Australian Government
Repatriation Medical Authority

PRODUCTIVITY COMMISSION

Compensation and Rehabilitation for Veterans

Inquiry into Veterans' Affairs Legislative Framework and Supporting Architecture for Veterans (Serving and Ex-serving Australian Defence Force Members)

Further Submission of the
Repatriation Medical Authority

April 2019

Introduction

The Productivity Commission produced an interim report *A Better Way to Support Veterans* on 13 December 2019 ("Interim Report"). A submission prepared by the Repatriation Medical Authority (RMA) including advice on the background and methods of developing Statements of Principles (SoPs), as well as addressing a number of the specific issues relating to SoPs, was provided to the Productivity Commission on 2 July 2018.

This further submission has been prepared by the RMA following advice from the Productivity Commission that the current inquiry would be assisted by the RMA addressing the following three issues:

a) Standard of proof;

b) RMA conducting or funding research; and

c) Internal review of decisions.

(a) Standard of Proof

The Interim report raised three issues associated with the standard of proof.

- The desirability of a single standard of proof.
- An alternative standard of proof.
- The proposal in the Interim Report of a quantifiable minimum probability for a factor being causally related to a condition.

Single Standard of proof

There are 696 principal SoPs for 348 injuries or diseases which have been determined by the RMA under section 196B of the *Veterans' Entitlements Act 1986* (VEA) and are currently in force.

Under its current methodology the RMA could operationalise a single standard of proof for determination of factors in its SoPs. If a two tier system was to operate while the Veterans support system was migrating to a single standard of proof, the RMA could also accommodate that outcome.

Pursuant to section 50 of the *Legislation Act 2003* (Legislation Act) a SoP is automatically repealed on 1 April or 1 October falling on or after the tenth anniversary of its registration. SoPs are therefore generally reviewed commencing around the seventh year after registration, to allow adequate time to produce an updated version. If a single standard of proof other than one of the two existing standards was to be adopted, then with current resources that change would only be fully integrated into the SoPs between seven (7) and ten (10) years after that change was in effect.

In addition, in the period prior to Legislation Act review, a 'focussed investigation' may be conducted either at the request of a person or organisation eligible under

section 196E of the VEA[1] or by the RMA on its own initiative[2]. Such a review may result in the amendment of the existing SoPs.[3] The RMA's ability to implement a new single standard in a timely manner would also be impacted by the number of focused investigations which are required in addition to the regular revision of the existing SoPs.

Alternative standard of proof

Under the current system, the RMA can include factors in the reasonable hypothesis SoP based on more limited sound medical scientific evidence (SMSE) than is required for a factor to be included in the balance of probabilities SoP. This provides potential additional benefits to members and veterans whose service qualifies them to be considered under the reasonable hypothesis SoP.

The Interim Report suggests that it might be appropriate to seek to frame an alternative standard of proof, perhaps "a middle ground", between the statutory test in s 196B(2) of the VEA which is directed to satisfaction about the existence of a connection between the disease and relevant service as a matter of reasonable possibility, and s 196B(3) of the VEA which requires a connection between the disease and relevant service to exist on the balance of probabilities.

One of the difficulties in framing such a test lies in the fact that "in English law there never were more than two standards of persuasion"[4], the criminal standard of beyond reasonable doubt and the civil standard of balance of probabilities, the reasonable hypothesis standard in s 196B(2) merely being the obverse of the criminal standard.

As well, the inherent difficulties in framing a coherent "middle ground" test draw attention to the legal risks associated with any change.

The provisions of the VEA providing the tests for inclusion of a factor in either SoPs mean that there is "an area of decisional freedom"[5] for the RMA, within which minds might differ. The width and boundaries of that freedom are generally seen as framed by the nature and character of the decision and the terms of the relevant statute operating in the factual and legal context of the decision. Here, the terms of the statute provide for an expert body, comprising the RMA members, to assess the SMSE in accordance with professionally accepted criteria, a process with an inherently wide area of decisional freedom.

This consideration needs be kept in mind in any revision of the statutory standards. There is a public interest in maintaining a predictable and responsive system of SoPs and ensuring claimants and decision makers have a clear understanding of their ensuing rights and entitlements. This necessitates a statutory test for the

[1] Section 196E enables any veteran, serving member or the organisations representing them or the Repatriation Commission or the Military Rehabilitation and Compensation Commission to request review of "some or all of the contents" of a SoP.

[2] Section 196B(7).

[3] In 2017-18 there were fifteen focussed reviews concluded.

[4] *Murray v Murray* (1960) 33 ALJR 521 per Dixon CJ at 524.

[5] See *Minister for Immigration and Citizenship v Li* [2013] HCA 18.

inclusion of factors that, as present, provides due regard to the professional nature of the RMA and a large area of "decisional freedom" for it.

