

Specialist Medical Review Council

**Declaration and Reasons for Decisions**

*Section 196W
Veterans’ Entitlements Act 1986*

**Re: Statements of Principles Nos. 01 and 02 of 2022,**

**in respect of Hashimoto thyroiditis**

Declaration No. 37

1. In relation to the RMA Statements of Principles **Nos. 01 and 02 of 2022** concerning **Hashimoto thyroiditis** made under subsections 196B of the *Veterans' Entitlements Act 1986* (the VEA), the Council under subsection 196W(5) of the VEA:

DECLARES that the sound medical-scientific evidence available to the RMA is insufficient to justify the amendment of:

1. Statement of Principles No. 2 of 2022 to include the following factors(s):

**posttraumatic stress disorder;** and

1. Factors 9(9) and 9(19) of Statement of Principles No. 1 of 2022 to replace ‘having posttraumatic stress disorder at the *time of* the’ with ‘having posttraumatic stress disorder *before* the’.

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# REASONS FOR DECISIONS

Introduction

1. In relation to the Repatriation Medical Authority (the RMA) Statements of Principles for Nos. 01 and 02 of 2022 concerning Hashimoto thyroiditis, made under subsection 196B of the Veterans’ Entitlements Act 1986 (the VEA), this document outlines the Reasons for Decisions (the Reasons) for the declaration and recommendation made by the Specialist Medical Review Council (SMRC) for these Statements of Principles to be amended.
2. This section of the Reasons will introduce the role of the SMRC (the Council), the events that led to a review of these Statements of Principles by the Council, and the types of information and how they were considered in this review.
3. The Council is an independent statutory body established by the VEA. In general terms, upon receipt of a valid application, the Council is to review as relevant:
* the contents of Statement/s of Principles in respect of a particular kind of injury, disease or death; or
* a decision of the RMA not to determine, not to amend, Statement/s of Principles in respect of a particular kind of injury, disease or death.
1. In March 2022, the Council received an application seeking a review of the RMA decision on 24 December 2021 about the Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 and 02 of 2022). Following an investigation, the RMA decided to include new factors, listed in subsections 9(9) and 9(19), concerning having posttraumatic stress disorder in the Statement of Principles concerning Hashimoto thyroiditis (Reasonable Hypothesis) (No. 01 of 2022), but not the Statement of Principles concerning Hashimoto thyroiditis (Balance of Probabilities) (No. 2 of 2022).

Subsection 9 of the Statement of Principles concerning Hashimoto thyroiditis (Reasonable Hypothesis) (No. 01 of 2022) now includes the following factors:

(9) having posttraumatic stress disorder at the time of the clinical onset of

Hashimoto thyroiditis;

(19) having posttraumatic stress disorder at the time of the clinical

worsening of Hashimoto thyroiditis;

1. In conducting a review, the Council must review all of the information (and only that information) available to the RMA when it made the decision under review. This is information that the RMA used instead of information that was generally available but not accessed by the RMA. A list of the information that was available to the RMA is listed in **Table 1 of Appendix A**.
2. Fundamental to Statements of Principles, and so to a Council review, is the concept of sound medical-scientific evidence, as that term is defined in section 5AB(2) of the VEA[[1]](#footnote-1).
3. The sound medical-scientific evidence relevant to this application (the relevant sound medical-scientific evidence) is listed in the **reference list at the end of this document.**
4. **Appendix B** sets out further details regarding the composition of the Council for this review and the legislation relating to the making of Statements of Principles.
5. **Appendix C** provides a list of abbreviations used in these Reasons.

Scope of this review

1. In his application, the Applicant contended that there was sound medical-scientific evidence (Jung et al. 2019 [RMA ID 102800], O’Donovan et al. 2015 [RMA ID 102934]) on which the RMA could have relied to amend both the Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 and 02 of 2022). The Applicant requested the SMRC review the decision by the RMA to include factors linking posttraumatic stress disorder with Hashimoto thyroiditis, having posttraumatic stress disorder before the clinical onset of Hashimoto thyroiditis.
2. The Council, when reviewing the sound medical-scientific evidence, must determine whether or not there is sound medical-scientific evidence that indicates a reasonable hypothesis[[2]](#footnote-2) connecting the particular injury, disease or death to the relevant service.
3. In a reasonable hypothesis, the evidence 'points to' as opposed to merely 'leaves open' a link between injury, disease or death and the relevant service. In a reasonable hypothesis, the link is not ‘obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous.’[[3]](#footnote-3)
4. If the Council is of the opinion that a reasonable hypothesis has been raised, the Council proceeds also to determine whether a connection exists to relevant service on the balance of probabilities (i.e., whether the connection is more probable than not)[[4]](#footnote-4) .
5. In these Reasons the association for both the reasonable hypothesis test and the balance of probabilities test are referred to as the ‘relevant association’.
6. The Council exercises its scientific judgement in weighing the evidence about the relevant association.

Council's decision on the scope of review

1. The Council wrote to the Applicant advising of its preliminary decision on the proposed scope of the review and inviting comment. No comments were received on the proposed scope of the review.
2. The Council decided it would have particular regard as to whether there was sufficient sound medical-scientific evidence before the RMA on which to determine factors linking posttraumatic stress disorder with Hashimoto thyroiditis and, if so, to determine relevant Statement of Principles.

# Submissions

Applicant’s Submission

1. The Council considered the submissions made to it, both written and oral.
2. In his application, the Applicant requested the SMRC review the decision by the RMA to include factors linking posttraumatic stress disorder with Hashimoto thyroiditis, having posttraumatic stress disorder before the clinical onset of Hashimoto thyroiditis.
3. In support of his contention, the Applicant cited Jung et al. (2019) [RMA ID 102800] and O’Donovan et al. (2015) [RMA ID 102934] in his application stating that:

Jung et al., using the well-known and well-respected US Nurses’ study of 45992 women, demonstrate a dose-dependent relationship between the number of PTSD [Posttraumatic Stress Disorder] symptoms and the risk of hypothyroidism over 24 years.

O'Donovan demonstrated trauma exposure and PTSD resulted in an elevated risk of developing autoimmune disorders, in both women and men, for thyroiditis the adjusted relative risk was statistically significantly higher in veterans with PTSD compared to those with no psychiatric disorder (see Table 2), from the paper ARR = 2.00 95% CI, 1.91–2.09; p <.001)

1. Through his representative, the Applicant advised the Council that the information provided with his application was the basis of his oral submission at the Council’s hearing of submissions held on 4 December 2024.
2. Through his representative, the Applicant contended at the hearing that there were available studies that meet the balance of probabilities test to amend the Statements of Principles concerning Hashimoto thyroiditis (Nos. 02 of 2022) to include a factor on posttraumatic stress disorder. The representative noted that the reasonable hypothesis test had been met. Consequently, the Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 of 2022) have been amended to include a factor for having posttraumatic stress disorder at the time of clinical onset or worsening of Hashimoto thyroiditis in the RMA’s most recent review of these Statements of Principles.
3. Through his representative, the Applicant noted that the wording of the factor for posttraumatic stress disorder in the Statements of Principles should state ‘having posttraumatic stress disorder before the clinical onset of Hashimoto thyroiditis’ instead of ‘having posttraumatic stress disorder at the time of clinical onset of Hashimoto thyroiditis’. However, the Applicant’s representative noted that this was not a significant point of contention for the Applicant.
4. The representative stated that Jung et al. (2019) [RMA ID 102800] and O’Donovan et al. (2015) [RMA ID 102934]) provide convincing and consistent evidence of a significant risk between posttraumatic stress disorder and thyroiditis. The representative noted at the hearing that in the large cohort study reported by Jung et al. (2019) [RMA ID 102800], the hazard ratios reported were consistently greater than 1.1, with some models showing hazard ratios up to 1.4 for the association between posttraumatic stress disorder and hypothyroidism. In a second large cohort study reported by O’Donovan et al. (2015) [RMA ID 102934], the relative risk of thyroiditis reported was above 2.0 for Veterans with posttraumatic stress disorder compared to veterans with no psychiatric disorders.
5. In summary, through his representative, the Applicant contended that these two studies provided enough evidence to meet the balance of probabilities test, in addition to the reasonable hypothesis test, to amend the Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 and 02 of 2022) to include a factor for having posttraumatic stress disorder before the clinical onset or worsening of Hashimoto thyroiditis.

# Council's decisions on the relevant SOUND MEDICAL-SCIENTIFIC EVIDENCE

1. The Council considered that the sound medical-scientific evidence to be considered in the review should comprise information:
* that was available to the RMA at the relevant times;
* which was sent by the RMA to the Council under section 196K of the VEA;
* which was considered by the Council to be sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:
	1. epidemiologists would consider appropriate to take into account; and
	2. in the Council's view, 'touches on' (is relevant to) matters within the scope of review.
1. The Council's final decision on the sound medical-scientific evidence for the review was that it should comprise the information listed in **Table 1 in Appendix A**.

# COUNCIL’S EVALUATION OF THE SOUND MEDICAL-SCIENTIFIC EVIDENCE

1. When evaluating the sound medical-scientific evidence, the Council focussed on information relevant to the scope of the review and the list in **Table 1 of Appendix A**.
2. In forming its decisions on the sound medical-scientific evidence, the Council brings to bear its scientific expertise and judgement. The Bradford Hill criteria and other tools or criteria appropriate to be considered by epidemiologists were applied to the articles as deemed appropriate.
3. The Council also considered any methodological limitations or flaws (including statistical power, control of confounders, bias, exposure assessment methods, etc.) in the various articles.
4. For ease of reference, the Bradford Hill criteria (noting that these are not exhaustive) are:
* strength of association
* consistency across the investigation
* specificity of the association
* temporal relationship of the association
* biological gradient
* biological plausibility
* coherence
* experiment
* analogy
1. The Council notes that these criteria are not necessary to establish a causal association. They may provide some evidence of association.

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# COUNCIL’S CONCLUSIONS ON THE RELEVANT SOUND MEDICAL-SCIENTIFIC EVIDENCE

1. This section of the Reasons outlines the Council’s conclusions on the relevant, sound medical-scientific evidence that it considered to be within the scope of their review.
2. The Council must consider and evaluate all sound medical-scientific evidence in deciding the existence or otherwise of a reasonable hypothesis. In the situation where there is a single piece of evidence, such as a single study or paper, in support of a reasonable hypothesis on its own, that may be enough to support the hypothesis. However, this information should be considered with other sound medical-scientific evidence to identify whether the sound medical-scientific evidence indicates a relation to the medical condition. It is, therefore, important that the Council considers all information in context.
3. From the information available to the RMA at the relevant time, the Council considered all studies pertinent to the scope of this review. In considering the matters within the scope of the review, the Council closely analysed these studies, both individually and collectively, considering both quantitative and qualitative evidence in its evaluations.
4. The Council considered that particular attention in their review should be paid to the material identified by the Applicant (Jung et al. (2019) [RMA ID 102800]; O’Donovan et al. (2015) [RMA ID 102934]). The Council was of the view that of all the available information, it was the most directly relevant to the scope of the review to determine factors linking posttraumatic stress disorder with Hashimoto thyroiditis, as no studies were identified that specifically examined the relationship between posttraumatic stress disorder and Hashimoto thyroiditis. These two studies used a cohort design to investigate associations between conditions closely related to Hashimoto thyroiditis (i.e., hypothyroidism and thyroiditis), providing stronger evidence for understanding causal relationships.
5. The retrospective cohort study by Jung et al. (2019) [RMA ID 102800] investigated the relationship between trauma exposure, posttraumatic stress disorder symptoms, and thyroid dysfunction (hypothyroidism and Graves' hyperthyroidism) in a longitudinal cohort of 45,992 civilian women from the Nurses' Health Study II over 24 years. Women who had reported thyroid dysfunction at baseline (n = 3268) were excluded from analyses. The Nurses’ Health Study II is an ongoing prospective cohort study, started in 1989 with 116 429 female registered nurses aged 25–42.
6. Over 24 years of follow-up, Jung et al. (2019) [RMA ID 102800] identified that 7993 women developed hypothyroidism. In multivariable-adjusted modelling accounting for variables such as age, race, parental education, body type classification, health behaviours, menopausal status and medication use (ibuprofen and antidepressants), the study found a significant association between the severity of posttraumatic stress disorder symptoms and hypothyroidism risk, with higher posttraumatic stress disorder symptom levels corresponding to increased hypothyroidism in women exposed to trauma compared to women not exposed to trauma (trauma with no symptoms, Hazard Ratio (HR) = 1.08, 95% CI [1.02,1.15]; trauma with 1–3 symptoms, HR = 1.12, 95% CI [1.04,1.21]; trauma with 4–5 symptoms, HR = 1.23, 95% CI [1.13,1.34]; and trauma with 6–7 symptoms, HR = 1.26, 95% CI [1.14,1.40]; *p*-trend <0.001).
7. Jung et al. (2019) [RMA ID 102800] also conducted prospective sensitivity analyses on their data set that excluded women with thyroid disease before 2009. They examined whether posttraumatic stress disorder status in 2008 predicted incident hypothyroidism in 2009-2013. The authors reported that for women (n=297) with four or more posttraumatic stress disorder symptoms, hypothyroidism risk was increased (HR = 1.21, 95% CI [1.03,1.42], *p*-trend = 0.012). The associations with less than four posttraumatic stress disorder symptoms were not significant.
8. The study by Jung et al. (2019) [RMA ID 102800] is limited by the reliance on self-reported diagnosis of thyroid dysfunction. Posttraumatic stress disorder and trauma were also assessed through self-report using the Brief Screening Scale for Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV-Posttraumatic Stress Disorder, as well as a violence questionnaire and a modified version of the 16-item Brief Trauma Questionnaire. These assessments were conducted retrospectively. Additionally, the sample consisted of female registered nurses and may not be generalisable to more diverse populations. These limitations may have introduced recall bias, misclassification bias, and selection bias, potentially reducing the validity of the findings.
9. The retrospective cohort study by O’Donovan et al. (2015) [RMA ID 102934] examined the association between posttraumatic stress disorder, other psychiatric disorders, and the risk of autoimmune disorders in a cohort of 666,269 Iraq and Afghanistan veterans under age 55.
10. O’Donovan et al. (2015) [RMA ID 102934] reported that within the sample of 666,269 veterans, 9743 (1.5%) received a diagnosis of an autoimmune diagnosis at two or more separate Department of Veterans Affairs clinical encounters: 6963 (1.0%) with thyroiditis. The study identified that Veterans with posttraumatic stress disorder had a significantly higher adjusted relative risk (ARR) for thyroiditis compared to Veterans with no psychiatric diagnoses (ARR = 2.17, 95% CI [2.06,2.29]).
11. A limitation of the study by O’Donovan et al. (2015) [RMA ID 102934] is that it relied on diagnostic codes from the Department of Veterans Affairs National Patient Care Database rather than clinical confirmation. This may have introduced misclassification errors, potentially reducing the validity of the findings. Another limitation of this study was that diagnoses were made when the Department of Veterans Affairs providers first coded the condition using ICD-9-CM criteria, which may not correspond with the emergence of these conditions.
12. The Council identified a third cohort study that investigated associations over time between autoimmune thyroid disease and stress-related disorders (Song et al. (2018) [RMA ID 102816]). In this study, it was not possible to distinguish posttraumatic stress disorder from other stress-related disorders in analyses with autoimmune thyroid disease. The study cross-linked census data with a national patient register. Among 7,689,628 Swedish-born individuals, the study identified a total of 106,464 patients diagnosed with stress-related disorders and 1,064,640 matched individuals without stress-related disorders. The study identified 8,284 individuals with diagnosed autoimmune diseases among patients exposed to stress-related disorders. Compared with the unexposed population, patients with stress-related disorders were at increased risk of autoimmune disease (HR = 1.36, 95% CI [1.33,1.40]). The risk for autoimmune thyroid disease was increased among patients with stress-related disorders, compared with matched unexposed individuals (HR = 1.49, 95% CI [1.42,1.56]).
13. The Council identified other available evidence on associations between hypothyroidism and posttraumatic stress disorder involving cross-sectional designs (Boscarino (2013) [RMA ID 49509]; Vaja et al. (2013) [RMA ID 103393]). Boscarino (2013) [RMA ID 49509] reported an association between comorbid posttraumatic stress disorder and hypothyroidism (Adj OR = 8.5 95% CI [1.9,37.9), based on three hypothyroidism cases. Vaja et al. (2013) [RMA ID 103393] identified a higher prevalence of autoimmune hypothyroidism in people with posttraumatic stress disorder compared to population data. The prevalence of hypothyroidism (3.4%) in the posttraumatic stress disorder subgroup was higher than the expected prevalence (0.3%).
14. The Council identified other information that examined relationships between thyroid function and posttraumatic stress disorder (Toloza et al. (2020) [RMA ID 102621]; Spaggiari et al. (2021) [RMA ID 102817]; Kamoi et al. (2006) [RMA ID 102801]). The Council acknowledges that while thyroid function measures may seem relevant, they must be interpreted in the context of other clinical features not reported in these studies to be considered a reflection of Hashimoto thyroiditis.

# The council’s conclusions on whether there should be NEW factor(s) FOR HASHIMOTO thyroiditis

1. Based on the Council’s conclusions regarding the relevant sound medical-scientific evidence, this section of the Reasons outlines the Council’s conclusions on whether there should be an amendment to the Statements of Principles under review.
2. The Council concluded that there should not be an amendment with respect to the Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 and 02 of 2022).
3. Consistent with the current Statements of Principles concerning Hashimoto thyroiditis (Nos. 01 and 02 of 2022), this conclusion was based on a finding that there was sufficient evidence available to satisfy the requirements of the reasonable hypothesis test but insufficient evidence available to satisfy the requirements of the balance of probabilities test to include a factor for having posttraumatic stress disorder.
4. The Council found only two studies that it considered to be most directly relevant to the scope of the review to determine factors linking posttraumatic stress disorder with Hashimoto thyroiditis (Jung et al. 2019 [RMA ID 102800]; O’Donovan et al. 2015 [RMA ID 102934]). These studies investigated associations between closely related conditions to Hashimoto thyroiditis (i.e., hypothyroidism and thyroiditis) and posttraumatic stress disorder. The Council considered that the requirements of the reasonable hypothesis test were met mainly because these two studies consistently identified an association and that there was little conflicting evidence among the other relevant descriptive literature the Council reviewed (Song et al. (2018) [RMA ID 102816]; Boscarino (2013) [RMA ID 49509]; Vaja et al. (2013) [RMA ID 103393]).
5. However, the strength of the associations found in these two studies were small and not statistically significant in all models (Jung et al. 2019 [RMA ID 102800]; O’Donovan et al. 2015 [RMA ID 102934]). The Council also considered the two studies to have methodological limitations, notably the potential for misclassification error through the lack of clinically confirmed diagnosis of thyroid or posttraumatic stress disorder and the inability across both studies to establish that posttraumatic stress disorder was present before the onset of hypothyroidism or thyroiditis. For these reasons, the Council found insufficient evidence to satisfy the balance of probabilities test requirements.

1. Furthermore, as it could not be confirmed in the reviewed studies that posttraumatic stress disorder was present before the development of hypothyroidism or thyroiditis, the Council found insufficient evidence available to amend the wording of factors (9) and (19) of Statement of Principles (No. 1 of 2022) to specify ‘having posttraumatic stress disorder before the onset (or worsening)’ instead of ‘having posttraumatic stress disorder at the time of clinical onset (or worsening)’.

# The Council’s analysis of new information

1. This section of the Reasons outlines the Council’s analysis of evidence that it considered related to the scope of their review but was not available to (not before) the RMA at the relevant times.
2. The Council has neither the capacity nor the jurisdiction to perform an investigative function, including undertaking a comprehensive literature search. However, because of the Councillors' specialist expertise in this kind of injury, disease or death, it may be aware of information to consider on a preliminary basis.
3. The Council would only consider new information to determine whether, in the Council's view, it warranted the Council making any recommendations to the RMA under section 196W(5) of the VEA.
4. In the Council's view, any such recommendation should only be made by the Council if it formed the view that the new information comprised sound medical-scientific evidence as defined in section 5AB(2) of the VEA and:

- in the Council's view, 'touched on' (was relevant to) the contended factor; and

- could potentially satisfy the reasonable hypothesis and/or balance of probabilities tests.

1. The Council was unaware of information that was not available to (not before) the RMA at the relevant times that would alter the recommendations made by the Council at this time.

# Decision

1. The Council made the declarations and recommendations summarised in the Declaration and Reasons for Decisions.

# References

Boscarino JA (2004) ‘Posttraumatic stress disorder and physical illness: results from clinical and epidemiologic studies’, *Ann N Y Acad Sci*, 1032: 141-53. [RMA ID 49509]

Jung SJ, Kang JH, Roberts AL, et al (2019) ‘Posttraumatic stress disorder and incidence of thyroid dysfunction in women’, *Psychol Med*, 49(15): 2551-60. [RMA ID 102800]

Kamoi K, Tanaka M, Ikarashi T, et al (2006) ‘Effect of the 2004 mid niigata prefecture earthquake on patients with endocrine disorders’, *Endocr J*, 53(4): 511-21. [RMA ID 102801]

O'Donovan A, Cohen BE, Seal KH, et al (2015) ‘Elevated risk for autoimmune disorders in Iraq and Afghanistan veterans with posttraumatic stress disorder’, *Biol Psychiatry*, 77(4): 365-74. [RMA ID 102934]

Song H, Fang F, Tomasson G, et al (2018) ‘Association of stress-related disorders with subsequent autoimmune disease’, *JAMA*, 319(23): 2388-400. [RMA ID 102816]

Spaggiari G, Setti M, Tagliavini S, et al (2021) ‘The hypothalamic-pituitary-adrenal and -thyroid axes activation lasting one year after an earthquake swarm: results from a big data analysis’, *J Endocrinol Invest*, 44(7): 1501-13. [RMA ID 102817]

Toloza FJ, Mao Y, Menon LP, et al (2020) ‘Association of thyroid function with posttraumatic stress disorder: a systematic review and meta-analysis’, *Endocr Pract*, 26(10): 1173-85. [RMA ID 102621]

Vaja R, Agius M, and Zaman R (2013) ‘Audit to assess the prevalence of autoimmune disorders among patients suffering from psychiatric illnesses’, *Psychiatr Danub*, 25(Suppl 2): S305-14. [RMA ID 103393]

# APPENDICES

## APPENDIX A: TABLE 1 MATERIAL BEFORE THE RMA

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| **RMA ID** | **Title** |
| 80967 | Administrative Appeals Tribunal of Australia (2015). Mahoney and Repatriation Commission [2015] AATA 379 (29 May 2015). Retrieved 15 March 2017, from http://www.austlii.edu.au/au/cases/cth/AATA/2015/379.html |
| 66926 | Agate L, Mariotti S, Elisei R, et al (2008). Thyroid autoantibodies and thyroid function in subjects exposed to Chernobyl fallout during childhood: evidence for a transient radiation-induced elevation of serum thyroid antibodies without an increase in thyroid autoimmune disease. J Clin Endocrinol Metab, 93(7): 2729-36. |
| 103521 | Aghini Lombardi F, Fiore E, