evolved gradually over a long period of time. They have been influenced by a generally sympathetic approach taken by governments and courts to the repatriation system.

2.6 The *Repatriation Act 1920* was repealed in 1986, and its successor, the VEA, ceased for the purposes of compensation from 1 July 2004. A number of the policies and processes from the original repatriation system can still be identified in military compensation arrangements today. For example, warlike and non-warlike service ('operational service') have the more beneficial standard of proof applied in the assessment of Commonwealth liability; and elements of the Special Rate of pension under the VEA continue in the form of a safety net payment, and are complemented by an increased focus on rehabilitation.

Beyond reasonable doubt standard of proof

2.7 The beyond reasonable doubt standard of proof that applies to operational service is unique to military compensation. It has evolved in the specific context of veterans' law. As far back as 1929, the *Australian Soldiers' Repatriation Act 1920* was amended to ensure that when veterans made a prima facie case of causation or aggravation due to war service, the onus of proof (that it was not caused by war service) lay with the determining authority, the Repatriation Commission.

2.8 In 1943, the legislation was further amended to lessen the burden on veterans to establish a prima facie case of causation. Veterans were given the benefit of any doubt in relation to the existence of any fact that would be favourable to them, or any question that arose for decision, and it was not necessary for them to furnish proof.

2.9 In 1977, the concept of the standard of proof 'beyond reasonable doubt', derived from the standard of proof used in criminal law, was introduced for the first time. This required the determining authority to allow the claim 'unless it is satisfied, beyond reasonable doubt, that there are insufficient grounds for granting the claim or application or allowing the appeal'. This was intended to ensure that the benefit of any doubt be given to veterans.

2.10 However, in 1981, the High Court found that the beyond reasonable doubt standard meant the same in repatriation law as it did in criminal law.[17] The reverse of the criminal standard of proof was to be applied.

2.11 In 1985, the High Court went further, finding that a mere possibility was enough for a claim to succeed unless the Repatriation Commission could be satisfied beyond reasonable doubt that the condition was not related to service.[18] Even if there was no evidence, or the evidence was neutral, the claim must succeed.

Reasonable hypothesis

2.12 In response to these High Court decisions, the Australian Government amended the legislation. This provided that a claim should not be accepted unless the material raised a reasonable hypothesis connecting the injury, disease or death to the veteran's service.

2.13 In 1992 and 1993, the High Court ruled on the meaning of the term 'reasonable hypothesis'.[19] The consequence of these decisions was that the view of a single responsible medical practitioner acting within his or her area of expertise (or a single expert eminent in the field) who supported a claim automatically satisfied the reasonable hypothesis standard of proof.

2.14 Before the High Court decisions of the early to mid 1980s, claims for smoking-related conditions were generally not accepted. But those decisions, along with developments in medical research, led to smoking being linked to a wide range of medical conditions. It became less a matter of establishing the link between smoking and the condition claimed, and more a question of whether or not the commencement of, or increase in, smoking could be connected to service. Given that many of these conditions were directly or closely associated with the cause of death of many veterans, the number of successful claims for the war widow(er)'s pension also increased.

Statements of Principles

2.15 Following the High Court decisions of the early 1990s, the Australian Government established a review led by Professor Peter Baume to examine the repatriation compensation system. The Baume Review reported in March 1994, recommending that:

- there should be a single standard of proof — the civil standard of balance of probabilities — for both operational and peacetime service;
- there should be provision for veterans with operational service whereby they are given the benefit of any doubt;

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[17] *Repatriation Commission v. Law* (1981) 147 CLR 635.
[18] *Repatriation Commission v. O'Brien* (1985) 155 CLR 422.
[19] *Bushell v. Repatriation Commission* (1992) 175 CLR 408 and *Byrnes v. Repatriation Commission* (1993) HCA 51.

- an expert medical committee should decide on generalised medical contentions; and
- where the predominant cause of a death, injury or disease is not related to war service, the pension should be assessed at a lower rate.

2.16 The Australian Government did not accept Baume's recommendations relating to the single standard of proof and reducing the rates of certain pensions.

2.17 The Australian Government did, however, establish the Repatriation Medical Authority (RMA) and the Specialist Medical Review Council (SMRC). The RMA was given the power to determine legislative instruments, known as Statements of Principles (SOPs), which set out the factors that cause certain medical conditions under the applicable standard of proof. SOPs are determined by the RMA in accordance with sound medical–scientific evidence. SOPs alone determine what factors could cause a medical condition that is the subject of a claim. The SMRC was set up to review the contents of a SOP (within three months of issue) or a decision by the RMA not to determine a SOP, on application from specified parties. The SOPs continue to be used to determine liability under both the VEA and the MRCA.

2.18 The result of the beneficial standard of proof and the SOPs is that there are substantial numbers of older veterans whose death or condition may be attributed to their service. In other words, many of the health conditions that are part of the normal ageing process are capable of being linked to military service.

2.19 The standards of proof and SOPs will be discussed in further detail in Chapter 5 of this report.

Special Rate of pension

2.20 The Special Rate of pension was introduced in the *Australian Soldiers' Repatriation Act 1920* and was granted to veterans who were blinded or totally and permanently incapacitated to such an extent that they could not earn a living wage. The payment was intended to benefit the most seriously disabled veterans, including those who were crippled or paralysed with no hope of restoration to health.

2.21 In the early 1980s, several Federal Court decisions[20] were seen as undermining the original intention of the Special Rate. Some veterans were granted the Special Rate of pension even though they had enjoyed a full working life. Some commentators remarked that the Special Rate of pension was seen as a type of retirement benefit.[21]

2.22 In 1985, the old provisions were replaced with provisions similar to those currently in the VEA to tighten up the criteria. It was restated that the Special Rate of pension was designed for severely disabled veterans of a relatively young age who could never go back to work and could never hope to support themselves or their families, or put away money for their old age.

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[20] *Bowman v. Repatriation Commission* (1981) ALR 556; *Smith, K.K. v. Repatriation Commission* (1982) 1 RPD 238; *Delkou v. Repatriation Commission* (1984) 2 RPD 327.

[21] Bruce Topperwein with Nicky Langhorne, 'Special Rate of Disability Pension: Analysis of the legislation and case-law concerning the special rate of pension', *VeRBosity*, Special Edition, 2003, p.6.

2.23 Before 1994, there were no special rules for veterans who were older than 65 years. In 1994, restrictive rules for veterans aged over 65 years were introduced.

2.24 In 1997, the introduction of the Veterans' Vocational Rehabilitation Scheme (VVRS) resulted in further changes. The VVRS is a totally voluntary scheme to assist veterans to find or continue in suitable employment.

2.25 The Special Rate Disability Pension (SRDP) under the MRCA is linked to the amount of the Special Rate of pension under the VEA. However, the eligibility criteria have a number of important differences. The SRDP paid under the MRCA is also subject to a number of offsets, including offsets against Commonwealth superannuation payments.

2.26 The SRDP is discussed in further detail in Chapter 11 of this report. Superannuation offsetting is discussed in further detail in Chapter 12 of this report.

Peacetime service compensation arrangements

2.27 At the same time as the repatriation system was being established, workers' compensation legislation in Australia was developing. The original Commonwealth scheme — forerunner to the SRCA — and the first state schemes were all in place by 1914, albeit in much more restricted forms than today. When the repatriation system was introduced, the Commonwealth Parliament had already accepted the principle of statutory workers' compensation and had passed legislation to that effect.

2.28 For many years, peacetime compensation coverage for military personnel was provided under the *Defence Act 1903* and the *Naval Defence Act 1910*. From 1949, Australian Defence Force (ADF) members were given formal access to Commonwealth workers' compensation legislation.

2.29 Compensation pensions under the VEA were generally more beneficial for ADF members engaged on 'active service' or who 'served in a theatre of war and incurred danger from the enemy', than the entitlements provided for those on peacetime service.

2.30 Governments arguably saw it as appropriate and necessary to provide a higher level of compensation and support to veterans, as a means of recognising their service in engaging with enemy forces in defence of Australia.

Dual eligibility post-Vietnam War

2.31 Until the early 1970s, the repatriation system and the compensation arrangements for ADF members on peacetime service were effectively two separate systems. What is now known as operational service was covered under the repatriation stream, and peacetime service in Australia was covered under the Commonwealth employees' compensation stream.

2.32 This changed in 1973 when the Australian Government extended the *Repatriation Act 1920* to peacetime service, subject to a qualifying period of three years. This change was significant because governments had, for many years, thought of the repatriation system as exclusive to war service, and the change was not consistent with the history of Australia's military compensation arrangements.

2.33 Compensation for peacetime service was also still available under the *Compensation (Commonwealth Government Employees) Act 1971*, which created a system of 'dual eligibility'.

2.34 This meant that those injured on peacetime service could choose between different benefits provided by two separate Acts, whereas those on operational service were restricted to one Act. The decision to combine these two systems began the complexity and confusion that was to characterise military compensation arrangements for years.

2.35 The introduction of the SRCA in 1988 was especially significant because of the pre-eminent role it gave to rehabilitation and helping injured employees return to the workforce. Enactment of the SRCA resulted in the two preceding Acts — the *Commonwealth Employees' Compensation Act 1930* and the *Compensation (Commonwealth Government Employees) Act 1971* — being repealed.

2.36 However, Part X of the SRCA gives employees and former employees of the Commonwealth, who are covered by the earlier Acts, the right to claim compensation under the SRCA as if the 1930 and 1971 Act continued to operate. This provision includes ADF members and former members. Thus, the SRCA is effectively three pieces of legislation.

2.37 In April 1994, the *Military Compensation Act 1994* was enacted. It introduced dual eligibility between the VEA and the SRCA for members on operational, peacekeeping or hazardous service. This added another significant layer of complexity to military compensation.

2.38 At the same time, it removed dual eligibility under the VEA and SRCA for members on peacetime service. With the exception of those who enlisted before May 1986 and served on continuous full-time service (CFTS) for three or more years, or who enlisted after May 1986 and served until April 1994, members on peacetime service were covered by only the SRCA from 1994 onwards. The table below demonstrates the complexity in compensation coverage for the ADF following the 1994 changes.

Table 2.1 Military compensation coverage before 1 July 2004

Type of service	Key date		
	7 December 1972	22 May 1986	7 April 1994
CFTS before 22 May 1986	SRCA and VEA		
CFTS on or after 22 May 1986 and less than 3 years before 7 April 1994	Not applicable	SRCA	
CFTS on or after 22 May 1986 and greater than or equal to 3 years CFTS before 7 April 1994	Not applicable	SRCA and VEA	SRCA
CFTS on or after 7 April 1994	Not applicable		SRCA
Warlike service (including service in operational areas)	VEA		SRCA and VEA
Non-warlike (including peacekeeping and hazardous) service	SRCA and VEA		
Part-time Reservist service	SRCA		

CFTS = Continuous full-time service, SRCA = *Safety, Rehabilitation and Compensation Act 1988*, VEA = *Veterans' Entitlements Act 1986*

Black Hawk helicopter accident and the Tanzer Review

2.39 On 12 June 1996, two Black Hawk helicopters collided and crashed at the High Range Training Area near Townsville, resulting in the deaths of 18 Australian Regular Army members and injuries to a further 12 members.

2.40 This accident focused public and political attention on the differences in military compensation benefits that applied to ADF members killed or injured in the same incident or circumstances. The dates of enlistment of those killed or injured determined whether they or their dependants were eligible for compensation under the VEA and the SRCA, or only under the SRCA.

2.41 Following the Black Hawk helicopter accident, an interdepartmental inquiry into compensation for ADF members was established. The principal outcome was an increase in the benefits pertaining to death and severe injury for ADF members covered by the SRCA under a *Defence Act 1903* determination, together with a number of criticisms about the adequacy of existing arrangements.

2.42 This inquiry was followed by the Tanzer Review, an independent review established to develop options for a single, self-contained compensation scheme encompassing all service short of declared war.

2.43 The recommendations of the Tanzer Review led to the Australian Government establishing a new military compensation scheme, the MRCA. This scheme is premised on modern compensation principles, including an increased focus on rehabilitation, and also maintains some important VEA features.

Development of the Military Rehabilitation and Compensation Act

2.44 Following the Australian Government's consideration of the Tanzer report, a 'Briefing Paper on the New Military Compensation Scheme' was prepared in March 2000 by the Department of Defence, in consultation with the Department of Veterans' Affairs (DVA). DVA undertook a program of briefings with ex-service organisations (ESOs) and departmental officials.

2.45 After the 2001 election, the momentum was renewed to develop the new single scheme. The briefing paper was revised and reissued in February 2002 with the following key features for the new single scheme:

- application to all military service, both in Australia and overseas;
- a better focus on military-specific requirements;
- a more integrated approach to management of safety, rehabilitation, resettlement and compensation;
- a basis in best-practice principles;
- prospective operation, with existing entitlements (under the VEA or SRCA) preserved for conditions arising before the commencement date of the new scheme;
- a benefits structure based on the current SRCA, plus the Defence Determinations, and additional benefits under the VEA;
- use of the VEA SOPs to determine initial liability, and the Guide to Assessment of Rates of Veterans' Pensions (GARP) to assess the lump sum for permanent impairments;
- removal of dual entitlements then existing between SRCA/VEA; and
- a dedicated regulatory body for the new scheme.

2.46 An ESO Working Group (ESOWG) representing the nine major organisations was formed to review the proposals for the new scheme, and six meetings were held between April and September 2002. Meetings were chaired by the President of the Repatriation Commission, and also attended by the other members of the Commission and senior Defence officers. ESOs also provided papers on particular issues of concern and, at the end of the process, a full set of the Departmental and ESO papers was issued to participants. Two organisations representing the Special Air Service and peacekeepers were later added to the ESOWG. ESO presidents and ESOWG members were briefed on developments with the new scheme at a meeting with the Repatriation Commission in March 2003.

2.47 An Exposure Draft of the Military Rehabilitation and Compensation Bill 2003 (MRCB) was prepared by the Office of Parliamentary Counsel and released in June 2003 for consideration by the wider community. ESOWG members were briefed on the day of release. An extensive round of presentations followed for ADF, Defence and DVA staff, and the ex-service community, at each major base and office in Australia, as well as for ADF members serving in East Timor.

2.48 A number of important changes were made as a result of the consultation process on the Exposure Draft in June–September 2003:

- withdrawal of the proposal to offset future payments of the Special Rate of pension under the VEA by the value of any Commonwealth superannuation received (this had been strongly opposed by ESOs);

- removal of an exclusion from the Commonwealth's liability to pay compensation where a person is injured or contracts a disease as a result of reasonable disciplinary action;
- relaxation of requirements for eligibility for the SRDP safety net payment to cover those who are unable to work more than 10 hours per week (no hours were stated in the Exposure Draft) — this removed the disincentive for a person receiving the safety net payment to return to some part-time work;
- extension of the time allowed to choose between a lump sum and weekly payments from three months to six months;
- removal of the bar on receiving more than one weekly death benefit payment where the partner is widowed a second time; and
- inclusion of a further choice of receiving part lump sum and part periodic payments for permanent impairment.

2.49 Following consideration of the comments on the Exposure Draft, the MRCB and the Military Rehabilitation and Compensation (Consequential and Transitional Provisions) Bill 2003 were tabled in the House of Representatives on 4 December 2003. The ESOWG met on several occasions during 2004 to discuss the new arrangements and the preparation of rehabilitation principles and protocols.

2.50 The MRCB was listed for review by the Senate Committee on Foreign Affairs, Defence and Trade. Submissions were sought by the Senate for response by 30 January 2004, and hearings were held in Perth, Canberra and Melbourne on 23–25 February 2004. The Bill was passed with amendments, resulting from the Senate Inquiry, to ensure that all death benefits were the same, regardless of the nature of service; and changes that made the VRB available to all ADF members, regardless of the type of service that gave rise to the claim.

2.51 The MRCA commenced operation on 1 July 2004.

MRCA Conclusions

2.52 The MRCA, which had bipartisan support, is the first compensation legislation specifically designed to cover the whole spectrum of military service. The MRCA came into operation on 1 July 2004, after approximately seven years of examining military compensation arrangements.

2.53 The MRCA's introduction was a pragmatic response to the complexity of military compensation arrangements in the mid 1990s. It was a significant change to Australia's military compensation arrangements; perhaps the most significant change since the inception of the repatriation system. However, changing from a complex system with a number of different pieces of legislation to a single Act would be difficult, particularly in relation to transitional arrangements and offsetting.

2.54 This Review of Military Compensation Arrangements is the latest in a long line of reviews, inquiries and analyses of the compensation arrangements that apply to military personnel and their dependants, undertaken on behalf of the Australian Government. Such attention underlines the sensitive and complex nature of this legislation, and the importance given to it by governments since the inception of the repatriation system in the aftermath of the First World War.

2. Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988

In 2017 the Parliament enacted the *Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988* (the DRCA), which is a re-enacted version of the *Safety, Rehabilitation and Compensation Act 1988* (the SRCA) that is modified to apply only to members of the Defence Force and their dependants. It is administered by the Department of Veterans' Affairs with the Military Rehabilitation and Compensation Commission (MRCC) having the responsibility for determining and managing relevant claims . The Minister for Veterans' Affairs now has the responsibility for all three of the separate compensation Acts that cover Defence Force members.

The DRCA applies in relation to an injury, disease, death, loss or damage that relates to certain employment in the Defence Force that occurred before the commencement of the MRCA on 1 July 2004.

The DRCA provides Defence Force members with access to a "military specific" compensation and rehabilitation scheme and enables the Military Rehabilitation and Compensation Commission (MRCC) to bring those compensation provisions into closer alignment with the MRCA.

3. Productivity Commission 2019, A Better Way to Support Veterans

In 2018 the Senate Foreign Affairs, Defence and Trade References Committee investiagted suicide by Veterans and ex-service personnel and produced a report entitled *The Constant Battle: Suicide by Veterans (Senate Inquiry)*. That report documented the complexity in the overall legislative framework for compensation and rehabilitation for veterans and sought a review of that scheme. The Governement accepted that recommendation and pursuant to Parts 2 and 3 of the *Productivity Commission Act 1998*, requested that the Productivity Commission to undertake an inquiry into the system of compensation and rehabilitation for veterans and produce a report within 15 months.

The Commission evaluated the SOP system and considered a range of objections to it including and concluded that:-

> The SOP system is robust and effective. It promotes consistency, predictability and transparency and draws a clear line between accepted and non-accepted conditions, based on sound medical-scientific evidence. [22]

The Commission also recommended that the SOPs be utilised in claims under the DRCA as well as this "would harmonise the initial liability process across all three Acts. It would also reduce complexity".

There were alos explicit recomemndations about the RMA as follows:

Recommendations 8.2 and 8.3 were expicilty about the RMA and were as follows:

[22] A Better Way to Support Veterans - Volume 1, page 365.

8.2. The Australian Government should provide additional resources to the Repatriation Medical Authority (RMA) so that the time taken to conduct reviews and investigations can be reduced to closer to six months.

Following any investigation, the RMA should routinely publish a full bibliography of the peer reviewed literature or other sound medical scientific evidence used to create or update the relevant Statement of Principles. Stakeholders interested in how different pieces of evidence were assessed and weighed can continue to request the RMA's briefing papers under s.196I of the *Veterans' Entitlements Act 1986*.

8.3 The Australian Government should abolish the Specialist Medical Review Council. The process for reviewing Repatriation Medical Authority decisions on Statements of Principles should instead be expanded to incorporate independent external medical specialists, where necessary.

Following the delivery of the report the RMA now publishes the Reference Lists for each condition on its website. As well, the Secreatry has provided an additional staff member to support the Authority's functions.

APPENDIX 3 - Parts XIA and XIB of the *Veterans' Entitlements Act 1986*

Part XIA—The Repatriation Medical Authority

Division 1—Establishment, functions and powers

196A Establishment of Authority

(1) A Repatriation Medical Authority is established.

(2) The Repatriation Medical Authority:
  (a) is a body corporate with perpetual succession; and
  (b) has a common seal; and
  (c) may sue and be sued.

(3) All courts, judges and persons acting judicially must:
  (a) take judicial notice of the imprint of the seal of the Authority appearing on a document; and
  (b) presume that the document was duly sealed.

(4) Debts incurred by the Authority in the performance of its functions are, for all purposes, taken to be debts incurred by the Commonwealth.

196AA Application of the *Public Governance, Performance and Accountability Act 2013* to the Authority

Despite paragraph 10(1)(d) of the *Public Governance, Performance and Accountability Act 2013* and the definition of ***Department of State*** in section 8 of that Act, the Repatriation Medical Authority is not a Commonwealth entity for the purposes of that Act and is taken to be part of the Department for those purposes.

Note: This means that the members of the Authority are officials of the Department for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

196B Functions of Authority

(1) This section sets out the functions of the Repatriation Medical Authority. The main function of the Authority is to determine Statements of Principles for the purposes of this Act and the MRCA.

Determination of Statement of Principles

(2) If the Authority is of the view that there is sound medical-scientific evidence that indicates that a particular kind of injury, disease or death can be related to:
  (a) operational service rendered by veterans; or
  (b) peacekeeping service rendered by members of Peacekeeping Forces; or
  (c) hazardous service rendered by members of the Forces; or
  (caa) British nuclear test defence service rendered by members of the Forces; or
  (ca) warlike or non-warlike service rendered by members;

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:
  (d) the factors that must as a minimum exist; and
  (e) which of those factors must be related to service rendered by a person;

before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

Note 1: For ***sound medical-scientific evidence*** see subsection 5AB(2).

Note 2: For ***peacekeeping service***, ***member of a Peacekeeping Force***, ***hazardous service***, ***member of the Forces*** and ***British nuclear test defence service*** referred to in paragraphs (2)(b), (c) and (caa), see subsection 5Q(1A).

Note 2A: For ***warlike service***, ***non-warlike service*** and ***members*** referred to in paragraph (2)(ca), see section 196KA. (These definitions are for the purposes of the MRCA.)

Note 3: For ***factor related to service*** see subsection (14).

(3) If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:

(a) eligible war service (other than operational service) rendered by veterans; or

(b) defence service (other than hazardous service and British nuclear test defence service) rendered by members of the Forces; or

(ba) peacetime service rendered by members;

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:

(c) the factors that must exist; and

(d) which of those factors must be related to service rendered by a person;

before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

Note 1: For ***sound medical-scientific evidence*** see subsection 5AB(2).

Note 2: For ***defence service***, ***hazardous service***, ***British nuclear test defence service*** and ***member of the Forces*** referred to in paragraph (3)(b), see subsection 5Q(1A).

Note 2A: For ***peacetime service*** and ***members*** referred to in paragraph (3)(ba), see section 196KA. (These definitions are for the purposes of the MRCA.)

Note 3: For ***factor related to service*** see subsection (14).

(3A) The Authority may determine a Statement of Principles under subsection (2) or (3) for the purposes of this Act, the MRCA, or both Acts.

Investigation

(4) If the Authority:

(a) receives a request under section 196E to carry out an investigation in respect of a particular kind of injury, disease or death; or

(b) of its own initiative, decides that a particular kind of injury, disease or death ought to be investigated for the purposes of this Act, or the MRCA, to find out whether a Statement of Principles may be determined in respect of it;

the Authority must carry out an investigation to obtain information that would enable the Authority to establish:

(c) how the injury may be suffered or sustained, the disease may be contracted or the death may occur; and

(d) the extent (if any) to which:

(i) the injury, disease or death may be war-caused or defence-caused; or

(ii) the injury, disease or death may be a service injury, a service disease or a service death.

Note 1: For ***war-caused*** see sections 8 and 9.

Note 2: For ***defence-caused*** see section 69.

Note 3: For ***service injury***, ***service disease*** and ***service death*** see section 196KA. (These definitions are for the purposes of the MRCA.)

(5) If, after carrying out the investigation, the Authority is of the view that there is sound medical-scientific evidence on which it can rely to determine a Statement of Principles under subsection (2) or (3), in respect of that kind of injury, disease or death, the Authority must do so as soon as practicable.

Note: This subsection does not mean that the Authority must carry out an investigation before it can determine a Statement of Principles under subsection (2) or (3).

(6) If, after carrying out the investigation, the Authority is of the view:

(a) that there is no sound medical-scientific evidence on which it can rely to determine a Statement of Principles under subsection (2) or (3) in respect of that kind of injury, disease or death; or

(b) that the sound medical-scientific evidence on which it can rely is insufficient to allow it to do so;

the Authority must make a declaration in writing:

(c) stating that it does not propose to make a Statement of Principles; and

(d) giving the reasons for its decision.

Subsequent investigation and review of determinations concerning Statement of Principles

(7) If the Authority:

(a) is asked under section 196E to review:

(i) some or all of the contents of a Statement of Principles; or

(ii) a decision of the Authority not to make a Statement of Principles in respect of a particular kind of injury, disease or death; or

(b) thinks that there are grounds for such a review; or

(c) is directed by the Review Council under subsection 196W(7) to carry out an investigation in respect of a particular kind of injury, disease or death;

the Authority must, subject to subsection 196C(4) and section 196CA in a case where paragraph (a) applies, carry out an investigation to find out if there is new information available about:

(d) how the injury may be suffered or sustained, the disease may be contracted or the death may occur; or

(e) the extent (if any) to which:

(i) the injury, disease or death may be war-caused or defence-caused; or

(ii) the injury, disease or death may be a service injury, a service disease or a service death.

Note 1: For ***war-caused*** see sections 8 and 9.

Note 2: For ***defence-caused*** see section 69.

Note 3: For ***service injury***, ***service disease*** and ***service death*** see section 196KA. (These definitions are for the purposes of the MRCA.)

(7A) If the investigation:

(a) relates to a request under section 196E to review some of the contents of a Statement of Principles; or

(b) is one to which paragraph (7)(b) applies and that relates to some of the contents of a Statement of Principles; or

(c) is carried out because of a direction under subsection 196W(7) by the Review Council following a request to the Council under section 196Z to review the Authority's refusal to carry out an investigation relating to a request under section 196E to review some of the contents of a Statement of Principles;

the Authority may limit its investigation to matters relating to those contents.

Note: For ***Review Council*** see subsection 5AB(1).

(8) If, after carrying out the investigation, the Authority is of the view that there is a new body of sound medical-scientific evidence available that, together with the sound medical-scientific evidence previously considered by the Authority, justifies the making of a Statement of Principles, or an amendment of the Statement of Principles already determined, in respect of that kind of injury, disease or death, the Authority must:

(a) determine a Statement of Principles in respect of that kind of injury, disease or death under subsection (2) or (3); or

(b) make a determination amending the Statement of Principles determined under subsection (2) or (3) in respect of that kind of injury, disease or death; or

(c) make a determination revoking the Statement of Principles determined under subsection (2) or (3), and determine a new Statement of Principles under subsection (2) or (3) in respect of that kind of injury, disease or death;

as the case requires.

Note: For ***sound medical-scientific evidence*** see subsection 5AB(2).

(9) If, after carrying out the investigation, the Authority is of the view:

(a) that there is no new sound medical-scientific evidence about that kind of injury, disease or death; or

(b) that the new sound medical-scientific evidence available is not sufficient to justify the making of a Statement of Principles, or an amendment of the Statement of Principles already determined in respect of that kind of injury, disease or death;

the Authority must make a declaration in writing:

(c) stating that it does not propose to make a Statement of Principles, or amend the Statement of Principles already determined (as the case may be); and

(d) giving the reasons for its decision.

(10) If the Review Council has, by a decision notified in the *Gazette*, directed the Authority to amend a Statement of Principles in respect of a particular kind of injury, disease or death, the Authority must make a determination amending the Statement of Principles determined in respect of that kind of injury, disease or death in accordance with the directions of the Council.

(11) If, after reviewing a decision of the Authority not to determine a Statement of Principles under subsection 196B(2) in respect of a particular kind of injury, disease or death, the Review Council has, by a decision notified in the *Gazette*, directed the Authority to make such a Statement of Principles, the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out, in accordance with the directions of the Council:

(a) the factors that must as a minimum exist; and

(b) which of those factors must be related to service rendered by a person;

before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

Note 1: For ***factor related to service*** see subsection (14).

Note 2: The Statement of Principles may be determined for the purposes of this Act, the MRCA, or both Acts, in accordance with the directions of the Council (see subsection 196W(4A)).

(12) If, after reviewing a decision of the Authority not to determine a Statement of Principles under subsection 196B(3) in respect of a particular kind of injury, disease or death, the Review Council has, by a decision notified in the *Gazette*, directed the Authority to make such a Statement of Principles, the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out, in accordance with the directions of the Council:

(a) the factors that must exist; and

(b) which of those factors must be related to service rendered by a person;

before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

Note 1: For ***factor related to service*** see subsection (14).

Note 2: The Statement of Principles may be determined for the purposes of this Act, the MRCA, or both Acts, in accordance with the directions of the Council (see subsection 196W(4A)).

(13) Despite section 12 of the *Legislative Instruments Act 2003*, a determination under subsection (10) of this section amending a Statement of Principles, or a Statement of Principles under subsection (11) or (12) is to be taken to have had effect from the day on which the decision of the Review Council was notified in the *Gazette*. The determination or Statement of Principles must specify that day.

(13A) A determination under this section:

(a) must be in writing; and

(b) is a legislative instrument.

(14) A factor causing, or contributing to, an injury, disease or death is ***related to service*** rendered by a person if:

(a) it resulted from an occurrence that happened while the person was rendering that service; or

(b) it arose out of, or was attributable to, that service; or

(c) it resulted from an accident that occurred while the person was travelling, while rendering that service but otherwise than in the course of duty, on a journey:

(i) to a place for the purpose of performing duty; or

(ii) away from a place of duty upon having ceased to perform duty; or

(d) it was contributed to in a material degree by, or was aggravated by, that service; or

(e) in the case of a factor causing, or contributing to, an injury—it resulted from an accident that would not have occurred:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service; or

(f) in the case of a factor causing, or contributing to, a disease—it would not have occurred:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service; or

(g) in the case of a factor causing, or contributing to, the death of a person—it was due to an accident that would not have occurred, or to a disease that would not have been contracted:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service.

196C Powers of Authority with respect to investigations

(1) The Repatriation Medical Authority may not, for the purposes of an investigation, carry out any new research work (including any test or experiment).

(2) The Authority may, for the purposes of an investigation, ask the Secretary:

(a) to forward to the Authority any information:

(i) in the possession of the Secretary; or

(ii) that the Secretary may obtain;

relating to the kind of injury, disease or death under investigation; or

(b) to carry out research (including any test or experiment) to obtain, confirm, or disprove, specific information about that kind of injury, disease or death and forward a report to the Authority.

(3) In forming any view during the investigation, the Authority:

(a) may rely only on sound medical-scientific evidence:

(i) that has been submitted to it; or

(ii) that it has obtained on its own initiative or from the Secretary (under subsection (2)) or from a consultant; and

(b) must consider and evaluate all the evidence so made available to it.

(4) If:

(a) the Authority has carried out the investigation in respect of a particular kind of injury, disease or death; and

(b) within 12 months after the Authority has, at the end of the investigation:

(i) determined or amended a Statement of Principles; or

(ii) declared that it does not propose to make or amend a Statement of Principles;

a person or organisation asks the Authority under section 196E to review:

(iii) some or all of the contents of the Statement of Principles; or

(iv) its decision not to make a Statement of Principles; and

(c) the Authority thinks that there are no grounds for such a review;

the Authority may decide not to carry out an investigation in respect of that kind of injury, disease or death. The Authority must then inform the person or organisation in writing of its decision, stating the reasons for it.

196CA Authority not required to investigate certain requests

(1) The Authority may decide not to carry out an investigation in respect of a request for a review made under paragraph 196E(1)(e) or (f) if:

(a) the request does not state the grounds on which the review is sought; or

(b) the Authority considers that the request does not identify sufficient relevant information:

(i) to support the grounds on which the review is sought; or

(ii) to otherwise justify the review; or

(c) the request is vexatious or frivolous.

(2) If the Authority decides not to carry out an investigation, it must inform the person or organisation in writing of the decision, stating the reasons for it.

196CB Authority may consolidate requests

If:

(a) 2 or more requests for review are made under subsection 196E(1); and

(b) the requests are in relation to the same injury, disease or death;

the Authority may carry out one investigation in relation to those requests.

196E Request for an investigation, review etc.

(1) Any of the following:

(a) the Commission;

(aa) the Military Rehabilitation and Compensation Commission;

(b) a person eligible to make a claim for a pension under Part II or IV of this Act;

(ba) a person eligible to make a claim for compensation under section 319 of the MRCA;

(c) an organisation representing veterans, Australian mariners, members of the Forces, members of Peacekeeping Forces, or members within the meaning of the MRCA, or their dependants;

may request the Repatriation Medical Authority:

(d) to carry out an investigation under subsection 196B(4) in respect of a particular kind of injury, disease or death; or

(e) to review a decision of the Authority under subsection 196B(6) not to make a Statement of Principles in respect of a particular kind of injury, disease or death; or

(f) to review some or all of the contents of a Statement of Principles in force under this Part.

(2) A request under subsection (1) must:

(a) be in a form approved by the Authority; and

(b) be lodged at an office of the Authority in Australia in accordance with the directions of the Chairperson of the Authority under subsection (2A).

(2A) The Chairperson of the Authority may give directions:

(a) as to the manner of lodging requests, including electronic requests, with the Authority for the purposes of subsection (1); and

(b) as to the time at which such requests are to be taken to have been so communicated.

(3) If the request is a request for a review made under paragraph (1)(e) or (f), the request must also:

(a) state the grounds on which the review is sought; and

(b) identify any information relied on to support those grounds.

196F Submissions to the Authority

(1) If the Repatriation Medical Authority is carrying out an investigation under subsection 196B(4) or (7), any person or organisation referred to in any of paragraphs 196E(1)(a) to (c) may make a submission in writing to the Authority on any matter (other than a legal matter) relevant to the investigation.

(2) A person having expertise in a field relevant to the investigation may make a submission in writing to the Authority on any matter (other than a legal matter) within his or her expertise that is relevant to the investigation.

(3) If an individual, the Commission, the Military Rehabilitation and Compensation Commission or an organisation has made a written submission, the individual or his or her representative, or a representative of the relevant Commission or of the organisation may, subject to subsection (4), appear before the Authority to make an oral submission complementing the written submission. The oral submission may not cover any legal matter.

(4) A person or organisation may not be represented before the Authority by a legal practitioner.

196G Notice of investigation

(1) As soon as practicable after the Repatriation Medical Authority:

(a) has been asked under section 196E to carry out:

(i) an investigation; or

(ii) a review of a decision of the Authority not to make a Statement of Principles; or

(iii) a review of some or all of the contents of a Statement of Principles;

regarding a particular kind of injury, disease or death; or

(b) has decided on its own initiative to carry out such an investigation or such a review;

the Authority must publish in the *Gazette* a notice:

(c) stating that the Authority intends to carry out an investigation in respect of that kind of injury, disease or death; and

(d) inviting persons or organisations authorised under subsection 196F(1) to do so to make written submissions to the Authority.

(2) A notice is to specify:

(a) the date on which the Authority will hold its first meeting for the purposes of the investigation; and

(b) the date by which all submissions must have been received by the Authority.

(3) A notice must be published in the *Gazette* at least 28 days before the date of the first meeting of the Authority.

(4) A notice is not invalid merely because it fails to comply with subsection (2).

196H Copyright in submissions

(1) The Repatriation Medical Authority is not the owner of any copyright subsisting in material (***submitted material***) contained in a submission made to the Authority for the purposes of an investigation under section 196B.

(2) In spite of the *Copyright Act 1968*, the Authority does not infringe any copyright subsisting in submitted material if, in performing its functions or exercising its powers, the Authority does an act comprised in the copyright without the licence of the owner of the copyright.

196I Access to information

(1) Subject to subsection (2), any person or organisation referred to in any of paragraphs 196E(1)(a) to (c) is entitled, on request made in writing to the Repatriation Medical Authority, to have reasonable access to any document containing information considered by the Authority for the purposes of an investigation.

(2) The Authority may not disclose any personal information about a particular person if the information is likely to reveal the identity of that person.

196J Notice of decision not to make etc. Statement of Principles

(1) When the Repatriation Medical Authority decides not to make, or not to review or not to amend, a Statement of Principles, it must, within 14 days, notify the Commission or the Military Rehabilitation and Compensation Commission (as the case requires) in writing of its decision.

(2) If the decision is made following a request from a person or organisation under section 196E, the Authority must also notify the person or organisation in writing of its decision.

196K Repatriation Medical Authority to send information to Review Council

The Repatriation Medical Authority must, within 28 days after being notified that the Review Council has been asked to review:

(a) a Statement of Principles; or

(b) its decision not to determine a Statement of Principles in respect of a particular kind of injury, disease or death; or

(ba) its decision not to amend a Statement of Principles in respect of a particular kind of injury, disease or death; or

(c) its decision under subsection 196C(4) not to carry out an investigation in respect of a particular kind of injury, disease or death;

send to the Council a copy of all the information that was available to it when it:

(d) determined, amended, or last amended, the Statement of Principles; or

(e) decided, or last decided, not to determine, or not to amend, a Statement of Principles in respect of that kind of injury, disease or death; or

(f) decided not to carry out the investigation.

196KA Definitions for the purposes of the MRCA

In this Division:

(a) for the purposes of paragraphs 196B(4)(d) and 196B(7)(e), ***service death*** has the same meaning as in the MRCA; and

(b) for the purposes of paragraphs 196B(4)(d) and 196B(7)(e), ***service disease*** has the same meaning as in the MRCA; and

(c) for the purposes of paragraphs 196B(4)(d) and 196B(7)(e), ***service injury*** has the same meaning as in the MRCA; and

(d) for the purposes of paragraphs 196B(2)(ca) and 196B(3)(ba), ***members*** has the same meaning as in the MRCA; and

(e) for the purposes of paragraph 196B(3)(ba), ***peacetime service*** has the same meaning as in the MRCA; and

(f) for the purposes of paragraph 196B(2)(ca), ***non-warlike service*** does not have the meaning given by this Act but instead has the same meaning as in the MRCA; and

(g) for the purposes of paragraph 196B(2)(ca), ***warlike service*** does not have the meaning given by this Act but instead has the same meaning as in the MRCA.

Division 2—Constitution and meetings

196L Membership

(1) The Repatriation Medical Authority consists of a Chairperson and 4 other members.

(2) All members are to be appointed on a part-time basis by the Minister.

(3) One of the members must be a person having at least 5 years experience in the field of epidemiology.

196M Qualifications

The Minister is to appoint a person as Chairperson or as a member only if the person is a registered medical practitioner, or a medical scientist, with at least 10 years experience.

196N Tenure of office

(1) Subject to this Act, a person appointed as Chairperson or as a member holds office for the period specified in the instrument of appointment.

(2) A person may not hold office for a period of more than 5 years but is eligible for reappointment.

196O Resignation

A member may resign from office by written notice given to the Minister.

196P Termination of appointment

The Minister may terminate the appointment of a person as Chairperson or as a member:

(a) for misbehaviour or for physical or mental incapacity; or

(b) if he or she becomes bankrupt, applies to take the benefit of a law for the relief of bankruptcy or insolvent debtors, compounds with his or her creditors or assigns remuneration or property for their benefit.

196Q Acting Chairperson

The Minister may appoint a member to act as Chairperson:

(a) during a vacancy in the office of Chairperson, whether or not an appointment has previously been made to the office; or

(b) during any period, or during all periods, when the Chairperson is absent from office.

196R Meetings

(1) The Chairperson may convene meetings of the Repatriation Medical Authority as he or she considers necessary for the performance of its functions. The Chairperson may delegate this power to another member or to a member of the staff of the Authority.

(2) The Chairperson presides at all meetings of the Authority.

(3) At a meeting, 3 members constitute a quorum.

(4) A question arising at a meeting is to be determined by a majority of votes of the members present and voting. The Chairperson has only a deliberative vote.

(5) The Authority must keep minutes of the proceedings at each meeting.

(6) Subject to this section, the Authority determines the procedures for convening its meetings and for conducting its business.

196S Remuneration and allowances

(1) A member shall be paid such remuneration as is determined by the Remuneration Tribunal but, if no determination of that remuneration by the Tribunal is in operation, a member shall be paid such remuneration as the Minister determines in writing.

(2) A member shall be paid such allowances as the Minister determines in writing.

(3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

Division 3—Staff and consultants

196T Staff

The staff necessary to assist the Repatriation Medical Authority consists of persons engaged under the *Public Service Act 1999* and made available to the Authority by the Secretary.

196U Consultants

(1) The Repatriation Medical Authority may, under written agreement, engage consultants to provide expert advice to the Authority about any disease, injury or death that the Authority is investigating.

(2) The Authority may not engage a consultant without the approval of the Minister.

Part XIB—The Specialist Medical Review Council

Division 1—Establishment and functions

196V Establishment of Council

(1) A Specialist Medical Review Council is established.

(2) The Review Council:

(a) is a body corporate with perpetual succession; and

(b) has a common seal; and

(c) may sue and be sued.

(3) All courts, judges and persons acting judicially must:

(a) take judicial notice of the imprint of the seal of the Review Council appearing on a document; and

(b) presume that the document was duly sealed.

(4) Debts incurred by the Review Council in the performance of its functions are, for all purposes, taken to be debts incurred by the Commonwealth.

196VA Application of the *Public Governance, Performance and Accountability Act 2013* to the Council

Despite paragraph 10(1)(d) of the *Public Governance, Performance and Accountability Act 2013* and the definition of ***Department of State*** in section 8 of that Act, the Review Council is not a Commonwealth entity for the purposes of that Act and is taken to be part of the Department for those purposes.

Note: This means that the councillors are officials of the Department for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

196W Functions of Review Council

(1) This section sets out the functions of the Review Council.

(2) If the Council is asked under section 196Y to review:

(a) some or all of the contents of a Statement of Principles in respect of a particular kind of injury, disease or death; or

(b) a decision of the Repatriation Medical Authority not to determine a Statement of Principles under subsection 196B(2), or a Statement of Principles under subsection 196B(3), in respect of a particular kind of injury, disease or death; or

(ba) a decision of the Repatriation Medical Authority not to amend a Statement of Principles in respect of a particular kind of injury, disease or death;

subject to subsection (3), the Council must, for that purpose, carry out a review of all the information that was available to the Authority when it:

(c) determined, amended, or last amended, the Statement of Principles; or

(d) decided, or last decided, not to determine, or not to amend, a Statement of Principles;

in respect of that kind of injury, disease or death.

(3) If the Council has been asked to review some or all of the contents of a Statement of Principles, the Council may carry out a review under subsection (2) only if:

(a) the period within which the Statement of Principles may be disallowed under section 42 of the *Legislative Instruments Act 2003* has ended; and

(b) the Statement of Principles has not been disallowed.

(3A) If:

(a) the Council has been asked to review some or all of the contents of a Statement of Principles in respect of a particular kind of injury, disease or death; and

(b) there is another Statement of Principles in force in respect of that kind of injury, disease or death, but the Council has not been asked to review some or all of the contents of that other Statement of Principles;

then the Council must also review that other Statement of Principles by reviewing the information subsection (2) requires it to review in reviewing the Statement of Principles it has been asked to review.

(4) If after carrying out the review, the Council is of the view that there is sound medical-scientific evidence on which the Authority could have relied:

(a) to amend either or both of the Statements of Principles in force in respect of that kind of injury, disease or death; or

(b) to determine a Statement of Principles under subsection 196B(2), or a Statement of Principles under subsection 196B(3), in respect of that kind of injury, disease or death;

the Council must make a declaration in writing stating its views, setting out the evidence in support and:

(c) directing the Authority to amend either or both of the Statements of Principles, or determine a Statement of Principles (as the case may be), in accordance with the directions given by the Council; or

(d) remitting the matter for reconsideration in accordance with any directions or recommendations of the Council.

(4A) The Council may give directions under subsection (4) for the purposes of this Act, the MRCA, or both Acts.

(5) If, after carrying out the review, the Council is of the view:

(a) that there is no sound medical-scientific evidence that justifies the making of a Statement of Principles, or an amendment of either or both of the Statements of Principles in force, in respect of that kind of injury, disease or death; or

(b) that the sound medical-scientific evidence available to the Authority is insufficient to justify the making of a Statement of Principles, or an amendment of either or both of the Statements of Principles, in respect of that kind of injury, disease or death;

the Council must make a declaration in writing to that effect giving the reasons for its decision. The Council may include in the declaration any recommendation that it considers fit to make about any future investigation that the Authority may carry out in respect of that kind of injury, disease or death.

(6) If the Council is asked under section 196Z to review a decision of the Repatriation Medical Authority under subsection 196C(4) not to carry out an investigation in respect of a particular kind of injury, disease or death, the Council must consider:

(a) the reasons given by the Authority for making the decision; and

(b) the information on which it relied in making that decision; and

(c) the grounds on which the request for the review was made and any submission made in support of those grounds.

(7) If, after considering the matters referred to in paragraphs (6)(a), (b) and (c), the Council is of the view that:

(a) there appears to be a new body of sound medical-scientific evidence in respect of that kind of injury, disease or death that has not been previously considered by the Authority; and

(b) that new body of evidence, together with the sound medical-scientific evidence available to the Authority, could justify the making of a Statement of Principles, or an amendment of the Statement of Principles already determined, in respect of that kind of injury, disease or death;

the Council must make a declaration in writing to that effect giving the reasons for its decision and directing the Authority to carry out an investigation under subsection 196B(7) in respect of that kind of injury, disease or death. The Council may include in the declaration any recommendation or direction that the Council considers fit to make about the carrying out of the investigation.

(8) If, after considering the matters referred to in paragraphs (6)(a), (b) and (c), the Council is not of the view referred to in subsection (7) in respect of that kind of injury, disease or death, the Council must make a declaration in writing:

(a) affirming the decision of the Authority not to carry out the investigation; and

(b) giving the reasons for its decision.

The Council may include in the declaration any recommendation that it considers fit to make about any future investigation that the Authority may carry out in respect of that kind of injury, disease or death.

196X Notification of decision of Review Council to be notified in *Gazette*

(1) A decision of the Review Council under section 196W must be notified in the *Gazette*.

(2) The Council must also give a copy of the decision to:

(a) the person or organisation that asked for the review; and

(b) the Commission, or the Military Rehabilitation and Compensation Commission, (if it is not the person referred to in (a)); and

(c) the Repatriation Medical Authority.

196Y Request for review of contents of Statement of Principles etc.

(1) Subject to subsection (2), any of the following:

(a) the Commission;

(aa) the Military Rehabilitation and Compensation Commission;

(b) a person eligible to make a claim for a pension under Part II or IV of this Act;

(ba) a person eligible to make a claim for compensation under section 319 of the MRCA;

(c) an organisation representing veterans, Australian mariners, members of the Forces, members of Peacekeeping Forces, or members within the meaning of the MRCA, or their dependants;

may ask the Review Council to review:

(d) some or all of the contents of a Statement of Principles in force under Part XIA; or

(e) a decision of the Repatriation Medical Authority not to make, or not to amend, a Statement of Principles in respect of a particular kind of injury, disease or death.

(2) The request must be made:

(a) in the case of a request to review some or all of the contents of a Statement of Principles—within 3 months after the Statement of Principles was made, amended or last amended; or

(b) if paragraph (a) does not apply—within 3 months after the decision of the Authority.

(3) A request must:

(a) be in a form approved by the Review Council; and

(b) state the grounds on which the review is sought; and

(c) be lodged at an office of the Department in Australia in accordance with section 5T.

(3A) A request lodged in accordance with section 5T is taken to have been made on a day determined under that section.

(4) The Secretary must send the request to the Review Council, and notify the Repatriation Medical Authority of the request, within 28 days.

196Z Request for review of decision of Repatriation Medical Authority not to carry out an investigation

(1) If:

(a) a person or organisation asks the Repatriation Medical Authority under section 196E to review:

(i) some or all of the contents of a Statement of Principles in respect of a particular kind of injury, disease or death; or

(ii) its decision not to make a Statement of Principles in respect of a particular kind of injury, disease or death; and

(b) the Authority refuses under subsection 196C(4) to carry out an investigation in respect of that kind of injury, disease or death;

the person or organisation may, within 3 months, ask the Review Council to review the decision of the Authority not to carry out the investigation.

(2) The request must:

(a) be in a form approved by the Review Council; and

(b) state the grounds on which the review is sought; and

(c) be accompanied by any submission that the person or organisation wishes to submit in support of those grounds; and

(d) be lodged at an office of the Department in Australia in accordance with section 5T.

(2A) A request lodged in accordance with section 5T is taken to have been made on a day determined under that section.

(3) The Secretary must send the request and any accompanying material to the Review Council, and notify the Repatriation Medical Authority of the request, within 28 days.

196ZA Submissions to Review Council

(1) If the Review Council is carrying out a review under subsection 196W(2), any person or organisation referred to in any of paragraphs 196Y(1)(a) to (c) may make a submission in writing to the Council about any information that was available to the Repatriation Medical Authority and is relevant to the review (***relevant information***).

(2) A person having expertise in a field relevant to the investigation may make a submission in writing to the Review Council on any relevant information pertaining to that field.

(3) If an individual, the Commission, the Military Rehabilitation and Compensation Commission or an organisation has made a written submission, the individual or his or her representative, or a representative of the relevant Commission or of the organisation may, subject to subsection (5), appear before the Review Council to make an oral submission complementing the written submission.

(4) If the Review Council is carrying out a review under subsection 196W(6) at the request of an individual, the Commission, the Military Rehabilitation and Compensation Commission or an organisation, the individual or his or her representative, or a representative of the relevant Commission or of the organisation may, subject to subsection (5), appear before the Review Council to make an oral submission complementing the written submission (if any) lodged under paragraph 196Z(2)(c).

(5) A person or organisation may not be represented before the Review Council by a legal practitioner.

(6) In this section, a reference to a submission does not include a submission on a legal matter.

196ZB Notice of investigation

(1) As soon as practicable after the Review Council has been asked under section 196Y to review:

(a) a decision of the Repatriation Medical Authority not to make, or not to amend, a Statement of Principles in respect of a particular kind of injury, disease or death; or

(b) some or all of the contents of a Statement of Principles in respect of a particular kind of injury, disease or death;

the Council must publish in the *Gazette* a notice:

(c) stating that the Council intends to carry out a review of the information available to the Authority about that kind of injury, disease or death; and

(d) inviting persons or organisations authorised under subsection 196ZA(1) to do so to make written submissions to the Council.

(2) A notice is to specify:

(a) the date on which the Council will hold its first meeting for the purposes of the review; and

(b) the date by which all submissions must have been received by the Council.

(3) A notice must be published in the *Gazette* at least 28 days before the date of the first meeting of the Council.

(4) A notice is not invalid merely because it fails to comply with subsection (2).

196ZC Copyright in submissions

(1) The Review Council is not the owner of any copyright subsisting in material (***submitted material***) contained in a submission made to the Council for the purposes of an investigation under section 196B.

(2) In spite of the *Copyright Act 1968*, the Review Council does not infringe any copyright subsisting in submitted material if, in performing its functions or exercising its powers, the Council does an act comprised in the copyright without the licence of the owner of the copyright.

196ZD Access to information

(1) Subject to subsection (2), any person or organisation referred to in any of paragraphs 196Y(1)(a) to (c) is entitled, on request made in writing to the Review Council, to have reasonable access to any document containing information considered by the Review Council for the purposes of an investigation.

(2) The Review Council may not disclose any personal information about a particular person if the information is likely to reveal the identity of that person.

Division 2—Constitution and meetings

196ZE Membership

(1) The Review Council consists of such number of members as the Minister determines from time to time to be necessary for the proper exercise of the functions of the Council.

(2) The councillors are to be appointed on a part-time basis by the Minister as provided in this section.

(3) When appointing councillors, the Minister must have regard to the branches of medical science expertise in which would be necessary for deciding matters referred to the Review Council for review. In respect of each of those branches, the Minister must ensure that, at any time, the number (not less than 2) of councillors having experience in that branch is sufficient for the proper exercise of the functions of the Council.

(4) Each person to be appointed councillor is to be selected from a list, or lists, of nominees submitted by such colleges or similar bodies of medical practitioners or medical scientists (for example, the Royal Australasian College of Physicians) as were asked by the Minister to submit nominees for the purposes of the appointment.

(5) The Minister must appoint one of the councillors to be the Convener.

196ZF Qualifications

The Minister is to appoint a person to be a councillor only if the person is a registered medical practitioner, or a medical scientist, with at least 10 years experience.

196ZG Tenure of office

(1) Subject to this Act, a person appointed as Convener or as a councillor holds office for the period specified in the instrument of appointment.

(2) A person may not hold office for a period of more than 5 years but is eligible for reappointment.

196ZH Resignation

A councillor may resign from office by written notice given to the Minister.

196ZI Termination of appointment

The Minister may terminate the appointment of a person as councillor:

(a) for misbehaviour or for physical or mental incapacity; or

(b) if he or she becomes bankrupt, applies to take the benefit of a law for the relief of bankruptcy or insolvent debtors, compounds with his or her creditors or assigns remuneration or property for their benefit.

196ZJ Acting Convener

The Minister may appoint a councillor to act as Convener:

(a) during a vacancy in the office of Convener, whether or not an appointment has previously been made to the office; or

(b) during any period, or during all periods, when the Convener is absent from Australia or from duty.

196ZK Conduct of reviews

(1) The Review Council is, for the purposes of a review, to be constituted by at least 3, but not more than 5, councillors selected by the Convener.

(2) If the Review Council as constituted for the purposes of a review includes the Convener, the Convener presides at all meetings of the Council as so constituted.

(3) If the Review Council as constituted for the purposes of a review does not include the Convener, the Convener must appoint one of the councillors selected for the purposes of the review (***presiding councillor***) to preside at all meetings of the Council as so constituted.

(4) The Convener or the presiding councillor may convene meetings of the Council as he or she considers necessary to carry out the review. The Convener may delegate this power to another councillor or to a member of the staff of the Council.

(5) A question before the Council is to be decided by a majority of the votes of the councillors present and voting. The Convener or presiding councillor has only a deliberative vote.

(6) The Council must keep minutes of the proceedings at each meeting.

(7) Subject to this section, the Council determines the procedures for convening its meetings and for conducting its business.

196ZL Remuneration and allowances

(1) A councillor is to be paid such remuneration as is determined by the Remuneration Tribunal but, if no determination of that remuneration by the Tribunal is in operation, a member is to be paid such remuneration as the Minister determines in writing.

(2) A councillor is to be paid such allowances as the Minister determines in writing.

(3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

Division 3—Staff

196ZM Staff

The staff necessary to assist the Review Council consists of persons engaged under the Public Service Act 1999 and made available to the Council by the Secretary.

Division 4—Payment of medical and travelling expenses

196ZN Medical expenses

(1) The Commonwealth may, subject to this section, pay to an applicant who asks the Review Council to conduct a review as provided for by this Part an amount to cover the medical expenses incurred by him or her in respect of relevant documentary medical evidence obtained for the purposes of the review and submitted to the Review Council.

(2) The applicant is not to be paid:

(a) if the applicant has submitted to the Review Council relevant documentary medical evidence relating to only one medical condition—more than the prescribed amount for medical expenses; or

(b) if the applicant has submitted to the Review Council relevant documentary medical evidence relating to more than one medical condition—more than the prescribed amount for the medical expenses incurred in respect of the evidence relating to any one of those conditions.

(3) An amount is not payable in respect of medical expenses unless:

(a) the person who has incurred the expenses; or

(b) any person approved by that person or by the Commission;

applies in writing to the Commission for payment.

(4) The application for payment must be:

(a) in accordance with a form approved by the Commission; and

(b) made within 3 months after the relevant documentary medical evidence was submitted to the Review Council; and

(c) be accompanied by any document that the applicant considers relevant; and

(d) be lodged at an office of the Department in Australia in accordance with section 5T.

(4A) A request lodged in accordance with section 5T is taken to have been made on a day determined under that section.

(5) For the purposes of this section ***relevant documentary medical evidence*** in relation to an application has the same meaning as is specified in section 133.

196ZO Travelling expenses for obtaining medical evidence

(1) If an applicant has had to travel to obtain any relevant documentary medical evidence submitted to the Review Council, the applicant is, subject to this section, entitled to be paid in relation to that travel the travelling expenses that are prescribed.

(2) If:

(a) the applicant is accompanied by an attendant when travelling to obtain the evidence; and

(b) the Commission is of the view that it is reasonable for the applicant to be so accompanied by an attendant;

the attendant is, subject to this section, entitled to be paid in relation to that travel the travelling expenses that are prescribed.

(3) Travelling expenses are not payable in respect of travel outside Australia.

(4) Travelling expenses are not payable unless:

(a) the person who has incurred the expenses; or

(b) any person approved by that person or by the Commission;

applies in writing to the Commission for payment under subsection (5).

(5) The application for payment must be:

(a) in accordance with a form approved by the Commission; and

(b) made within:

(i) 12 months after the completion of the travel; or

(ii) if the Commission thinks that there are exceptional circumstances that justify extending that period—such further period as the Commission allows; and

(c) be accompanied by any document that the applicant considers relevant; and

(d) be lodged at an office of the Department in Australia in accordance with section 5T.

(5A) A request lodged in accordance with section 5T is taken to have been made on a day determined under that section.

(6) The Commonwealth is to pay the travelling expenses to which a person is entitled under this section.

196ZP Advance of travelling expenses

(1) If the Commission is satisfied that:

(a) it is reasonable to expect that a person may become entitled to travelling expenses under section 196ZO; and

(b) it is appropriate, in all the circumstances, that the person should be paid an advance on account of those expenses;

the Commission may authorise the payment of that advance to the person.

(2) If:

(a) a person has received an advance on account of any travelling expenses that the person is likely to incur; and

(b) the person:

(i) does not incur those travelling expenses; or

(ii) incurs travelling expenses that are less than the amount of the advance;

the person is liable to repay to the Commonwealth:

(c) the amount of the advance; or

(d) the difference between the amount of the advance and the amount of the travelling expenses;

as the case requires.

APPENDIX 4 - User Guide to the RMA's Statements of Principles

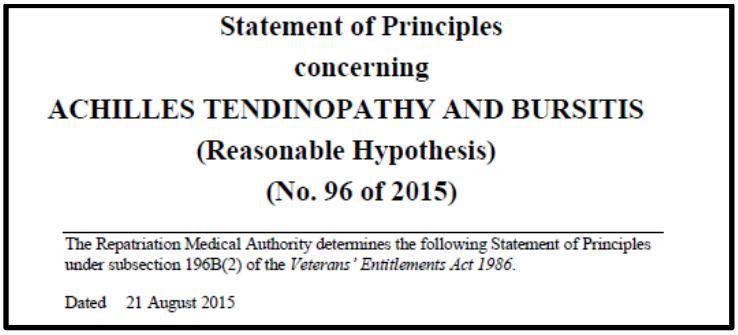
1. The main role of the Repatriation Medical Authority (RMA) is to determine Statements of Principles (SOPs), in accordance with subsections 196B(2) and 196B(3) of the Veterans' Entitlements Act 1986 (VEA). SOPs are used to determine claims for pension made under the VEA. They are also used to determine claims made under the Military Rehabilitation and Compensation Act 2004 (MRCA).

2. The SOPs are legislative instruments, as defined by the Legislation Act 2003 (Legislation Act) and in order to be valid, must be compliant with the LA.

3. The first SOPs were determined in 1994, and despite minor stylistic changes since that time, havefollowed essentially the same format until 2015. From mid-2015 the RMA introduced a number of changes to the format of the SOPs.

4. The RMA introduced the changes to ensure that the content of the SOP is fully consistent with the legislative framework that authorises it, and to improve readability for users of the SOP.

5. The following commentary explains the purpose and use of each section of a SOP, and should be read in conjunction with a SOP drafted using the revised (August 2015) format. Section numbering may vary from SOP to SOP. The commentary is illustrated using as an example one of the first SOPs issued by the RMA using the changed format, the Statement of Principles concerning Achilles tendinopathy and bursitis No. 96 of 2015. Each section of this SOP is reproduced below (in full or part), followed by corresponding explanatory comments.



Statement of Principles
concerning
ACHILLES TENDINOPATHY AND BURSITIS
(Reasonable Hypothesis)
(No. 96 of 2015)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

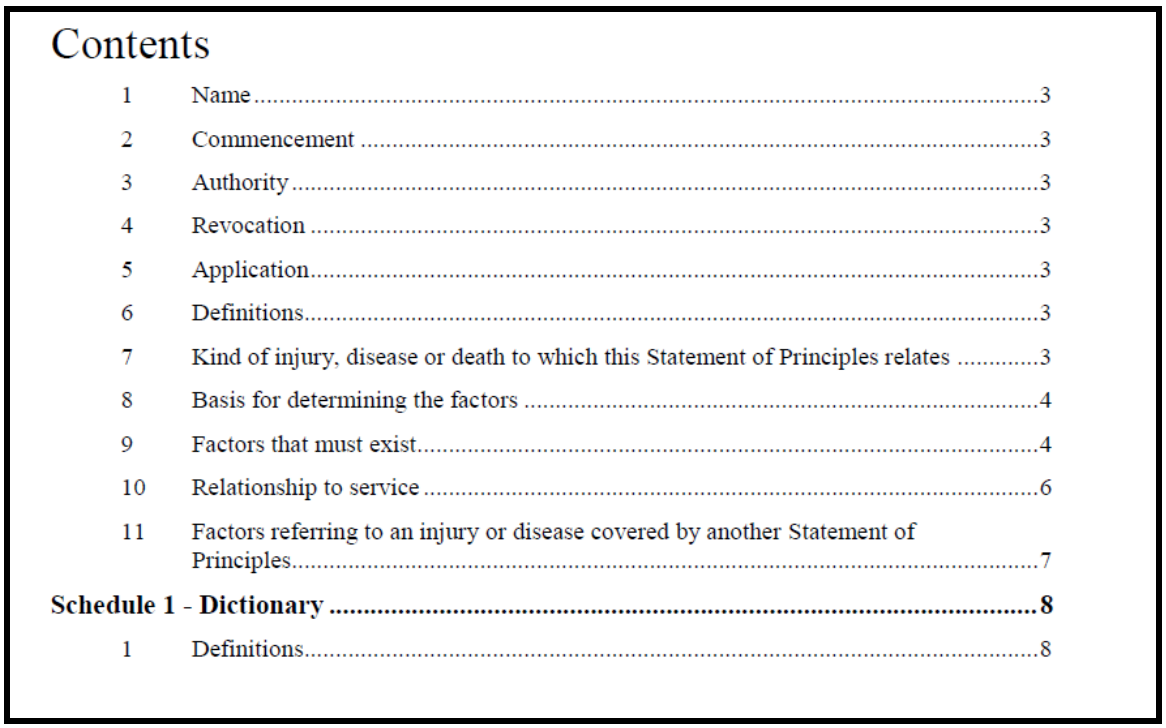
Dated 21 August 2015

6. The title page (page 1) starts with the name of the injury or disease that is covered by the SOP. Note that the SOP also covers death from the specified injury or disease. A detailed definition of the injury or disease can be found in Section 7.

7. The name of the injury or disease is followed by the type of SOP in brackets (Reasonable Hypothesis or Balance of Probabilities) and the number and year of the SOP in brackets. The section of the VEA under which the SOP is made is also specified.

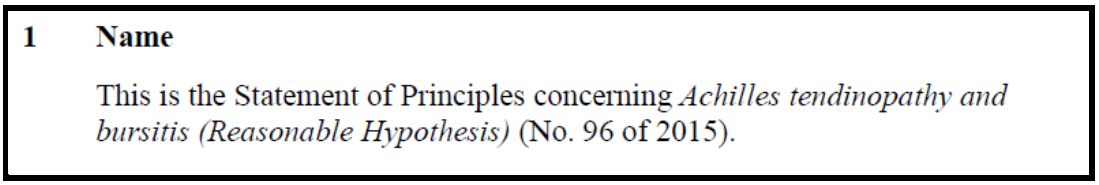
8. If the SOP is an amendment, this will be stated on the title page. The Amendment SOP is drafted in the format of the instrument it is amending.

9. The title page also records the date of signing of the instrument and the signature of the RMA Chairperson.



Contents

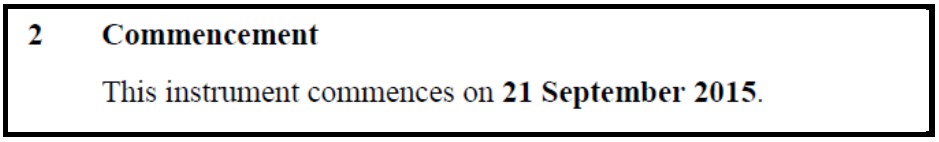
10. The contents page (page 2) lists the sections of the SOP and the page number of each section.



1 Name

This is the Statement of Principles concerning *Achilles tendinopathy and bursitis (Reasonable Hypothesis)* (No. 96 of 2015).

11. This section states the name of the particular kind of injury or disease covered by the SOP, exactly as on the title page.



2 Commencement

This instrument commences on **21 September 2015**.

12. The RMA specifies the date of commencement of the SOP. This date must be after the registration date of the SOP, and is selected so that factors can be applied as soon as possible in the assessment of claims.

3 Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

13. This section informs the reader of the section of the VEA under which the RMA has determined, amended or revoked the SOP. The RMA determines new SOPs under either subsection 196B(2) (reasonable hypothesis) or 196B(3) (balance of probabilities) of the VEA. An amendment to a SOP also relies upon subsection 196B(8) of the VEA.

4 Revocation

The Statement of Principles concerning Achilles tendinopathy and bursitis No. 37 of 2007 made under subsection 196B(2) of the VEA is revoked.

14. If a SOP concerning this kind of injury or disease has previously been determined, this section specifies that the older version is being repealed (in order to be replaced by the current one).

5 Application

This instrument applies to a claim to which section 120A of the VEA or section 338 of the *Military Rehabilitation and Compensation Act 2004* applies.

15. This section informs the reader of the Act, and section of the Act, that specify the kind of claim that can be assessed utilising the factors in the SOP.

6 Definitions

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

16. This statement lets the reader know that some words or phrases in the SOP are used with a specific meaning, and that these words, along with their definitions for the purpose of the SOP, can be found in Schedule 1.

17. Wherever a defined word or phrase is used in the SOP, a note referring the reader to Schedule 1 is included immediately under the section or subsection containing the word or phrase.

> **7 Kind of injury, disease or death to which this Statement of Principles relates**
>
> (1) This Statement of Principles is about Achilles tendinopathy and bursitis and death from Achilles tendinopathy and bursitis.
>
> *Meaning of* ***Achilles tendinopathy and bursitis***
>
> (2) For the purposes of this Statement of Principles,
>
> (a) Achilles tendinopathy means a condition characterised by painful inflammation associated with degeneration in the Achilles tendon, including degenerative tears of the Achilles tendon, or inflammation of the paratendinous tissues; and
> (b) bursitis means inflammation and thickening of the deep retrocalcaneal bursa about the Achilles tendon; and
> (c) excludes posterior adventitial heel bursitis.
>
> (3) While Achilles tendinopathy and bursitis attracts ICD-10-AM code M76.6, in applying this Statement of Principles the meaning of Achilles tendinopathy and bursitis is that given in subsection (2).

18. This section defines the injury or disease covered by the SOP. Subsection (1) restates the name of the injury or disease, and explicitly mentions that the SOP covers death from the injury or disease.

19. Subsection (2) provides a detailed definition, in medical terminology, intended to inform people with medical or other relevant training what types of injury or disease the RMA intends to be covered by the SOP. This more detailed definition is necessary because the names of injuries or diseases do not always have universally agreed meanings. The definition of the injury or disease may be broadened or narrowed in various ways in order to assist claimants and decision-makers using the SOP.

20. A subsection (3) is often (but not always) included in a SOP, which refers the reader to *The International Statistical Classification of Diseases and Related Health Problems* (ICD), which specifies a code (or multiple codes) for injuries or diseases that are most comparable to those covered by the SOP. The ICD codes are included as a general guide for readers. The subsection also emphasises that, regardless of the ICD code specified, the legally binding meaning of the injury or disease covered by the SOP remains that defined in subsection (2).

> (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification* (ICD-10-AM), Ninth Edition, effective date of 1 July 2015, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-020-5.

21. Subsection (4) provides the full reference for the ICD manual (if relevant).

> *Death from* ***Achilles tendinopathy and bursitis***
>
> (5) For the purposes of this Statement of Principles, Achilles tendinopathy or bursitis, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's Achilles tendinopathy or bursitis.
>
> Note: ***terminal event*** is defined in the Schedule 1 – Dictionary.

22. The final subsection informs the reader that the SOP may be relevant to claims regarding a person who has died, provided the injury or disease covered by the SOP contributed to the person's death.

> **8 Basis for determining the factors**
>
> The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that Achilles tendinopathy or bursitis and death from Achilles tendinopathy or bursitis can be related to relevant service rendered by veterans, members of Peacekeeping Forces, or members of the Forces under the VEA, or members under the MRCA.
>
> Note: ***relevant service*** is defined in the Schedule 1 – Dictionary.

23. The wording of this section depends on whether the SOP is being determined under subsection 196B(2) (as above) or 196B(3) of the VEA (i.e., whether it is using the reasonable hypothesis or balance of probabilities standard of proof). The section follows the statutory language of the VEA, in stating a causal link can be made as a result of the factor or factors listed in the subsequent section, between relevant service and the particular kind of injury or disease covered by the SOP. The RMA must be satisfied that this link exists before it can determine a SOP.

24. There are a range of types of service that are recognised as being "relevant" to each of the two SOP types, as defined in Schedule 1.

9 Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting Achilles tendinopathy or bursitis or death from Achilles tendinopathy or bursitis with the circumstances of a person's relevant service:

(1) running or jogging an average of at least 30 kilometres per week for the four weeks before the clinical onset of Achilles tendinopathy or bursitis;

(2) undertaking weight bearing exercise involving repeated activity of the ankle joint of the affected leg, at a minimum intensity of five METs, for at least four hours per week for the four weeks before the clinical onset of Achilles tendinopathy or bursitis;

Note: ***MET*** is defined in the Schedule 1 - Dictionary.

(3) increasing the frequency, duration or intensity of weight bearing activity involving the ankle joint of the affected leg by at least 100 percent, to a minimum intensity of five METs for at least two hours per day, within the seven days before the clinical onset of Achilles tendinopathy or bursitis;

Note: ***MET*** is defined in the Schedule 1 - Dictionary.

25. This section is made up of a list of the SOP's 'factors'. A SOP may contain "onset" factors, each of which describes a way in which injury or disease covered by the SOP can be caused. It may also contain "worsening" factors, each of which describes a way in which the disease can be made worse.

(24) inability to obtain appropriate clinical management for Achilles tendinopathy or bursitis.

26. A SOP may contain an "inability" factor, which states that the injury or disease may be worsened if a person is unable to get appropriate clinical management.

27. For a factor to be included in a SOP, the RMA will have concluded that the factor could potentially arise in the context of service.

10 Relationship to service

(1) The existence in a person of any factor referred to in section 9 must be related to the relevant service rendered by the person.

(2) The factors set out in subsections 9(12) to 9(24) apply only to material contribution to, or aggravation of, Achilles tendinopathy or bursitis where the person's Achilles tendinopathy or bursitis was suffered or contracted before or during (but did not arise out of) the person's relevant service.

28. Subsection 10(1) states that if a SOP factor is used to support a person's claim, at least one of the factors in Section 9 must apply to the person, and must be related to that person's 'relevant service'. The definition of 'relevant service' can be found in Schedule 1.

29. Subsection 10(2) is about 'worsening factors' (see Section 9). It notes that a worsening factor can only be applied if the injury or disease already existed before or during 'relevant' service (i.e., prior to discharge or the last day of 'relevant' service, whichever is the earlier).

11 Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

(1) if a factor referred to in section 9 applies in relation to a person; and

(2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

30. This section relates to the situation where a person wishes to make a claim for an injury or disease covered by a particular SOP, and in that SOP one of the factors is an injury or disease which itself is covered by a second SOP. If so, the claim for the injury or disease covered by the first SOP can succeed if it meets one or more factors in the current version of the second SOP. In order to do so, the factor in the second SOP must be related to relevant service.

31. It is not sufficient for the injury or disease covered by the second SOP to have previously been accepted as related to service. The only exception occurs in claims to have death accepted as related to service, where the death results directly from an accepted injury or disease (ss 8(1)(f) and 70(5)(e) of the VEA).

Schedule 1 - Dictionary

Note: See Section 6

1 Definitions

In this instrument:

Achilles tendinopathy and bursitis—see subsection 7(2).

being obese means having a Body Mass Index (BMI) of 30 or greater.

BMI = W/H^2 and where:
W is the person's weight in kilograms; and
H is the person's height in metres.

crystal-induced arthropathy means arthropathy resulting from the deposition of monosodium urate, calcium pyrophosphate dihydrate, calcium hydroxyapatite or calcium oxalate.

glucocorticoid drug as specified means any of the corticosteroid drugs listed in the following table, in the specified combinations of administration, dose level and duration of treatment:

Drug or Class of Drugs	Mode*	Dose	Minimum Duration of Treatment	Duration
prednisolone or pharmacologically equivalent glucocorticoid	IV, IM, O	≥ 0.5 grams over 6 months	6 months	within the 3 years
		≥ 3 grams	NS	within the 5 years
		≥ 10 grams	NS	NS

Abbreviations: IV = intravenous; IM = intramuscular; O = oral; NS = not specified.

MET means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute, or 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

MRCA means the *Military Rehabilitation and Compensation Act 2004*.

relevant service means:

(a) operational service under the VEA;
(b) peacekeeping service under the VEA;
(c) hazardous service under the VEA;
(d) British nuclear test defence service under the VEA;
(e) warlike service under the MRCA; or
(f) non-warlike service under the MRCA.

32. The Schedule includes all words and phrases that have specific definitions in the SOP, in alphabetical order.

33. If a word or phrase is not defined in a SOP, then the ordinary meaning found in a relevant technical (usually medical) dictionary may be used, or a general dictionary. As SOPs are

legislative instruments made under the Legislation Act, the courts and Tribunals may have provided guidance on how to interpret the meaning of a word or expression, which is then binding on decision-makers.

34. The interpretation of a term used in a SOP is a matter for the decision-maker, where no definition is included and where no judicial guidance is available. The RMA does not determine claims or make a final determination on the meaning of words or phrases in SOPs.

APPENDIX 5 - RMA Practices and Procedures

Australian Government

Repatriation Medical Authority

Repatriation Medical Authority

Practices and Procedures

This document sets out the current practices and procedures of the Repatriation Medical Authority (RMA). It is endorsed by the RMA and reviewed regularly.

Overview of the Statements of Principles System

What are Statements of Principles?

1. Statements of Principles (SOPs) are legal instruments, based on sound medical-scientific evidence (SMSE), which state the factors that must exist for a particular disease, injury or death to be linked causally to prior service. They are tabled in the Australian Parliament and are binding on decision makers at all levels, including the Courts. SOPs are the instruments used to determine eligibility for entitlements under the *Veterans' Entitlements Act 1986* (VEA) and the *Military Rehabilitation and Compensation Act 2004* (MRCA).

2. The VEA is "beneficial legislation" and is intended to be generous. This is seen in the legislative tests for the inclusion of factors set out in Part XIA of the VEA, which permit factors at standards of proof lower than those that might be considered appropriate in clinical and other public health settings.

What is the RMA?

3. The Repatriation Medical Authority (RMA) is an independent statutory authority responsible to the Minister for Veterans' Affairs. It consists of five practitioners eminent in the field of medicine or medical science, and includes at least one experienced epidemiologist. The main role of the RMA is to determine SOPs. The RMA formally meets as a body on a regular basis to consider and finalise SOPs.

Disease or injury

4. The RMA must first consider whether or not the condition in question is a disease or injury. Disease is defined in subsection 5D of the VEA as follows:

> *Disease* means:
> (a) any physical or mental ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
> (b) the recurrence of such an ailment, disorder, defect or morbid condition but does not include:
> (c) the aggravation of such an ailment, disorder, defect or morbid condition; or
> (d) a temporary departure from:
> (i) the normal physiological state; or
> (ii) the accepted ranges of physiological or biochemical measures;
> that results from normal physiological stress (for example, the effect of exercise on blood pressure) or the temporary effect of extraneous agents (for example alcohol on blood cholesterol levels).

5. The RMA determines whether the condition is a particular kind of disease or injury using its own expertise, relevant evidence and the common understanding of the meaning of these terms.

Sound medical-scientific evidence

6. The statute provides for the RMA to have regard to the SMSE in assessing which factors can link the condition to service. SMSE is defined in subsection 5AB(2) of the VEA as follows:

> Information about a particular kind of injury, disease or death is taken to be *sound medical–scientific evidence* if:
> (a) the information:
> (i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or
> (ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and
> (b) in the case of information about how that kind of injury, disease or death may be caused- meets the applicable criteria for assessing causation currently applied in the field of epidemiology

Two standards of proof

7. The RMA determines SOPs at two standards of proof. Figure 1 shows the process for making SOPs at each standard.

8. SOPs determined under s 196B(2) specify the factors that can connect an eligible person's injury, disease or death to operational service or its equivalent[23]. These SOPs are known as reasonable hypothesis (RH) SOPs. For a factor to be included in this instrument, the SMSE has to indicate or point to a reasonable hypothesis of a causal association between the factor and disease. In making this determination, all of the available SMSE is taken into account, and single studies are assessed within this context.

9. SOPs determined under s 196B(3) specify what factors can connect an eligible person's injury, disease or death to non-operational service[24]. These SOPs are known as balance of probabilities (BOP) SOPs. For a factor to be included in this instrument, the SMSE has to show that it is more probable than not that the factor is causally related to the disease.

10. In considering what is meant by the term "reasonable hypothesis", the RMA is guided by relevant judicial decisions prior to its establishment, particularly the deliberations of the High Court of Australia in the cases of *Bushell* (1992)[25] and *Byrnes* (1993)[26]. A definition of reasonable hypothesis is cited in *Bushell* as follows:

> *"To be reasonable, a hypothesis must possess some degree of acceptability or credibility - it must not be obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous. For a reasonable*

---

[23] The relevant service is defined in s 196B(2) of the VEA as including peacekeeping service rendered by members of Peacekeeping Forces, hazardous service, British nuclear test defence service, and warlike or non-warlike service rendered by serving members.

[24] This type of service is defined in s 196B(3) of the VEA as including eligible war service (other than operational service), defence service (other than hazardous service and British nuclear test defence service) and peacetime service for serving members.

[25] *Bushell vs Repatriation Commission* (1992) 175 CLR 408.

[26] *Byrnes vs Repatriation Commission* (1993) 177 CLR 564.

hypothesis to be 'raised' by material …, we think it must find some support in that material - that is, the material must point to, and not merely leave open, a hypothesis as a reasonable hypothesis."

11. On the other hand, the BOP SOP test of "more probable than not" was the subject of consideration by the High Court in *Bradshaw v McEwans Pty Limited* (1951)[27] as follows:

> *"By more probable than not is meant no more than that upon a balance of probabilities such an inference might reasonably be considered to have some greater degree of likelihood*"

12. A review of the RMA conducted in 1997[28] confirmed that the quality of decision making by the RMA was generous, while remaining within the bounds of scientific credibility.

13. Depending on the strength of the evidence supporting a causal association, a factor may be in both instruments (stronger evidence), the RH instrument only (weaker evidence), or neither (inadequate or insufficient evidence, or evidence of no association). Sometimes a factor may be in both instruments but described in a way that is easier to meet in the RH instrument in accordance with the more generous standard of proof. For example, the required exposure dose may be lower or the time to clinical onset longer in the RH instrument.

14. For factors that can be described in terms of levels of exposure, the dose may be quantified in various ways. Examples include pack-years for smoking, sieverts for ionising radiation, numbers of hours or days within a specified time period for certain chemicals or activities and body mass index for overweight or obesity. Some factors are not quantifiable. Examples include having a specified disease or injury or being exposed to a particular virus or other kind of infectious agent.

15. The amount and quality of available evidence may affect the RMA's ability to differentiate the dose in the two standards. Where a causal relationship is well-established for a quantifiable factor, and there is detailed information concerning the relationship between the exposure dose and the condition, it may be possible to accurately determine a dose consistent with the reasonable hypothesis standard, i.e., which is associated with a small but measurable increase in risk. When such information is absent, the lower dose in the range can be applied to the reasonable hypothesis standard. For risk factors with less information, a reliable distinction between the doses for the two standards is harder to make based on empirical evidence.

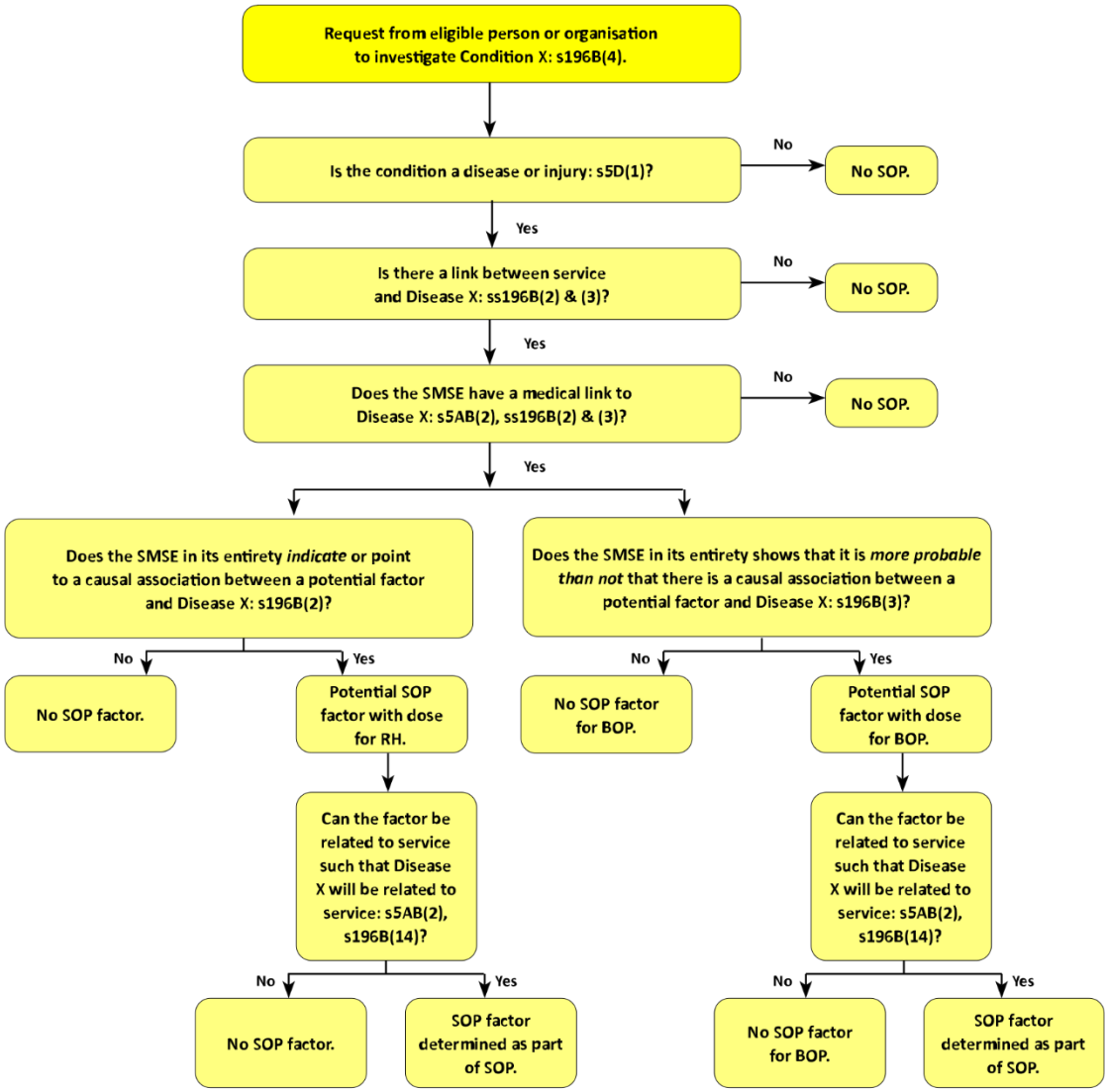
16. The following diagram summarises the process of SOP determination for a new condition. The process is the same for a review of an existing condition, except that consideration of whether the condition is a disease or injury is not usually necessary.

---

[27] Unreported, 27 April 1951; cited with approval in *Holloway v Mc Feeters* (1956) 94 CLR 470 at 480-1.

[28] Pearce D, Holman D (1997) *Review of the Repatriation Medical Authority and Specialist Medical Review Council*. Commonwealth of Australia, p. 101-103.

Figure 1: Determination of SOPs for new condition - Disease X



* Statutory references are to the VEA.

* Request for amendment of an existing SOP is dealt with in a similar manner save that it is an existing disease.

Regular review of SOPs

17. SOPs are regularly updated as new SMSE emerges. The *Legislation Act 2003* requires that legal instruments are reviewed and reissued every ten years, which the RMA regards as a maximum period within which to review medical-science to ensure that it is up-to-date. The RMA aims to review SOPs on a more regular basis where required by the emergence of new SMSE.

18. SOPs may also be reviewed more frequently if there is a request from an eligible party to do so, where sufficient, relevant information is included in the request. Eligible parties include Veterans, defence personnel, organisations representing Veterans or members of the Australian Defence Force (ADF), and the Repatriation Commission or the Military Rehabilitation and Compensation Commission. Eligible parties can also request the RMA to make a SOP for a condition not covered by an existing SOP, and have the right to request that the contents of a SOP or a decision not to make a SOP or amend a SOP be reviewed by the Specialist Medical Review Council.

19. When reviewing a SOP, the RMA considers all the available SMSE that was previously available to it, and the new information. The new information may reinforce existing factors, suggest a change of dose, suggest new factors or occasionally suggest that a factor be removed. There is a higher threshold for removing a factor than putting one in. This is logical as convincing negative evidence sufficient to alter an overall assessment of the relevant SMSE is required before the RMA could properly be satisfied that a factor should be removed. Thus, it is far more common for new factors to be added at a review than for factors to be removed.

Evidence gathering and assessment processes

Briefing papers

20. Researchers from the RMA secretariat prepare comprehensive briefing papers for the consideration of the RMA. These papers systematically describe and analyse the available SMSE concerning potential risk factors for the condition under investigation, and identify issues warranting consideration by the RMA. Using this information, the evidence relating to each factor and the disease in question is summarised, and draft disease definitions and factors developed.

21. The researchers also categorise the strength of the evidence according to predetermined levels or grades (refer Attachment 1). Grades are assigned by the researchers after a critical appraisal and assessment of the available evidence pertaining to each contended risk factor. They serve as a guide to RMA Members in determining whether factors should be included in the RH instrument, both instruments, or neither instrument.

22. The evidence, grading recommendations, draft definitions and draft factors are discussed with and approved by an RMA Member who has been assigned responsibility for the particular investigation or review. They are further discussed by the RMA as a whole at its regular meetings. At these meetings the RMA decides whether or not to endorse or modify draft factors and draft definitions for inclusion in the SOPs.

Sources of sound medical-scientific evidence

23. The process for sourcing evidence for the briefing papers follows standard practices for systematic reviews. There is an initial search of medical-scientific databases and other sources of information, a selection of relevant studies or reports identified in the search or by a review of citations, then a critical appraisal of the information.

24. The medical-scientific databases used are *PubMed*, *Ovid Medline* and *PsycInfo*. Other relevant information may be found by looking at reference lists of identified articles, reports or monographs from reputable research organisations (e.g., the International Agency for Research on Cancer, the Health and Medicine Division of the National Academies of Science), and textbooks (e.g., *Harrison's Principles of Internal Medicine*). Material taken directly from web sites can be used but only if the

author or organisation is recognised as authoritative. Information submitted by applicants and other interested parties is also considered during this process. From time to time, the RMA may also consult with experts to clarify a technical issue, or to seek current clinical opinion.

Searches

25. Databases are searched for studies of aetiological factors in humans and articles are selected on the basis of relevance, study quality, reliability and journal authority. Publications are largely limited to those in English. Animal and experimental studies are usually only obtained if they have a particular relevance to an association in question.

Critical appraisal

26. Appraisal of the information first involves critical assessment of the quality and strength of each article individually, prior to assessment of all of the information relevant to the association in question.

27. Articles are categorised by study design, which is an important characteristic for determining the quality of a study. Randomised controlled trials are considered the strongest evidence, but are often not feasible for risk factors which cannot be randomly allocated for ethical reasons. Next in the hierarchy of evidence quality are prospective cohort studies, followed by retrospective cohort studies, case-control studies, cross-sectional studies and case reports. Mendelian randomisation studies may contribute to the assessment of causation in conjunction with traditional epidemiological studies.

28. Other important characteristics in appraising the quality of a study are the method of selection of study subjects, the way in which the factors of interest and outcomes are measured, the assessment and control for potential confounders (alternative risk factors), the sample size and the statistical significance of the results.

Assessment of causation

29. The RMA Members' assessment of causation takes into account the body of relevant SMSE, in conjunction with the Members' own expertise in epidemiology and clinical medicine. The beneficial nature of the legislation, as embodied in the relevant statutory tests, allows the RMA to make judgements of causality on the basis of weaker evidence than would be accepted in many other contexts. The RMA aims to assess the SMSE in a manner that is as consistent as possible across factors, and across SOPs.

30. Standard epidemiological criteria are used by the researchers and RMA Members in the assessment of causation. They are consistent with standard frameworks, such as the criteria listed by Bradford Hill[29], and include the following:

- temporality - the cause should precede the effect,
- strength of association - the greater the increase in risk of disease in the exposed group compared to the unexposed group, the stronger the indication of causality,

---

[29] Hill AB. The Environment and Disease: Association or Causation? *Proc R Soc Med* 1965; 58: 295-300.

- observation of a dose-response effect - the greater the amount of exposure, the greater the risk of disease (a gradient effect),
- biological plausibility - evidence from animal or experimental studies demonstrates a mechanism of disease,
- consistency with other evidence - studies in different populations and over different time periods give the same results,
- absence of alternative explanations for an association - the relationship between the risk factor and the disease is not due to random error or the way in which studies have been designed, subjects are selected or risk factors and outcomes are measured (chance, bias or confounding).

31. When a number of these criteria are met, the association is more likely to be causal. No single criterion is sufficient to determine causation, and only temporality is a necessary condition. Some general propositions which inform the RMA's approach can be stated.

32. Most importantly, it is necessary to review the whole body of evidence to avoid selective interpretation of the results. The conclusions of studies of a more sophisticated design and which are methodologically sound carry greater weight than less well conducted studies because alternative explanations for associations are less likely.

33. In the situation where there are a large number of studies concerning the relationship between a factor and the condition of interest, the RMA looks for consistency of the results. If most of the studies show no association and are of good quality, their conclusions will outweigh those of a small number of studies that find an association, unless there is a clear methodological reason to prefer the latter group of studies. On the other hand, if there are only a few studies of a relationship and there is a discrepancy in the findings, the factor is more likely to be included, though usually in the RH SOP only.

34. While these and other sound logical propositions guide the RMA in its deliberations, it is the expertise and experience of its Members which enables sound judgement to be made about the factors pertinent to each disease or injury. This approach also informs the formulation of factors.

Formulation of factors

35. The RMA aims to express factors in a way which accurately and clearly reflects the evidence. It is also mindful that factors that are similar in different conditions should be expressed as consistently as possible, while still having regard to the evidence for that particular condition. Parameters considered when assessing consistency include dose, latency between exposure and disease onset, cessation periods where relevant and relativities between the two standards of proof.

36. Only some studies will provide enough detailed information to determine the level of exposure at which risk increases, or the length of time between exposure and onset of disease. When quantifying dose, the RMA does not generally take into account individual background levels of exposure, making the assumption that the factor will have the same effect on causation of the condition regardless of background exposure (for example background exposure to sunlight or radiation).

37. The RMA recognises that there can be synergistic effects between some pairs or groups of factors, but generally includes factors singly in its SOPs. To formulate a factor taking into account synergy,

the interaction would need to be quantified by levels of exposure to one factor in terms of level of exposure to the other factor, and would go well beyond the available evidence for most factors. The use by the RMA of doses that are the lowest consistent with the evidence means that a SOP factor makes allowances for groups that may be at higher risk due to exposure to some other factor.

38. Females can be at higher risk for some conditions. There are SOPs and factors for injuries, diseases or exposures which only or largely apply to women. Where the evidence allows, different doses in factors may be specified for females. A distinction between doses for males and females is often difficult to quantify due to lack of studies which specifically measure exposures in females. However, as noted above, the use by the RMA of doses that are the lowest consistent with the evidence means that a SOP factor makes allowances for groups that may be at higher risk due to intrinsic risk factors, including gender.

39. Sometimes there is evidence that an exposure may be protective, that is, it reduces the risk of developing or worsening a particular kind of disease. In that case, the RMA may include a factor expressed as an "inability" to undertake the protective activity.

40. In general, the RMA considers that exposures which can cause a condition may also permanently worsen that condition. Some exceptions are cancers and infectious diseases, in which some causes logically only relate to the onset of the condition. Information concerning factors which might worsen a condition is often not available, but generally where a risk factor is related to onset, it can, consistent with the statutory tests, be assumed to contribute to the worsening of that condition. Before any exposure can be included as a worsening factor, it is necessary to be satisfied that the exposure is able to be related to service after the onset of that condition. Again, the expertise and experience of the RMA is applied here in assessing the circumstances relevant to each condition.

Procedural matters

Prioritisation of investigations and reviews

41. As a general principle, investigations and reviews are prioritised by chronological age (taken from date of gazettal notification rather than date of receipt of request). However, there are a number of situations where the RMA may prioritise a particular investigation or review. These situations include the following (not in order of importance):

- Claims for conditions for which there are no existing SOPs (non-SOP conditions) cannot legally be determined once an investigation notice has been gazetted. In order not to hold up an excessive number of claims, non-SOP conditions may be prioritised when there are more than ten claims outstanding.
- In any case where a notified review is identified by the RMA legal adviser, either of the Commissions, a national ex-service organisation (ESO) or the Minister as raising a serious problem warranting prioritisation, consideration will be given by the RMA to such a request.
- The RMA can notify a full or partial (focussed) review. The terms of a focussed review are notified in the government gazette. Part of the basis for restricting the focus of the review is to enable a speedier finalisation of the matter(s) under review. To ensure that this occurs and to avoid additional issues outside of the notified focus of the review arising, focussed reviews are generally given priority.
- From time to time, investigations or reviews are more efficient when considered in conjunction with one or more other related investigations or reviews. Examples include the concurrent

reviews of migraine, cluster headache and tension-type headache, and the concurrent consideration of cervical, thoracic and lumbar spondylosis.

Operational issues

42. Operational issues associated with factors include the way in which factors are worded or set out in order to be relevant to service personnel and easy to comprehend and use. Advice on these issues is obtained at the informal meetings held immediately prior to RMA formal meetings, which are attended by advisers from the Department of Veterans' Affairs (DVA), an adviser from the ADF and an ESO adviser. This advice draws on those advisers' knowledge and experience, especially knowledge of service conditions and experience of difficulties when making or assessing claims.

43. Since 2014, New Zealand has incorporated the SOPs into its decision making framework, under its *Veterans' Support Act 2014*. A review of this Act in 2018 recommended that a New Zealand Veterans' Affairs (NZVA) medical practitioner attend RMA meetings. The RMA agreed to extend an invitation to an NZVA nominee to attend RMA meetings as an expert adviser.

44. Where a factor has been removed, draft SOPs are sent out for stakeholder consultation for a minimum period of three months. Any comments are taken into consideration before the SOPs are finalised.

Finalisation of SOPs

45. Once factors and definitions have been discussed at one or more RMA meetings, a draft SOP is drawn up for further discussion and final approval at the following RMA meeting. The final SOPs are registered with the Federal Register of Legislation and are available on the corresponding website. As part of the registration process, an Explanatory Statement for each SOP is prepared. Each SOP and its Explanatory Statement are tabled in Parliament. SOPs are listed both alphabetically and by category of disease or injury on the RMA website.

Attachment 1 - levels of evidence

General considerations

Application of criteria

1. The Authority is unaware of any single set of recognised criteria that can be uniformly applied in the classification of a factor, or that would adequately capture the subtleties and methodological variations of all studies considered. The best available evidence varies across different medical fields and different types of exposures. There is often uncertainty about the boundaries between grades and there may be minimal information concerning such parameters as dose and latency. For these reasons scientific judgment, based on the Authority's considerable clinical and epidemiological experience, is needed to assess the strength of the SMSE concerning the likelihood that a risk factor is causally related to the disease or injury under investigation.

Aetiological focus

2. As far as possible, the Authority seeks to identify specific agents considered most likely to be responsible for any excess risk of the disease or injury that is the subject of a Statement of Principles. However, it is recognised that available studies often report on broader types of exposure, such as a chemical mixture, an industrial process or activity, or even an entire occupational category. The evaluation is therefore focused as narrowly as the available data on exposure and other aspects permit. In some circumstances, it may be possible to narrow the focus enough to determine a factor (e.g., solvents, working as a painter), but in other circumstances the category may be so broad as to preclude a meaningful association (e.g., pesticides).

Levels of evidence

Grade 1 Convincing

3. There is evidence strong enough to support a judgement of a convincing causal relationship. A consistent association has been observed between exposure to a risk factor and the disease or injury under investigation, and chance, bias and confounding can be ruled out with reasonable confidence.

4. Some examples of the types of evidence which would meet this test are as follows:

    1) A consistent finding across the totality of studies, statistically significant relative risks generally above 1.5, no obvious biases or confounding and evidence for biological plausibility. Studies are of high quality, and usually several cohort studies are available.
    2) If there are only case reports or case series, evidence of temporal link and a biomechanical or pathophysiological mechanism, plus (especially for drugs or chemicals) evidence of reversibility or recurrence on re-exposure.

Grade 2 Suggestive

5. There is evidence strong enough to support a judgement of a suggestive causal relationship. A consistent association has been observed between exposure to a risk factor and the disease or injury under investigation, but chance, bias or confounding cannot be ruled out with reasonable confidence.

6. Evidence in this category does not clearly meet the criteria in Grade 1, but consideration of the upgrading features listed below may allow the factor to be assigned to the higher grade.

Grade 3 Limited

7. The evidence is too limited to permit a judgement of a suggestive or convincing causal relationship, but supports a judgement of a possible causal relationship. A generally consistent association has been observed between exposure to a risk factor and the disease or injury under investigation, but the evidence is limited in quality or quantity.

8. Some examples of the types of evidence which would meet this test are as follows:

    1) Where no other relevant studies are available, a finding of a significantly increased relative risk based on only one high quality study, and no obvious biases or confounding.

    2) A finding of significantly increased relative risks, generally in the range of 1.1-1.5, based on several studies that are mostly consistent, but with some evidence of bias or confounding.

    3) If there are only case reports or case series, evidence of temporal link and a biomechanical or pathophysiological mechanism.

Grade 4 Very limited

9. The evidence is too limited to permit a judgement of a possible causal relationship. An association is demonstrated in some studies, but the evidence is inconsistent and studies are limited in quality or quantity. Chance, bias or confounding are likely to account for observed associations.

10. Evidence in this category does not clearly meet the criteria in Grade 3, but consideration of the upgrading features listed below may allow the factor to be assigned to the higher grade.

Grade 5a Inadequate

11. The evidence is so limited that no firm conclusion can be made. The evidence is very limited in amount, or the available studies are of insufficient quality, consistency or statistical power to permit a conclusion regarding the presence or absence of a causal association between exposure and injury or disease, or no data in humans are available.

Grade 5b Evidence suggesting no causal association

12. The evidence is strong enough to support a judgement that a particular risk factor is highly unlikely to have a causal relation to the disease or injury. There are several adequate studies covering the full range of levels of exposure that humans are known to encounter, in which the weight of evidence is consistent in not showing a positive association between exposure to the agent and any studied injury or disease at any observed level of exposure. Bias and confounding can be ruled out with reasonable confidence, and the studies have an adequate length of follow-up. The evidence is robust enough to be unlikely to be modified in the foreseeable future as new evidence accumulates, though a conclusion of “no association” is inevitably limited to the conditions, exposures, and length of observation covered by the available studies.

13. An example of the type of evidence which would meet this test is as follows:

    1) A consistent finding across the totality of studies, relative risks generally in the range of 0.9 to 1.1, no obvious biases or confounding and no plausible biological mechanism. Studies are of high quality, and usually several cohort studies are available.

Upgrading and downgrading features

14. These features may apply for any grade, but may be especially useful where there is most uncertainty about the grading (grades 2 and 4).

Upgrading features

(a) Presence of a biological gradient ('dose-response') in the association.

(b) A large summary effect size (a statistically significant odds ratio or relative risk of 2.0 or more) after appropriate control for confounders.

(c) Evidence from randomised, controlled trials in humans.

(d) Evidence that the effect is reduced if the exposure is reduced or ceased (for example, quitting smoking).

Downgrading feature

- Evidence of a plausible biological mechanism is absent or weak.

Application of grades to decision points

15. The table below summarises the way in which the grading usually translates to a decision in terms of whether or not it suggests a factor for RH or RH and BOP. The final decision about a factor may not match the grading for a number of reasons. These reasons include ambiguity in the evidence, different interpretations of underlying conceptual issues or practical considerations about the SOP in which a factor most appropriately belongs.

Table 1 Application of grades to decision points

Assigned grading	Decision for consideration	
	RH	BoP
Grade 1	Yes	Yes
Grade 2	Yes	Maybe
Grade 3	Yes	No
Grade 4	Maybe	No
Grade 5a	No	No
Grade 5b	No	No

Acknowledgements

16. In documenting these criteria, the RMA gratefully acknowledges that it has drawn upon and adapted grading criteria produced by the Institute of Medicine, the International Agency for Research on Cancer and the World Cancer Research Fund/American Institute for Cancer Research.

APPENDIX 6 - Guidelines for RMA Researchers

This document sets out the current standards for processes and procedures used by researchers when undertaking investigations for the purposes of assisting the consideration of sound medical-scientific evidence (SMSE) by the Repatriation Medical Authority (RMA). It is endorsed by the RMA and reviewed regularly.

Writing briefing papers

1. The assistance provided to the RMA by the medical researchers is focussed on identifying and evaluating the sound medical-scientific evidence (SMSE) relevant to the disease or injury under consideration. The suite of decision support papers includes:

    a) The main briefing paper summarising the SMSE relevant to the disease or injury under consideration;

    b) A summary of studies table or Forest plot, where relevant;

    c) A comparison table (a working document, comprising the suggested revisions to a Statement of Principles (SOP) with the content of the current SOP and suggestions for change and reasons for changes; or suggested factors and definitions for a new SOP); and

    d) Draft SOPs setting out the phrasing of the contents of the proposed SOPs.

2. There are standard templates for each of these documents and these must be used without variation of structure or alteration of formatting. Briefing templates are available in HPE Content Manager container 1605769.

3. There are also documents which provide standardised wording for factors and definitions. These documents are available in HPE Content Manager container 1302948 (hitherto referred to as the Standard Definitions and Factors container).

Main briefing paper

4. The purpose of the main briefing paper is to provide the information needed to make a decision as to whether there is evidence to support the inclusion of a factor for that condition, and if so at what standard. There may also be issues of dose and latency to decide.

5. The following standard subheadings are utilised in the main briefing paper:

Current Statements of Principles

6. The number/date of the current SOPs is stated, with a list of current factors. It is not necessary to copy the full wording of the factors in the current SOPs. The differences between the reasonable hypothesis (RH) and balance of probabilities (BOP) SOPs are highlighted in a table.

Background

7. This section summarises the reason for carrying out the investigation.

Correspondence/submissions

8. The researcher should list all submissions. This includes letters, requests for investigation and submissions. If the investigation is being undertaken because of a request from an eligible person or organisation, it is included in the section entitled “background”, and any subsequent correspondence or submissions are summarised here. For privacy reasons the name of the correspondent is not given; instead use initials or the term "a veteran" or "a widow" as appropriate.

9. Submissions may include an amount of material which is not peer-reviewed or not relevant. The researcher should examine the material provided and obtain full articles that might be relevant or informative. The rationale for not obtaining information should be explained.

Literature search

10. See section on searching.

Definition of disease or injury

11. The current definition and ICD codes should be listed. Relevant definitions are provided from authoritative sources and adapted as necessary. The suggested definition is written in the comparison table rather than in the main briefing paper. ICD codes are included in the suggested definition if they correspond closely to the word definition. If there is poor correspondence between the ICD codes and the word definition, then their inclusion may cause confusion and it is preferable to omit them. If there is uncertainty about the use of ICD codes this can be discussed at the RMA meeting.

Introduction

12. The purpose of the introduction is to provide a *brief* overview of the main facts about the condition (usually no more than two pages). Some more detail may be required if it impacts on relevant decisions. For example, the definition may not be clear cut, or there may be factors that might be relevant to only some forms of the condition (for example, a certain histological subtype of a cancer).

13. Resources which are useful for giving good background information include *Harrison’s Principles of Internal Medicine*, *UpToDate* and the *Oxford Textbook of Psychiatry*. There are various textbooks relevant to particular specialty areas in the RMA library (available in hard copy and digitally in HPE Content Manager Container 1306038). A Google search is often useful. For definitions, useful references include *Dorland’s Medical Dictionary*, DSM-5 and the ICD codes.

Factors

14. If there is a current factor for a particular exposure, the wording of the factor and any associated definition should be included.

15. Where relevant and useful, there should be an indication or “sign-posting” of the major issues and the conclusions pertaining to each factor at the beginning of the presentation of evidence (without

repeating all the evidence) in the Summary of Important Issues section. “Sign-posting” helps the reader understand where to direct the focus of his or her attention. For example, the researcher could state something like “While there is little disputation about the factor being causally related to disease x, there is considerable uncertainty in the literature about the dose/exposure required". Where a factor is complex, there may need to be a brief background explanation of what the factor is about, or difficulties with classification and measurement (e.g., what is meant by the term “organochlorines”, how the term “sedentary” is defined and measured). Where there has been a request for review into the particular factor, this should be stated here.

16. In this section the papers that have been identified as relevant from your search are analysed separately, then the information from all the studies is synthesized in the summary. The papers should be discussed in order of study type, from the highest quality to the lowest quality:

    - Meta-analyses, systematic reviews
    - Cohort studies (prospective studies first)
    - Case-control studies
    - Cross-sectional studies
    - Case series, case reports.

17. General (non-systematic) reviews are of varying quality, but may be included before the other studies if they help to give an overview of the evidence or highlight important issues.

18. In the interests of efficiency, you should in the first instance obtain information from systematic reviews, meta-analyses, International Agency for Research on Cancer (IARC) monographs, Health and Medicine Division reports, Veterans and Agent Orange updates, UpToDate or other relevant reviews, where such information exists and provided that it is of good quality and from a reputable source. Further information may be necessary if such reviews are not recent, or if more detailed information about dose, latency or cessation periods is needed to formulate a factor. Information from case-control studies or cross-sectional studies may not be needed if there are a reasonable number of good quality cohort studies.

19. Some systematic reviews are very recent and comprehensive, and in that case there is no need to separately analyse the papers that were included in the review. However, there may be a need to separately obtain papers that have been published more recently, or to obtain papers that are particularly influential or informative.

20. There are sometimes studies which don’t fit the above categories. If the study design is distinctive, you may wish to include a separate heading, e.g., record linkage studies, case-cohort studies, nested case-control studies, case-time-control studies, genetic studies. On reading a paper it sometimes becomes apparent that the authors have categorised their study incorrectly. You should place it where you think it belongs and explain why.

21. Randomised controlled trials (RCTs) are seldom available in the field of causation, but can add to the coherence of an argument for or against causation. For example, if RCTs of vitamin D supplementation do not consistently increase bone mineral density, it can go against an argument for a causal association between vitamin D and osteoporosis (bearing in mind mechanism of action, adequacy of dosage and adherence to treatment).

22. Case reports can provide evidence for causation when a combination of the criteria below are met.

- a close temporal link between exposure and effect
- reversibility
- recurrence of symptoms or pathology on repeat exposure
- absence of likely alternative explanations
- multiple case reports (usually at least three, though one or two reports may be enough if they are convincing using the other criteria)
- a likely mechanism for the effect is known (biological plausibility)
- a dose-response effect

23. Information in textbooks needs to be treated with caution, as it is often out of date by the time it is published, and broad lists of factors may be perpetuated without reference to the original research, or without consideration of the quality of the source.

24. PhD, Masters and Honours' theses are sometimes submitted by applicants. These documents are subject to a peer review process and published by universities, therefore the Authority considers them to be SMSE. The usual requirement for critical evaluation of the quality of the evidence applies. However, researchers are not required to search for and obtain these types of theses when conducting investigations.

25. Nearly all SOPs have a factor for "inability to obtain appropriate clinical management". However, this factor is not automatic. The management of the condition needs to be briefly documented, and consideration given as to whether such management would prevent worsening of the condition, or delay death from the condition.

26. Consider whether or not or any of the factors should be differentiated by gender. Different doses for males and females should be specified where there is sufficient evidence to do so.

27. In general, the RMA considers that exposures which can cause a condition may also permanently worsen that condition or increase the rate of progression beyond that normally expected. Some exceptions are cancers and infectious diseases, in which some causes logically only relate to the onset of the condition. Before any exposure can be included as a worsening factor, it is necessary to be satisfied that the exposure is able to be related to service after the onset of that condition (as per s196B *Veterans' Entitlements Act 1986*). For example, a chronic disease could not logically worsen an infectious disease of acute onset because it would have to occur after the onset of the infectious disease.

28. Drug factors require special consideration in situations where there is uncertainty about inclusion of a drug as a possible or probable cause of the disease under investigation. At its April 2018 meeting, the RMA agreed that in those situations specific criteria should be applied. Details of these criteria can be found in Attachment 3 – Paragraph 11. *Drug factors and lists*.

Summary and conclusions

29. The amount of information in this section will clearly depend on the number of studies available, and whether or not the conclusions are obvious. Where there are a number of studies and the

outcome is not immediately evident, an assessment of the evidence in terms of the Bradford Hill criteria is usually the most useful method of summarising and weighing the material before you.

30. For example, you would summarise the number of cohort studies, and how many were significantly positive and how many were null. Then you would do the same with case-control studies, etc. You would comment on the strength of the effect in positive studies, and whether or not there were concerns with bias and confounding. You might comment whether studies showing lack of effect were underpowered. You would look for studies that measured a dose-response effect, and state how many showed such an effect. You would briefly describe the proposed biological mechanisms, or the lack of knowledge thereof. If it is difficult to judge the consistency of the evidence, you might make a Forest plot or a summary of studies table.

31. At the end of the summary you should state the conclusions in terms of the levels of evidence, including assigning a grade (e.g., the evidence for that particular association supports a judgement of a convincing/suggestive/possible causal association, or the evidence is too limited/inadequate/insufficient to suggest a causal association).

32. You should carefully consider at each review whether or not factors should be retained in either the RH or BOP SOPs. New evidence may alter the balance of the total body of SMSE, such that it may not reach the threshold for an RH or BOP factor. Conversely, the evidence may have strengthened. In the absence of new information, the available SMSE should still be evaluated afresh against the grading system.

Referencing

33. All material should be referenced. The standard referencing style in the body of briefing paper is numerical footnoting. In the summary and conclusions use author/date citations to support your statements (no need to footnote again). In general the full article is obtained, but if only the abstract is used in an investigation (.e.g., foreign language articles) then the reference must state “abstract only”.

34. Articles may be obtained by yourself online or by the administrative staff. They can use a printout of a search, or a printout of an abstract, or you can email them a list of requested articles. Let them know your name, the name of the condition and the date requested. Make a note on the request if you require the abstract only.

35. You should allow 4 weeks to receive the requested articles. To maintain a flow of work it is advisable to start searching for articles for a new investigation while completing a current investigation. In some circumstances articles may be needed more urgently and you should discuss this with the Principal Medical Officer (PMO) or administrative staff. Such a circumstance might include follow up of a request from the RMA at a meeting for more information, or the need to finalise a briefing paper in time for an RMA meeting.

36. The reference to any material obtained from the internet must be entered by the administrative staff into the RMA Database and the relevant HPE Content Manager container, including the date the information was accessed. Therefore, if you download an article or internet page yourself, you must provide a pdf version of the document to the administrative staff.

37. A bibliography for each investigation should be compiled and added to the finalised briefing paper. This is most easily accomplished by transforming the footnotes. Ensure that the reference style in

the footnotes matches the standard reference style. The bibliography is included in the briefing paper and saved in the appropriate investigation container so that the administrative staff can check the references against the database.

Comparison Table

38. A working document referred to as the comparison table is used during the RMA's consideration of an investigation. The document succinctly records the implications and recommendations arising from the main briefing paper and associated tables. This document is also used to record your grading of the evidence, summarise the reasons for changes, highlight issues for discussion and document directions given at RMA meetings.

39. For reviews of existing conditions, the comparison table lists the current condition definition, current factors and current factor definitions in the left hand column, and the proposed definition, factors and factor definitions in the middle column. The right hand column provides the grade. The comparison table also lists all factors for which the evidence was examined but no risk factors were proposed, as well as any factors which are being removed on the basis of new evidence.

40. The wording of the proposed factor should provide doses/timeframes for each standard of proof, where such parameters are relevant. Proposed factors and definitions must be discussed with the supervising professor before the RMA meeting (see Interactions with Professors).

41. For a new condition the left hand column lists only the contended factor (e.g., smoking) and the middle column is used to list the proposed factors and definitions as usual.

42. Issues and reasons are recorded above the SOP definition and factors - issues in left hand column and reasons in the right hand column. The progress of the investigation is updated by the Deputy Registrar at the beginning of the table.

43. In the third column of the table you should record your assessment of the level or grade of evidence next to the proposed factor, after discussion with and approval by the lead Professor. Grades are assigned by the researchers after a critical appraisal and assessment of the available evidence pertaining to each contended risk factor. They serve as a guide to RMA members in determining whether factors should be included in the RH instrument, both instruments or neither instrument. The grades, and the basis for each grade, can be found in the "RMA Practices and Procedures" document in the Researcher Procedures Container 1303660 or on the RMA website.

Consistency of factor wording and doses

44. To ensure consistency across SOPs, factors and definitions should be written in the same style and format as that of previous similar factors and definitions, unless the evidence requires that the factor be updated or differentiated.

45. Documents describing standard factors and standard definitions are kept up to date and can be found in the Standard Definitions and Factors container (HPE Content Manager Container 1302948).

46. Documents in this container include tables of SOPs with common factors, such as smoking, mefloquine, dioxin and radiation. So that these tables are kept up to date, you should alert the Deputy Registrar of any changes or additions which affect factors in the tables whenever an investigation is finalised.

47. It is also important to search previous SOPs for similar factors, paying particular attention to the wording of more recent SOPs. SOPs can be searched by two methods: a factor search on the RMA website, or a word or phrase search in the HPE Content Manager container entitled “All operative SOPs for searching”. It is often useful to search by both methods, as one or other method may not be comprehensive.

48. Some commonly used factors and definitions have been the subject of discussion at RMA meetings and a standard form of words has been endorsed. These factors are listed in Attachment 3 of these guidelines and should be used unless the evidence suggests otherwise.

49. Advice was provided at the December 2016 RMA meeting concerning the use of notes. Notes have legal standing and are to be used when a part of a definition or factor provides useful but non-essential information. Guidance on the application of notes may be sought from the PMO, the Deputy Registrar or the Registrar.

50. When referring to eponymous conditions in factors, the possessive apostrophe 's' should be omitted, unless there are SOPs which use the possessive form. For example, there is a SOP for "Parkinson's disease", so factors should continue to be spelt this way rather than changing to "Parkinson disease".

51. The two standards of proof allow for different doses in RH and BOP, but the amount and quality of available evidence may affect the ability to differentiate between the suggested factors. Where there is detailed information concerning the relationship between the exposure dose and the condition, it may be possible to accurately determine a dose consistent with the reasonable hypothesis standard, i.e., which is associated with a small but measurable increase in risk. When such information is absent, the lowest dose in the range can be applied to the reasonable hypothesis standard. For risk factors with less information, a reliable distinction between the doses for the two standards is harder to make based on empirical evidence and it may not be possible to make a differentiation between the doses suggested in the RH and BOP standards.

Summary of studies table

52. A summary of studies table is sometimes useful, but is time consuming to construct and not necessary for every investigation. It may be useful where the information is complex and inconsistent, making it difficult to get a clear picture of the weight of the evidence in relation to a particular factor. The column layout allows the study design, study numbers, control for confounding and main results to be presented in a clear and simplified way. A template is available in HPE Content Manager Container 1605769.

Forest plots

53. These may be useful when the evidence is complex and inconsistent and a visual representation of the data would assist understanding of consistency. Results should be grouped by exposure type, study design, or in whatever grouping best enhances the meaning of the data. The Briefing Paper Templates Container 1605769 has an example of how to make a Forest plot in Excel using the chart wizard and standard stock plots.

54. It is inherent in these graphs that much qualitative information is not represented. It may be useful to add additional relevant information in text windows or in the author-date label on the x-axis.

55. The final plot or plots must be copied into the main briefing paper.

Searching

Databases

56. The databases most commonly used are *PubMed*, *Ovid Medline* and *PsycInfo*. The latter two are available via the DVA intranet. ToxNet is a public website which may be useful when researching toxic substances. Another public website, *PubChem* provides chemical synonyms and has sections on "Toxicity" and "Associated Diseases and Disorders" which are cross-referenced with articles in PubMed.

Standard database searches

57. The standard Medline search for doing an initial "sweep" of the literature is "condition/ epidemiology, aetiology, chemically induced." It is often useful to limit your initial search to systematic reviews and meta-analyses, as a way of scoping the information. The initial search is usually limited to humans and English language, but you may choose not to have these limits if you need to consider animal studies or foreign language abstracts/articles.

58. For a new condition generally do a ten year search. For reviews of existing conditions generally do a search from the year before the existing SOPs were determined to the present. For both new conditions and reviews, your research may indicate that older articles are important and require consideration.

59. After the initial search, additional specific searches for the condition and each factor of interest are conducted. Searches should be updated if your initial search was not conducted in the last month.

60. Check the HPE Content Manager articles container for the condition you are researching for any recent, relevant articles that may have been added since the last investigation (key papers may have been saved there for later review).

61. Printouts of search results do not need to be retained, but your search strategy should be clearly described, especially if it varies from the standard method.

Checklist of common factors

62. There are a number of factors which are of particular interest to veteran and military groups. These should be routinely considered, depending on the type of condition you are investigating. They include: alcohol, smoking, dioxin/herbicides, pesticides, solvents, fuels, benzene, asbestos, stressors, mefloquine/antimalarials, firefighting, per- and poly-fluoroalkyl substances (PFAS), repetitive trauma, ionising radiation and non-ionising radiation.

63. Any mefloquine, passive smoking, benzene, radiation or dioxin-related factors should be brought to the attention of the administrative staff in case they need to be tagged so that they will be identified on a factor search on the RMA website. For example, a search for the term mefloquine will not identify factors for "quinoline derivatives" unless these factors are tagged.

Standard reference texts

64. Some standard references that should be checked if they are relevant to the condition are listed below. Most are available in the RMA library or on the internet.

- IARC Monographs on causes of cancer;
- ATSDR (Agency for Toxic Substances and Disease Registry) toxicological profiles for toxic substances;
- The latest update of the US VAO (Veterans and Agent Orange) review of the literature concerning the health effects of exposure to dioxin-contaminated herbicides and dioxin;
- UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) for the health effects of ionising radiation;
- The Australian Study of Health Outcomes in Aircraft Maintenance Workers (SHOAMP) for solvents;
- The US Institute of Medicine's Gulf War and Health series of literature reviews of the health effects of fuels, infectious diseases, stress, depleted uranium, pyridostigmine bromide, sarin, vaccines, traumatic brain injury and other Gulf War related exposures;
- The World Cancer Research Fund/American Institute of Cancer Research and IARC Handbooks of Cancer Prevention for cancer risks related to diet, obesity and physical activity;
- The US Surgeon General's reports on the health consequences of exposure to tobacco smoke and environmental tobacco smoke.

Interactions and correspondence

Interactions with Professors

65. One of the RMA members is designated the "lead Professor" for each investigation. The lead professor-researcher arrangement enables the detailed review and epidemiological analysis of the SMSE with respect to the disease or injury in question to proceed in a timely and effective manner.

66. An initial planning discussion with the lead Professor should occur in order to scope the investigation before the detailed investigation is commenced.

Preparation for initial planning discussion

67. If the condition has a current SOP the researcher should prepare for the initial discussion by:

- reviewing the previous comparison tables and the previous briefing paper;
- conducting a standard database search of the condition to identify any contentious issues that may have arisen since the previous investigation; and
- reviewing any correspondence or submissions that have been received about the condition to see if any issues raised require attention (peruse the Investigation container including the *Correspondence – Destruction permitted* folder).

68. If the condition is non-SOP the researcher should conduct initial standard database searches and review standard texts to gain an understanding of the condition and any potential contentious issues.

69. The researcher should consider developments in the literature which may bear on nomenclature, status as a SOP condition, relationship to other SOPs and whether the RMA has varied current factors in other SOPs in a relevant manner. The RMA may have already flagged these issues in its decision to investigate.

Scoping document and discussions

70. In conjunction with your supervisor/the PMO, a scoping document about the proposed investigation should be prepared and circulated to the lead Professor. The scoping document should be in the form of a draft comparison table and should include the established factors, the likely contentious issues and the new issues arising in the literature which may require greater focus.

71. The purpose of the scoping paper is to identify where most effort should be spent in evaluating the literature and writing up the findings. Little effort should be spent on the reinvestigation of established factors, unless the scoping search throws up unexpected information about the factor, its dose or some other relevant matter. Most effort needs to be spent on investigating and writing up possible new factors and proposed variations of existing factors.

72. Once the scope is settled, additional discussions with the lead Professor and PMO may occur in the course of the investigation as required. In particular during the investigation the nature of the issues requiring investigation and the focus of the investigation may change. This may lead to variation of the delivery date and overall work plan. When such a circumstance becomes apparent, further discussion should be held with the PMO and the lead Professor and the Registrar notified so that the work plan can be amended.

First Draft – Final Papers

73. There should be a discussion of the two briefing papers, the main briefing paper and the comparison paper, at the first draft stage with the lead Professor.

74. Prior to that discussion, the comparison table with proposed factors and proposed definitions will be given to the PMO and Principal Medical Researcher for review and to the Deputy Registrar and Registrar for drafting approval.

75. Following approval, the comparison table should be delivered to the lead Professor with the main briefing paper for consideration. These papers should be available on HPE Content Manager.

76. Following discussions with the lead Professor as necessary and endorsement, the two briefing papers are tabled at the RMA meeting. Those discussions may include further discussions with the PMO and the Registrar as necessary.

Meetings

77. It is the responsibility of the researcher to arrange any meetings with the lead Professor, which are usually by teleconference or videoconference but may occur in the course of meeting days. Additional discussions or email clarification may be necessary between the initial RMA meeting and

subsequent RMA meetings. The outcome of any discussion may be reflected in changes to the comparison table or a file note, depending on the circumstances.

78. In addition, the researcher may seek guidance from the PMO, Deputy Registrar, Principal Medical Researcher or the Registrar, as appropriate.

Interactions with outside sources

79. Occasionally the RMA may consider that expert advice is necessary to clarify a technical issue, or to seek current clinical opinion. The information request should be filed, as should any responses. A summary of the advice should be recorded in the main briefing paper.

Meeting and post-meeting procedures

Presentation of briefing papers at RMA meetings

80. The researcher and supervising Professor give a brief introduction which could include the following: reason for the investigation, plus any defining features of the condition that need to be highlighted (e.g., particular problems with the quality of the evidence, or issues with defining the condition or a major change in thinking about the nature or causes of the condition).

81. The researcher goes through the comparison table, starting with the definition, then current factors, then new factors, then factors that were investigated but not proposed. There is no need to discuss in detail the factors that are not changing. There is no need to read out the factor or go through the evidence in detail unless it is something you are seeking clarification about.

82. Factors “investigated but not proposed" are listed at the end of the table. You need not go through each factor, but you should highlight any contentious factors (e.g., factors which were reviewed as part of a request).

83. Look to the Chair to signal that the discussion of the factor/issue/SOP is complete or for any final directions.

Briefing papers

84. Briefing papers should be sent to the Deputy Registrar on the Monday which occurs two weeks before the RMA meeting is scheduled, to allow time for the material to be distributed and considered by all of the RMA members. An electronic version and the HPE Content Manager version of each document should be sent. Discussions with Professors should occur well before this deadline so that no late papers are presented.

85. Feedback from advisers on operational issues is usually received in the week before the RMA meeting and discussed by researchers as a group during that week. Each researcher should give consideration to the comments pertaining to his or her investigation prior to the researcher and RMA meetings. Following the view concluded at the researcher meeting, the Deputy Registrar will draw up a document incorporating the stakeholder view and the Secretariat's response for consideration by the Authority members. Further discussion with your lead Professor may be

required before the meeting if changes have been proposed following the discussion. The content of those discussions will inform what is included in the Deputy Registrar's document.

86. At the RMA meeting the relevant researcher is responsible for recording the decisions that have been taken with regard to a particular condition. The decisions are documented in the comparison table in a different coloured font, using the subheading “month meeting” to indicate the words that were agreed to, whether or not the factors are in RH only, RH and BOP or neither, and whether or not the factor is for both onset and worsening. If there are any changes to the factor or definition, then the whole factor and definition should be copied below the proposed factor. This makes clear the exact wording that has been approved. The templates for comparison tables provide the correct format for documenting meeting decisions (see container 1605769). Where a change to a proposed factor is significant or important, the reason should be documented in the table.

87. Normally the comparison table will only need to record one decision. If a factor is changed at multiple meetings, use a different coloured font to record the change for each meeting.

88. The final row of the post-meeting comparison table should state which factors or sub-parts of factors have been removed. If a factor has been removed but subsumed by another factor, then this should be stated. The post-meeting comparison table is sent to the Deputy Registrar for drafting the SOPs for that condition, which will appear at the next RMA meeting. The Deputy Registrar drafts the SOPs presented to the RMA meeting for second mention and approval by the Authority. These drafts are based on the updated comparison table. The responsible Medical Researcher will be asked to check and affirm that the draft is accurate in terms of words, doses, punctuation, differences between RH and BOP and use of onset and worsening factors.

89. The briefing paper and comparison table, should be updated and finalised and sent to the Deputy Registrar well before the meeting at which the draft SOPs are considered (ideally within a week of the meeting at which they were considered). If the grading of a factor has been changed at the direction of the RMA, the change should be reflected in the briefing papers. If a draft SOP has gone out for stakeholder consultation due to the removal of an existing factor, it is the Medical Researcher’s responsibility to ensure that the briefing papers and the amended comparison table are updated and provided to the Deputy Registrar well before the meeting at which the SOPs will be determined.

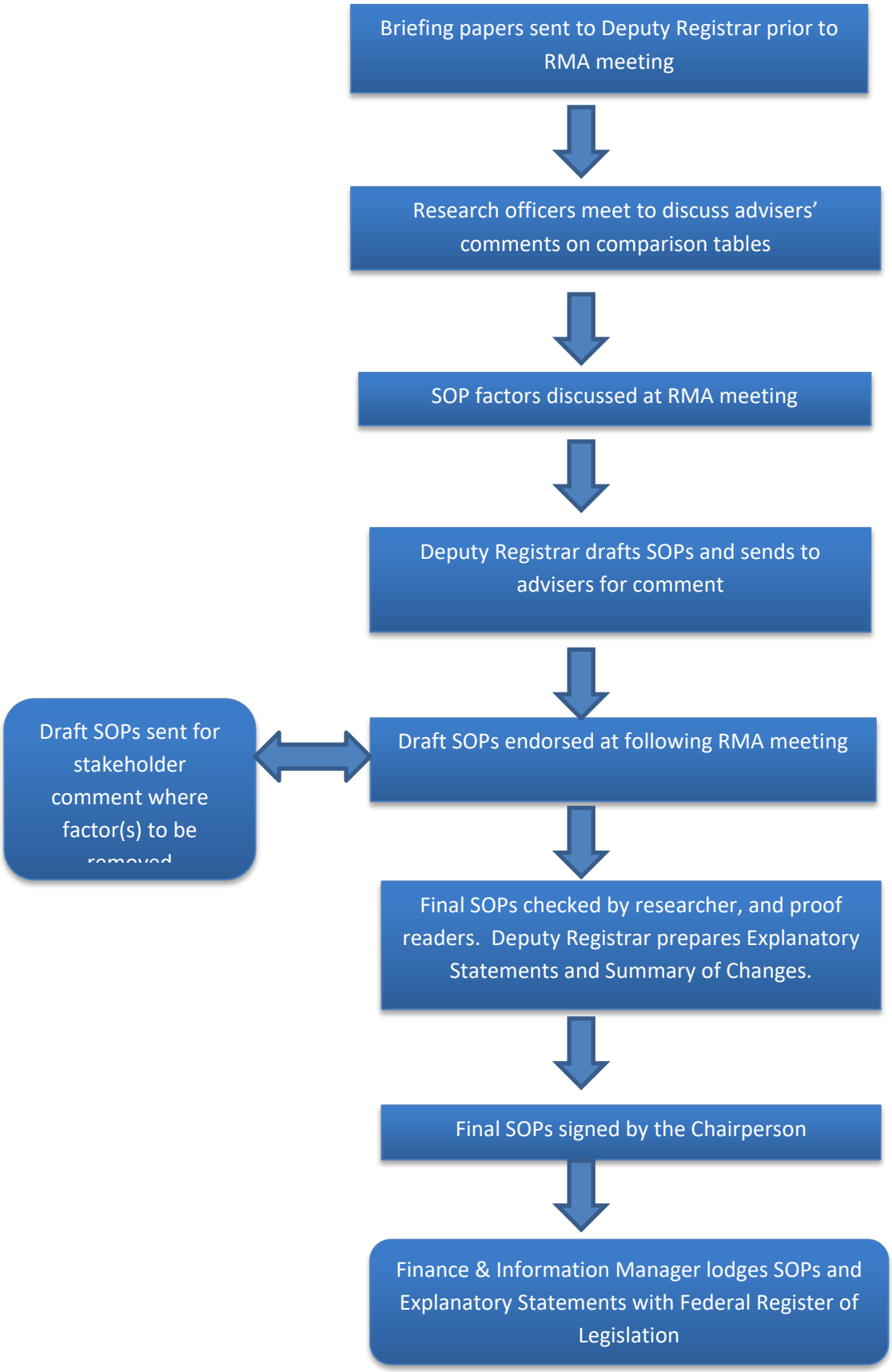
90. A separate bibliography should be prepared and stored in the appropriate HPE Content Manager container for that investigation. The administrative staff use the bibliography to check that all articles have been entered into the RMA database before preparing a reference list for that condition.

91. The finalised versions of the papers are available to the Authority members at the meeting at which the SOPs are determined by the RMA. For the purposes of reviews by the SMRC, the main briefing paper, the comparison table and, if completed, a summary of studies table comprise the information that was available to the RMA.

92. In preparing all documentation, researchers should be mindful that any document may potentially be subject to public scrutiny or may be the subject of legal consideration. It is important that the writing is of a high standard and that attention is paid to professional-looking formatting in the finalised documents, including correction of errors, removal of template prompts and unnecessary spaces, updating of footers, and inclusion of the bibliography. If an additional briefing paper has

been developed and presented subsequent to the main briefing paper, it must be incorporated into one finalised briefing paper.

Attachment 1 Flowchart for SOP processing procedures



Attachment 2 Glossary/Abbreviations

BOP	balance of probabilities
CI	confidence interval
DVA	Department of Veterans' Affairs
ESO	Ex-Service Organisation
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
OR	odds ratio
RH	reasonable hypothesis
RMA	Repatriation Medical Authority
RR	relative risk
SMRC	Specialist Medical Review Council
SMSE	sound medical-scientific evidence
SOP	Statement of Principles

Attachment 3 Standard wording for specified factors and definitions

There are standard forms of words for some factors and definitions. Over the course of the year these may change, so always check the standard definitions and standard factors documents (HPE Content Manager reference 1374904R and 1374905R) and the RMA website for the most recent version and the variations of factors that may exist.

1) Infectious disease SOPs and factors concerning infectious disease
2) Standard radiation factors
3) Genetic risk factors and genetic disorder SOPs
4) Smoking factors in SOPs
5) Obesity factors
6) Immunosuppression factors
7) Wording of transplantation factors and associated definitions in cancer SOPs
8) Chronic kidney disease and chronic renal failure
9) Dietary factors
10) Harmonisation of ingredient names
11) Drug factors and lists
12) Periods of one month
13) Generic exposure factors

1) Infectious disease SOPs and factors concerning infectious disease

Infectious disease SOPs

A standard approach for infectious disease SOPs was agreed at the February 2020 RMA meeting as listed below. The following recommendations are to be implemented for infectious diseases SOPs whenever a new SOP is created, or an existing SOP is revised. The recommendations do not apply to diseases which are defined as having an infectious aetiology but for which there is not a requirement in the definition to specify a particular organism, such as osteomyelitis.

There should be good documentation in the underlying Briefing Paper of the evidence and reasoning to support the inclusion of an additional clinical onset factor. The clinical worsening factors should be checked to ensure that they are not already covered by the generic inability to obtain appropriate clinical management factor.

1. The title of an infectious disease SOP should always include the term infection. For example, hepatitis A would become hepatitis A infection. An exception to this rule may occur when the infection is widely known by a commonly used name, such as malaria.
2. The definition of diseases specific to an organism should use one of two types of wording, in which x is the name of the organism:
    a) Means an infection caused by x; or
    b) Means an illness caused by infection with x, followed by the symptoms and signs which characterise the illness.

3. The definition should not require specific types of testing, unless there are particular reasons to do so.
4. Factors in infectious disease SOPs are one of four categories:
   (i) an exposure factor;
   (ii) a proxy for exposure;
   (iii) additional clinical onset factor;
   (iv) clinical worsening.

Factors concerning infectious disease

Infectious disease factors included in SOPs should generally follow the standard wording "having infection with", although there will be variations in latency/cessation periods, or if the factor refers to a particular circumstance or specified list. Examples are given below.

Standard infection factor:

having infection with y virus before [within the z days/weeks/months before] the clinical onset/worsening of *disease x*;

Example:

having infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) within the three months before the clinical onset of deep vein thrombosis;

Examples of varied wording of infectious disease factors included in SOPs:

having a *Streptococcus pyogenes* infection of the pharynx, tonsils or skin within the 30 days before the clinical onset of psoriasis;

having an infection from the specified list of infections before the clinical onset of spinal adhesive arachnoiditis;

Note: ***specified list of infections*** is defined in the Schedule 1 – Dictionary.

2) Standard radiation factors

Standing rules for radiation factors were agreed upon by the RMA in 2011 and modified at the October 2016 RMA meeting in respect of therapeutic radiation factors. Revisions to the definition of cumulative equivalent dose were accepted at the August 2017 RMA meeting. There is a set of rules for radiation factors in cancer SOPs and another set of rules for radiation factors in non-cancer SOPs.

Cancer SOPs

Solid cancer factor

having received a cumulative equivalent dose of at least 0.1 [BOP 0.5] sievert of ionising radiation to the [affected organ/region] at least 5 years [BOP 10 years] before the clinical onset of malignant neoplasm of the *organ/site*;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in *Guide to calculation of 'cumulative*

equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Part XIA of the Veterans' Entitlements Act 1986 (Cth), Australian Radiation Protection and Nuclear Safety Agency, as in force on 2 August 2017.

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

Leukaemia factor

having received a cumulative equivalent dose of at least 0.01 [BOP 0.05] sievert of ionising radiation to the bone marrow at least 1 year [BOP 2 years] before the clinical onset of *leukaemia x*;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

Non-cancer SOPs

Circulatory disease

Two factors, one quantitative and one qualitative:

having received a cumulative equivalent dose of at least 0.5 sievert [1 sievert BOP] of ionising radiation to the affected organ [latency] before the clinical onset/worsening of *disease x*;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

undergoing a course of therapeutic radiation for cancer, where the affected organ was in the field of radiation, [latency] before the clinical onset/worsening of *disease x*;

Non-circulatory disease

Only a qualitative factor, unless there is evidence for a quantitative factor as well:

undergoing a course of therapeutic radiation for cancer, where the affected organ was in the field of radiation, [latency] before the clinical onset/worsening of *disease x*;

Generally no latency period is required, on the grounds that effects could be prompt if an organ was directly exposed to high doses. However, if the mechanism was by fibrosis then a latency period of 1 to 2 years might be appropriate. Depending on the evidence for a particular condition, a longer latency period might be warranted.

3) Genetic risk factors and genetic disorder SOPs

It was agreed at the April 2011 RMA meeting that genetic risk factors would be included if they met the tests listed below. It was further agreed at the December 2012 RMA meeting that the below criteria would also apply to determining SOPs for genetic disorders.

(i) the condition would not preclude entry to service; and

(ii) the condition could be worsened by some service-related factor; or

(iii) the condition could be worsened by inability to obtain appropriate clinical management.

4) Smoking factors in SOPs

To maintain consistency of wording and doses in factors in cancer SOPs, the researcher should refer to the smoking relativities table (1374913R) and include the table with the briefing papers. When determining doses for new smoking factors, refer to doses in other factors in the table to ensure that dose relativities are consistent with other conditions with similar relative risks.

A consistent approach is taken to the assessment of cessation periods for smoking factors. Studies which assess cessation will report the number of years it takes for the relative risk to return to null, compared to never smokers. Where there is more than one study, there may be a category which is common to most studies. There is usually some uncertainty about number of years because of the size of the categories (which can range from 5 to 20 years).

In general:

(i) the cessation period for the BOP standard should reflect the majority of the evidence; and

(ii) the cessation period for the RH standard can be relaxed by five years in most cases (possibly ten years in some cases), to allow for uncertainty in the data.

The standard smoking factor in all SOPs should include the dose, and where the evidence is available, should also include a latency period and a cessation period. The dose may be expressed in pack-years or cigarettes per day or the equivalent thereof in other tobacco products. Additional wording may be added with regard to whether the person is a current smoker.

Examples of smoking factors and associated definitions as finalised in April 2021 are given below.

Example of standard smoking factor with dose expressed as pack-years:

having smoked at least y pack-years of tobacco products before the clinical onset/worsening of *disease x*;

having smoked tobacco products:

(a) in an amount of at least x pack-years before the clinical onset/worsening of *disease x*; and
(b) commencing at least y years before the clinical onset/worsening of *disease x*; and

if smoking has ceased before the clinical onset/worsening of *disease x*, then that onset/worsening occurred within z years of cessation;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

one pack-year means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

Example including dose expressed as cigarettes per day:

having smoked tobacco products:

(a) in an amount of at least 10 cigarettes per day or the equivalent thereof in other tobacco products; and
(b) commencing at least y years before the clinical onset/worsening of *disease x*; and

if smoking has ceased before the clinical onset/worsening of *disease x*, then that onset/worsening occurred within z years of cessation;

Note: ***cigarettes per day or the equivalent thereof in other tobacco products*** is defined in the Schedule 1 - Dictionary.

cigarettes per day or the equivalent thereof in other tobacco products means:

(a) cigarettes, pipe tobacco or cigars, alone or in any combination; and
(b) 1 gram of cigar, pipe or other smoking tobacco (including roll your own smoking tobacco) is equivalent to one tailor made cigarette.

5) Obesity factors

Cancer SOPs

It was agreed at the October 2014 RMA meeting that a standard form of words be used for obesity factors in cancer SOPs, unless the evidence suggests otherwise. An overweight factor might be considered if there is strong evidence to suggest effects at this level. Waist circumference can be added to the definition of being overweight or obese if the evidence supports it.

being obese for at least five years [ten years BOP] within the 20 years before the clinical onset of malignant neoplasm of the *organ/site*;

Note: ***being obese*** is defined in the Schedule 1 – Dictionary.

being obese means having a Body Mass Index (BMI) of 30 or greater.

Note: ***BMI*** is also defined in the Schedule 1 - Dictionary.

BMI means W/H^2 where:

(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

Non-cancer SOPs

It was agreed at the February 2015 RMA meeting that a standard form of words be used for obesity factors in non-cancer SOPs, unless the evidence suggests otherwise.

It was also agreed that the definition of being obese or overweight should be amended to remove reference to "an increase in body weight by way of fat accumulation. Any latency periods should reflect the evidence. Waist circumference can be added to the definition of being overweight or obese if the evidence supports it.

<u>For factors where mechanical effects are likely to be the predominant mechanism</u>:
being obese at the time of the clinical onset of *condition y*;

Note: ***being obese*** is defined in the Schedule 1 – Dictionary.

<u>For factors where systemic effects are likely to be the predominant mechanism</u>:
being obese for at least 5 years [no difference RH and BOP] within the x years before the clinical onset of *condition y*;

Note: ***being obese*** is defined in the Schedule 1 – Dictionary.

Definition of being obese

For all obesity factors, the definition of being obese is as below. Waist circumference may be added to the definition of being obese if the evidence supports it.

being obese means having a Body Mass Index (BMI) of 30 or greater.

Note: ***BMI*** is also defined in the Schedule 1 - Dictionary.

BMI means W/H^2 where:

(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

6) *Immunosuppression factors*

The following factor and definitions were adopted at the December 2014 RMA meeting and modified slightly at the February 2015 RMA meeting. They should be used unless the evidence suggests a different wording.

being in an immunocompromised state as specified at the time of the clinical onset/worsening of *disease x*;

immunocompromised state as specified means a condition of substantially lowered immune function, such as would occur in the following conditions or circumstances:

(a) having a haematological or solid organ malignancy;
(b) having chronic renal failure;
(c) having infection with human immunodeficiency virus;
(d) having severe malnutrition;
(e) taking an immunosuppressive drug; or
(f) undergoing solid organ, stem cell or bone marrow transplantation.

Note: ***chronic renal failure*** and ***immunosuppressive drug*** are also defined in the Schedule 1 - Dictionary.

immunosuppressive drug means a drug or an agent which results in substantial suppression of immune responses.

Note: Examples of an immunosuppressive drug include:

(a) chemotherapeutic agents used for the treatment of cancer;
(b) corticosteroids, other than inhaled or topical corticosteroids;
(c) drugs used to prevent transplant rejection; and
(d) tumour necrosis factor-α inhibitors.

chronic renal failure means (see updated definition below).

7) *Wording of transplantation factors and associated definitions in cancer SOPs*

The RMA agreed at its February 2020 meeting to adopt a generic transplantation factor and definition in cancer SOPs.

Transplantation factors in cancer SOPs should include the explicit mention of the use of immunosuppressive drugs if there is evidence that immunosuppression is the main mechanism. For example:

taking an immunosuppressive drug for organ or tissue transplantation before the clinical onset of malignant neoplasm of the *organ/site*;

Note: ***organ or tissue transplantation*** and ***taking an immunosuppressive drug*** are defined in the Schedule 1 – Dictionary.

organ or tissue transplantation means the transplantation of:

(a) all or part of an organ or tissue; or
(b) a substance obtained from an organ or tissue.

The definition of taking an immunosuppressive drug (whether or not the drugs are being used in relation to transplantation) should include temporal duration, proximity and latency, provided the relevant data can be obtained from the sound medical-scientific literature. Where this information is available, the preferred format would be as follows:

taking an immunosuppressive drug means taking a drug or agent which results in substantial suppression of immune responses:

(a) for a cumulative period of least x months [duration] before the clinical onset of malignant neoplasm of the *organ/site*; and
(b) where the first treatment occurred at least y months before [latency] the clinical onset of malignant neoplasm of the *organ/site*; and
(c) if that exposure has ceased before the clinical onset of malignant neoplasm of *organ/site*, then that onset occurred within z years of cessation [proximity].

Note: Examples of an immunosuppressive drug include:

(a) chemotherapeutic agents used for the treatment of cancer;
(b) corticosteroids, other than inhaled or topical corticosteroids;
(c) drugs used to prevent transplant rejection; and
(d) tumour necrosis factor-α inhibitors.

In any event these three issues should be specifically addressed in the Briefing Paper.

Where immunosuppression is not the main mechanism, the transplantation factor should be worded as follows:

undergoing organ or tissue transplantation, excluding corneal transplant, before the clinical onset of malignant neoplasm of the organ/site;

Note: ***organ or tissue transplantation*** is defined in the Schedule 1 – Dictionary.

organ or tissue transplantation means the transplantation of:

(a) all or part of an organ or tissue; or
(b) a substance obtained from an organ or tissue.

8) Chronic kidney disease and chronic renal failure

The RMA agreed to adopt standard factors and definitions in future SOPs at its February 2016 meeting. The factor and definition of chronic kidney disease will progressively replace current factors for chronic renal failure. The factor and definition of chronic renal failure will progressively replace current factors for end-stage renal disease.

At its meeting in December 2021, the RMA revised the factor and definition concerning chronic kidney disease.

Chronic kidney disease

having chronic kidney disease at the time of the clinical onset of *disease x*;

chronic kidney disease means:

(a) having a glomerular filtration rate of less than 60 mL/min/1.73 m^2 for at least 3 months; or
(b) having albuminuria for at least 3 months; or
(c) having kidney damage, as evidenced by renal biopsy, imaging studies, urinary sediment abnormalities or other markers of abnormal renal function; or
(d) having had a kidney transplant.

Note: ***albuminuria*** is also defined in the Schedule 1 - Dictionary.

albuminuria means an albumin to creatinine ratio of at least 3 milligrams/millimole.

Chronic renal failure

having chronic renal failure at the time of the clinical onset of disease x;

Note: ***chronic renal failure*** is defined in the Schedule 1 - Dictionary.

chronic renal failure means:

(a) having a glomerular filtration rate of less than 15 mL/min/1.73 m^2 for a period of at least 3 months; or
(b) a need for renal replacement therapy (dialysis or transplantation) for treatment of complications of decreased glomerular filtration rate which would otherwise increase the risk of morbidity and mortality; or
(c) undergoing chronic dialysis.

9) Dietary factors

The RMA agreed to adopt standard wording for dietary factors at its February 2016 meeting.

For protective factors:

an inability to consume an average of at least x grams per day of any combination of fruit and vegetables, for at least 5 consecutive years within the 20 years before the clinical onset of *disease x*;

For risk factors:

consuming an average of at least x grams per day of processed meat product, for at least 5 consecutive years within the 20 years before the clinical onset of *disease x*;

10) Harmonisation of ingredient names

From April 2016 the Therapeutics Goods Administration (TGA) will be updating some medicine ingredient names used in Australia to align with names used internationally. The RMA is adopting the same policy for drug factors, to be applied progressively to SOPs from April 2016. A list of affected ingredients is available on the TGA website at https://www.tga.gov.au/updating-medicine-ingredient-names-list-affected-ingredients

11) Drug factors and lists

At its April 2018 meeting, the RMA agreed that in situations where there is uncertainty about inclusion of a drug as a possible or probable cause of the disease under investigation, the following criteria will be applied.

Basic criteria (first 3 plus 4 or 5) for limited association (RH)

(1) Plausible/reasonable temporal association- onset precedes effect within reasonable time frame for that particular drug-disease association; and
(2) Dechallenge - recovery occurs on drug cessation; and
(3) At least two independent reports (where no additional criteria are met); and
(4) Other aetiologies possible but not likely (e.g., other diseases or other drugs); or
(5) Plausible biological mechanism.

Additional criteria (one or more) for suggestive or convincing association (RH and BOP)

(6) Rechallenge - response recurs on repeat administration (may be to the same drug or the same class of drug).
(7) Recovery on administration of an antagonist (e.g., anticholinergics after organophosphate poisoning).
(8) Proven biological mechanism in that patient (e.g., drug dependent antibodies, positive hypersensitivity testing).
(9) A significant association is demonstrated in adequately powered epidemiological studies or randomised controlled trials.
(10) Other aetiologies excluded or highly unlikely.
(11) Characteristics of the patient are linked to the metabolism of the drug (e.g., presence of a relevant genetic polymorphism, renal or liver impairment).
(12) Dose-response effect (not always present, there may be a threshold for toxicity or an idiosyncratic reaction).
(13) Commonality of reports across different reviews (unless there is an indication of perpetuation of single case reports or the reviews are based on loose criteria).
(14) A large number (usually at least 10) of independent reports.
(15) The drug is not common and the effect is not common (so that the association is less likely to be coincidental).
(16) Length of time the drug has been on the market - all but rare adverse effects are likely to be known for older drugs, previously unreported effects may plausibly occur for newer drugs once they are marketed to a wider population.
(17) The drug is in the same class as a drug which has a probable association.

At the February 2020 RMA meeting, it was agreed that drugs should be listed separately in drug lists, unless there is evidence that the entire class of drugs is causally associated with the condition under investigation. Generally, three examples of common drugs used within a class may be included following the class name.

All drug factors should start with “taking a drug”, along with the relevant time frames, with no requirement to mention 'class of drugs' if these are included in the list. The drugs, either classes or individual drugs, are included in a specified list of drugs. There is also a standard generic drug factor for idiosyncratic drug reactions, although there are variations depending on the particular condition. Examples are given below.

taking a drug from the specified list of drugs within the y days before the clinical onset/worsening of *disease x*;

Note: ***specified list of drugs*** is defined in the Schedule 1 – Dictionary.

specified list of drugs means:

(a) alpha-adrenoceptor agonists;
(b) alprazolam;
(c) amantadine;
(d) amphetamines including methamphetamine and 3,4-methylenedioxymethamphetamine; or
(e) anabolic-androgenic steroids.

Generic drug factor

taking a drug which is associated in the individual with the development/worsening of *disease x* during drug therapy and either:

(a) the improvement of disease x within y months of discontinuing or tapering drug therapy; or
(b) the redevelopment/worsening of *disease x* on rechallenge with the same drug; and

where taking the drug continued for at least the z days before the clinical onset/worsening of *disease x*;

Where drug lists are long (> 20), a table of drugs will be formatted during the drafting process and included in a Schedule 2 – Drugs.

12) Periods of one month

A standard way to express periods of one month was agreed at the June 2015 RMA meeting. Where duration of exposure is concerned, the factor should be expressed as 4 weeks. Where the exposure must have occurred within a certain time period, the factor should be expressed as 30 days. Examples are given below:

living or working in a hostile or life-threatening environment for a period of at least 4 weeks before the clinical onset of posttraumatic stress disorder;

having a cerebrovascular accident involving the brainstem within the 30 days before the clinical onset of trigeminal neuropathy;

13) Generic exposure factors

With the refinement of the smoking factors in 2021, the wording of factors for other exposures (e.g., chemical agents) should be expressed and formatted in the same way where there is evidence for dose, and latency with or without cessation. Examples are given below:

inhaling, ingesting or having cutaneous contact with *chemical agent:*

(a) for a cumulative period of at least x hours, within a consecutive period of y years before the clinical onset/worsening of *disease x*; and
(b) commencing at least z years before the clinical onset/worsening of *disease x; and*

if that exposure has ceased before the clinical onset/worsening of *disease x*, then that onset/worsening occurred within x years of cessation;

<u>If no cessation period</u>

inhaling, ingesting or having cutaneous contact with a chemical agent,

(a) for a cumulative period of at least x hours, within a consecutive period of x years, before the clinical onset/worsening of *disease x*; and
(b) commencing at least x years before the clinical onset/worsening of *disease x*;

APPENDIX 7

The concept of 'beneficial legislation' and the RMA

Veterans' Entitlements Act 1986 as "beneficial legislation"

1. The *Veterans' Entitlements Act 1986* (VEA) establishes a scheme whereby the Commonwealth of Australia is liable to pay pensions, benefits or allowances to veterans who have eligible service and have suffered an injury or a disease as a result of that service.

2. It has long been acknowledged that the VEA and its predecessors are beneficial legislation. Effectively, this is a term used to refer to legislation which gives some benefit to a person and thereby remedies some perceived injustice. As well as veterans legislation, the commonly cited examples are social welfare and pension legislation, Workers Compensation Acts and the like.

What is the concept of "beneficial legislation"?

3. This is a concept that assists the interpretation of legislation which gives some benefit to a person and thereby remedies some perceived injustice.

4. The relevant principle can be summarised thus:

> *If legislation is beneficial in nature and its provisions are ambiguous or alternative interpretations of relevant provisions are suggested, the interpretation which gives force to the relief sought as the object of the legislation or provisions, consistent with the subject matter and the fair meaning of the language of the provisions, is the one which will be adopted by the Courts.*[30]

5. The operation of this principle should be understood against the background of the general principles governing statutory interpretation.

6. Firstly, the operation of this principle does not mean:

> *that the true signification of the provision should be strained or exceeded, but that it should be construed so as to give the fullest relief which the fair meaning of its language will allow.*[31]

7. In particular, while beneficial construction has regard to the purpose of the statute:

> *When the express words of a legislative provision are reasonably capable of only one construction and neither the purpose of the provision nor any other provision in the legislation throws doubt on that construction, a court cannot ignore it and substitute a different construction because it furthers the objects of the legislation.*[32]

8. Secondly, the characterisation of legislation as beneficial does not mean that every provision or amendment affected will be construed beneficially. It is the purpose of the provision in the context of the legislation itself that will govern the interpretation. There is no mechanical process where any interpretation consistent with this purpose is adopted.[33]

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[30] *Bull v Attorney-General (NSW)* (1913) 17 CLR 370.
[31] Ibid at page 384.
[32] *Newcastle City Council v GIO General Ltd* (1997) 191 CLR 85.
[33] *ADCO Constructions Pty Limited v Goudappel* [2014] HCA 18.

9. A good example of the application of this concept is found in *Re Baverstock and Repatriation Commission*[34], where a Veteran who had defence service as a marine technician and radio operator had duties including aerial maintenance, chipping and painting, replacing equipment and re-assembling sleeping quarters, and was exposed to asbestos fibres in dust, in that during some period of service he was on vessels which were fitted with steam pipes insulated with asbestos which deteriorated due to the ships vibration and ordinary use.

10. At that time, the Statement of Principles for his disease Adenocarcinoma of the kidney (Instrument No. 88 of 2001) provided that factor 5(b):

> *inhaling respirable asbestos fibres for a cumulative period of at least 2000 hours: at the time material containing asbestos fibres was being applied, removed, dislodged, cut or drilled.*

11. In the circumstances, the issue for the Tribunal was whether, "dislodged" could contemplate the circumstances of the veteran's service. There is a syntactical presumption applicable, *noscitur a sociis*, a thing is known by its associates, which in its ordinary operation would limit the meaning of "dislodge" to "shift position of", implying some direct human action on the subject matter.

12. Here, the Tribunal applying the principle of beneficial legislation to the Statement of Principles, it being a legislative instrument and subject to the cannons of statutory interpretation including this principle, found that "dislodge" could comprehend the situation where the position of steam pipes shifted through vibration or ordinary human use. This allowed the Veteran to access the benefit of the factor and the relevant presumption in the cause of his disease.

13. This accords with the approach to statutory interpretation outlined by the High Court in *Project Blue Sky v Australian Broadcasting Authority*[35].

"Beneficial Legislation" and Part XIA VEA

14. The VEA is "beneficial legislation" and is intended to be generous. This is seen in the legislative tests for the inclusion of factors set out in Part XIA of the VEA, which permit factors at standards of proof lower than those that might be considered appropriate in clinical and other public health settings.

15. The operation of those legislative tests and their beneficial nature is reflected in the approach adopted by the RMA outlined in the policy document, "*How the Repatriation Medical Authority Interprets and Applies the two Standards of Proof*".

16. However, the principle of "beneficial legislation" does not affect the operation of the statutory processes governing the operation of the RMA.

17. This has the following import. Firstly, the statute requires that the RMA must make a decision anterior to the conduct of an investigation that there is a particular kind of disease that can be the subject matter of such an investigation.

18. While a request under s 196E of the VEA, is not to be disregarded if veterans or their advisors inadequately or incorrectly describe diseases, the RMA must form a view that there is a disease of a particular kind as a first step in the discharge of its investigative functions. Secondly, the procedures adopted by the RMA do not apply the beneficial purpose outlined in the legislative tests to "give the benefit of the doubt" to evidence which does not meet the statutory criteria.

19. Section 196C of the VEA provides that:

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[34] (2008) AATA 467
[35] (1998) 194 CLR 355

(3) In forming any view during the investigation the Authority

(a) may rely only on sound medical-scientific evidence. and

(b) must consider and evaluate all the evidence so made available to it.

20. Whilst the RMA is an expert body and utilises its knowledge and clinical experience in the application of the statutory tests for factors in the various Statements of Principles, the insertion of particular factors arises from the beneficial nature of the legislative provisions, not because of the application or the concept of "beneficial legislation".

APPENDIX 8

How the Specialist Medical Review Council operates

Applications for Review

1. A valid application made by an eligible person or organisation as defined in s196Y of the VEA is the trigger for an SMRC review.

2. Under s196Y of the VEA the SMRC can review on request:

   - some or all of the contents of a SOP in force under Part XIA; or
   - a decision of the RMA not to amend a SOP in respect of a particular kind of injury, disease or death, or not to make a SOP in respect of a particular kind of injury, disease or death under subsection s196B(2) or (3).

3. Under s196Z of the VEA, the SMRC can review a decision by the RMA not to carry out an investigation.

Review Councils

4. The VEA sets out some procedural requirements, including that:

   - each Review Council is made up of three to five Councillors;
   - the Convener or Presiding Councillor may convene meetings of the Review Council as is considered necessary;
   - questions are decided by a majority of the votes of Councillors; and
   - the SMRC must keep minutes of each meeting

5. Apart from these specified matters, each Review Council determines its procedures for convening meetings and conducting its business within general guidelines.

The Information subject to review

6. This 'available' information is that information that was in fact used by the RMA. It does not include information that may have been available for the use of the RMA at the time but was not accessed by the RMA.

7. Eligible persons and organisations are entitled to reasonable access to the information that was available to the RMA in its determination of a SOP.[36] Lists of information obtained by the RMA in the course of an investigation or review are routinely provided to eligible persons and organisations on request.

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[36] s196I of the VEA

8. The available information is made available to Councillors and parties to a review through an on-line repository called FILEForce.

New Information

9. 'New information' is information the RMA advises was not available to it when it made the decision under review. This may include relevant information published before or after the date that the RMA determined the SOPs under review, including during the time the SMRC undertakes the review.

10. Generally people seeking a SMRC review because of such new information are referred to the RMA in the first instance.

11. In appropriate circumstances, the SMRC can consider new information for the different purpose of deciding whether there seems to be SMSE not previously considered by the RMA, which might justify a recommendation to the RMA that it conduct a fresh investigation into the injury, disease or death, considering the new information.

Submissions

12. The Council must publish in the Australian Government Gazette a notice of its intention to carry out a review. That notice specifies the date by which all submissions must be received.

13. Eligible persons and organisations may make a written submission to the SMRC. A person having expertise in a field relevant to the review may also make a written submission.

14. The SMRC asks that written submissions refer to the information that was available to the RMA, and which is relevant to the review, rather than an individual case.

15. An eligible individual or organisation making written submissions may appear before the SMRC to make an oral submission complementing their written submission.

16. Guidelines for making written submissions are available on the SMRC website.

SMRC tasks

17. Having considered 'the information' subject to review, the Applicant's contentions and any submissions, the Review Council:

- forms a view on the scope of the review, i.e., whether any factors, in addition to that contended by the applicant, should be considered in the review. These can be factors already in the SOPs (which the Council may want to consider amending or excising), or the inclusion of new factors;

- evaluates the 'information' to decide those factors the Council has decided as a minimum exist connecting the injury / disease / death (condition) to service.

Decisions available to the SMRC

18. The decision for the SMRC is whether the available information (the sound medical-scientific evidence (SMSE) available to the RMA at the time of its decision) justifies the making of a SOP or an

amendment to the SOP under review, by applying the relevant legal tests of reasonable hypothesis and balance of probabilities.

19. Whatever the outcome of the review, the SMRC cannot itself make or amend SOPs.

20. If the SMRC is of the view that there is SMSE on which the RMA could have relied to amend one or both of the SOPs, by amending, adding or deleting a factor or factors it may:

- direct the RMA to amend the SOPs to insert such a factor(s) or otherwise amend the SOPs in accordance with directions given by the SMRC; or
- remit the matter to the RMA for reconsideration in accordance with any directions or recommendations the SMRC may make.

21. If the SMRC is of the view that there is:

- no SMSE justifying an amendment; or
- that the SMSE is insufficient to justify an amendment;

the SMRC may make any recommendation that it considers should be taken into account by the RMA in any future investigation.

22. If the SMRC is reviewing a decision of the RMA not to determine a SOP, it can determine whether the available SMSE justifies making a SOP concerning the particular kind of disease, injury or death.

23. If the SMRC is reviewing a decision of the RMA not to not to carry out an investigation under s196C(4), it can, under s196Z, determine whether there appears to be a new body of SMSE, not previously considered by the RMA, that with the SMSE that was available to the RMA, could justify making or amending a SOP.

24. If the SMRC is of the view that the new and available SMSE justifies making or amending a SOP it can:

- direct the RMA to carry out an investigation; and
- make any recommendation that it considers fit.

Recording decisions

25. The SMRC is required to give reasons for its decisions. The SMRC makes a Declaration and Statement of Reasons setting out its evaluation and decisions. The declarations are published in the Australian Government Gazette.[37]

26. The RMA is not required to give reasons for its determination of a SOP and does not do so. A brief summary is included in correspondence to applicants who have requested an investigation or review, or lodged a submission, where a decision is made not to include a factor sought.

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[37] s196W(4) of VEA.

Role of Convener and Presiding Councillors on Reviews

27. The Convener is appointed by the Minister, oversees the operations of the SMRC, and presides at all meetings of a Review Council constituted for the purposes of a review.

28. When the Convener is not available to preside over a new review, he can appoint a presiding councillor to manage the functions for the term of that specific review.

29. During reviews, the Convener or the Presiding Councillors will be required to:

- participate in the selection of councillors for the review over which they will preside;
- work with the secretariat on preparing for the review, including liaison with the Australian Government Solicitor Legal Adviser as required;
- preside at all meetings of an SMRC Review Council constituted for the purposes of a review;
- provide guidance and counsel to members; and
- provide continuity and guidance that is necessary for the SMRC to ensure consistency of decision-making.

SMRC and the management of reviews

30. Role of the Convener (if not presiding):

31. The Convener is available for support and advice and values feedback from Presiding Councillors. The Convenor reviews drafts of decisions before sign off by each Council.

Role of the SMRC Secretariat

32. SMRC Secretariat staff are employees of the Department of Veterans' Affairs, made available to the SMRC. They:

- provide support and guidance on all administrative matters, and offer advice and any cautions where necessary;
- manage all correspondence and are responsible for all liaison with applicants, the Commissions and anyone making submissions;
- liaise with the RMA about the available information and other review related matters; and
- manage the contracts with the Legal Adviser, FILEForce and contracted medical science writers.

33. The Secretariat will engage in detailed discussion with the Presiding Councillors about the application, any risks/issues, timeframes, and councillors/composition of council.

34. This early meeting will be an opportunity for the Presiding Councillor and staff to discuss working arrangements.

Role of Medical Science Writer

35. The SMRC is now working with contracted medical science writers on all reviews.

36. It engages with contractors who have a background in health or medical sciences and qualifications in epidemiology.

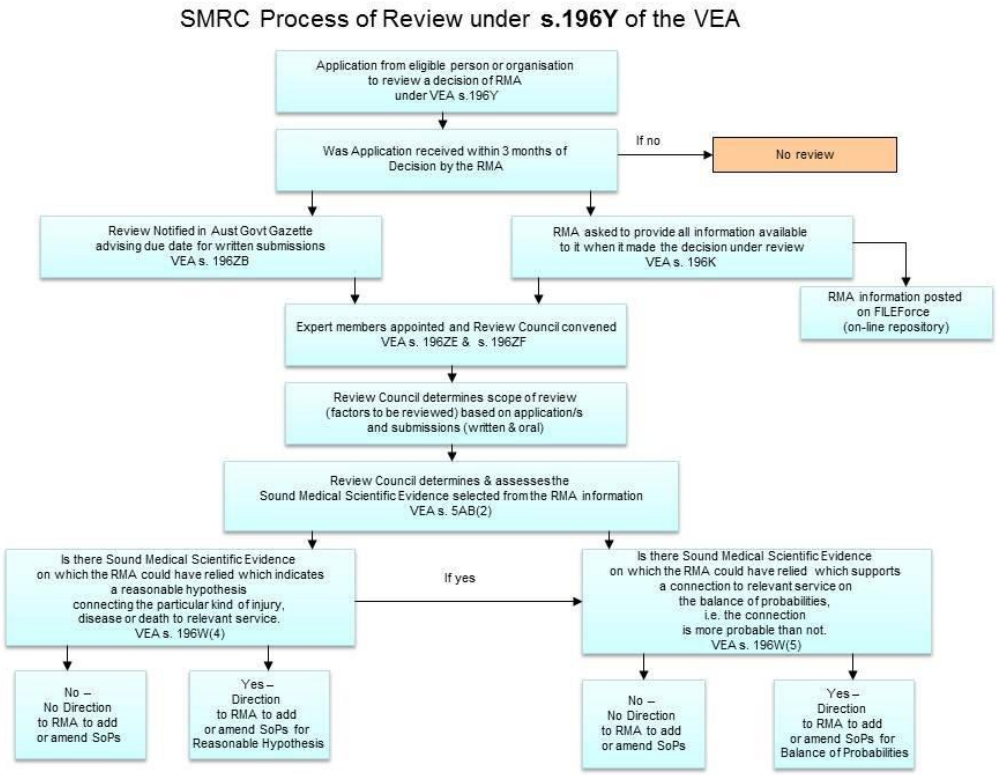
Selection of councillors

37. The composition of the Review Council will depend on the issues relevant to the particular SOPs or factor under review.

Meetings of Council

38. Each review council should determine the number and length of meetings.

39. There are usually three to four meetings in all. Apart from the hearing of oral submissions, which is held face-to-face, all other meetings are held by teleconference (no longer than two hours).



SMRC Process of Review under **s.196Z** of the VEA