In seeking to simplify the standards of proof an analysis would need to be undertaken about the risk of associated Court challenges and the effect of uncertainty until resolution. In short, given the experience of the RMA, a "middle ground" approach may enlarge, not reduce, the potential for different interpretations of the statutory requirements and make any determination of factors (including dose) potentially contingent on challenge with ensuing uncertainty in the compensation system.

Quantifiable minimum probability

In seeking a "middle ground" approach the Interim Report suggests

> *Legislating a specific number to represent the minimum probability for a factor being causally related to a condition ...* [page 341]

In drafting the SoP factors connecting an injury, disease or death of that kind with the circumstances of service, the RMA may rely only on SMSE: s 196C VEA. That SMSE includes information about the causes of an injury, disease or death which "meets the applicable criteria for assessing causation currently applied in the field of epidemiology": s 5A VEA.

The field of epidemiology and its application to issues of causation was described in the United Kingdom Supreme Court in *Sienkiewicz v Greif (UK) Ltd*[6] as follows

> *Epidemiology is the study of the occurrence and distribution of events (such as disease) over human populations. It seeks to determine whether statistical associations between these events and supposed determinants can be demonstrated. Whether those associations if proved demonstrate an underlying biological causal relationship is a further and different question from the question of statistical association on which the epidemiology is initially engaged.*
>
> *Epidemiology may be used in an attempt to establish different matters in relation to a disease. It may help to establish what agents are capable of causing a disease, for instance that both cigarette smoke and asbestos dust are capable of causing lung cancer, it may help to establish which agent, or which source of an agent, was the cause, or it may help to establish whether or not one agent combined with another in causing the disease.* [per Lord Phillips at 551]

In this respect, the RMA's Practices and Procedures document[7] states

> *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*

[6] [2011] 2 WLR 523, [2011] UKSC 10.

[7] See http://www.rma.gov.au/assets/FOI/80cce17817/The-RMA-practices-and-procedures-document.pdf at paragraph 30, (referenced at page 683 of the Interim Report).

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.

Here, if regard is had to these standard epidemiological criteria and the nature of the SMSE available to the RMA, it appears clear that the adoption of a legislative standard requiring a minimum level of probability would have two results:

- It would, for many potential factors, be seriously inconsistent with the use of standard epidemiological criteria.
- It would result in a substantial reduction of the number of factors in the 696 principal SoPs currently in force.

(i) Standard epidemiological criteria

The use of standard epidemiological criteria such as the Bradford Hill criteria to assess causation would be inconsistent with adoption of a quantitative standard.[8]

There are nine (9) criteria under the Bradford Hill formulation, including several which have quantitative aspects. The criteria are used collectively to reach a decision about causation, in a manner that is not quantitative. Indeed, and importantly for the determination of SoPs, the likelihood of a particular factor being adopted can be strengthened by meeting qualitative criteria in the formulation, even when the quantitative criteria are met only weakly or indeed not at all by available SMSE. Furthermore, for many factors, the available SMSE does not allow for the estimation of the probability of causation, as noted in more detail below. Therefore if a minimum level of probability standard were to be mandated, there would need to be an amendment to the statutory requirement to use epidemiological criteria as the basis for determining the level.

The effect of the current position was helpfully summarised by Chief Justice French in *Amaca Pty Ltd v Booth*[9] where the High Court considered the effect of epidemiological evidence associated with the effect of asbestos in brake linings on the development of asbestosis suffered by a career mechanic.

> *The [Bradford Hill] criteria were expressed as the aspects of an association between two variables that should be considered before inferring that the most likely interpretation of the association is causation. The nine factors… were not presented as necessary conditions of a cause and effect relationship. They have the character of circumstantial evidence of such a relationship.* [44]

[8] See Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?* In *Evolution of Epidemiologic Ideas: Annotated Readings on Concepts in Methods*, Sander Greenland (Ed), Epidemiology Resources Inc., Massachusetts, 1987, pp 7-12, and *The GRADE approach and Bradford Hill's criteria for causation* by Holger Schunemann et al, *Journal of Epidemiology & Community Health*, 2011, 65: 392-395.
[9] (2011) 246 CLR 36, supra.

The judgement then quoted the American Law Institute's *Restatement Third, Torts: Liability for Physical and Emotional Harm* as follows:

> *Whether an inference of causation based on an association is appropriate is a matter of informed judgment, not scientific methodology, as is a judgment whether a study that finds no association is exonerative or inconclusive. No algorithm exists for applying the Hill guidelines to determine whether an association truly reflects a causal relationship or is spurious. Because the inferential process involves assessing multiple unranked factors, some of which may be more or less appropriate with regard to a specific causal assessment, judgment is required.* [45]

(ii) *Nature of available SMSE*

This consideration is supported by an examination of the nature of the evidence which is available to the RMA.

There is a hierarchy of the types of studies that are useful for the RMA's assessment of causation, ranked in descending order as follows:

- Meta-analyses, systematic reviews. A meta-analysis is a quantitative, formal analysis involving the systematic assessment of the results of previous research to derive quantitative conclusions about that body of research. A systematic review is used to consolidate research on a specific topic, that may be qualitative, quantitative or both.[10]

- Cohort studies. A prospective cohort study watches for outcomes, such as the development of a disease, during the study period and attempts to relate this to characteristics of cohort members measured prior to the occurrence of the outcomes, that may be inferred as causal. A retrospective cohort study is based on the same principle, but makes use of information on cohort characteristics and outcomes that has already been recorded.

- Case-control and cross sectional studies: Compare people with and without a disease or other outcome of interest in regard to current or historical factors, to detect associations that may be causal.

- Case series, case reports. Describe one or more cases of disease, sometimes including information about characteristics that are potentially causal.

For some factors under investigation as causes of disease or injury in SoPs, there have been multiple published meta-analyses, based on strong, well-conducted cohort studies. This type of SMSE is available for example in relation to the question of whether tobacco smoking is a cause of particular types of cancer. Such factors would be amenable to analysis of a "minimum level of probability", in a manner that is consistent with the available SMSE.

[10] See also Rohit Borah et al, *Analysis of the time and workers needed to conduct systematic reviews of medical interventions using data from the PROSPERO registry*, *BMJ Open* 2017, 7: e012545, where the mean estimated time to complete and publish a systematic review was found to be 67.3 weeks and involved a mean of 6.8 authors and team members.

However, for the vast majority of factors, determination of causation by the RMA must be made on much weaker evidence, very often a small number of cross-sectional or case-control studies and a handful of case reports. If there was to be a requirement that a factor could only be determined on the basis of a "minimum level of probability", factors heavily reliant on qualitative material to connect the disease or injury under consideration with service would have to be discarded.

Further legal considerations

Alternatively, if the RMA was to be required to impose a quantitative estimate on the largely qualitative nature of the epidemiological assessment to determine whether a "minimum level of probability" has been met, that may be viewed as akin to granting the RMA a largely self-regulating statutory discretion. Of course, "every statutory discretion, however broad, is constrained by law"[11] and this arrangement may further accentuate the risk of associated Court challenges on the basis of alternative epidemiology.

(b) RMA conducting or funding research

Recommendation 8.2 of the Interim Report was that the RMA should be given

> *the legal and financial capacity to fund and guide medical and epidemiological research into unique veteran health issues, such as through a research trust fund.* [page 50]

The RMA's current role is to conduct investigations sufficient to relate a particular kind of injury, disease or death to military service as defined for the purpose of assisting the efficient operation of schemes of military and veterans' compensation. The investigations undertaken by it are for that purpose. The process of the investigations involves rigorous literature-based searching, data abstraction and sometimes, re-analysis of published data, and as such may be viewed as research. However, it is a vastly different matter for the RMA to undertake primary research, as opposed to its existing role of conducting research using secondary sources. As such, even if s 196C of the VEA did not prohibit the RMA from carrying out any new research work for the purposes of an investigation, it is unlikely that it would seek to undertake such activity because:

- Funding, commissioning and conducting such research requires special expertise.
- Most of the SMSE of high quality relates to the general population and specifically, the non-veteran or serving member component of the population.
- Where there is a gap in the SMSE, other bodies would be better equipped to undertake the research.

The RMA is of the view that a separate body, either an existing body or a body specifically dedicated to veterans' health research would be better placed to conduct primary research. The RMA could refer matters to that body and provide assistance as required.

[11] See *Minister for Immigration and Citizenship v Li* [2013] HCA 18, 23.

(c) Internal Review of Decisions

The Interim Report examined the arrangements for the review of the decisions of the RMA by the Specialist Medical Review Council and contrasted the current statutory arrangements with an internal RMA review concluding with the following information request.

> *The Commission is seeking participants' views on whether there is merit in the Specialist Medical Review Council remaining as a standalone organisation, or whether its role should be folded into an augmented Repatriation Medical Authority review process that brings in additional medical specialists.* [page 50]

The RMA makes no submission on the merits of any legislative arrangements for the review of its decisions. The current arrangements provide for review at "arms length" and work to the benefit of veterans.

The RMA could also operationalise a system of internal review such as the following:

- Any person or organisation eligible under s 196E of the VEA could request a review of a relevant RMA decision as currently stipulated in s 196W.
- The member of the RMA having the conduct of the matter the subject of the request for review would be excused from any discussion or decision on it.
- Upon receiving the request the RMA would appoint an independent medical specialist to review the material considered by it in making that decision and provide a report to the RMA about the request for review.
- That report would be provided to the person seeking the review and submissions sought about its contents.
- The report and those submissions would be considered by the RMA at a subsequent meeting and a decision made about the matter.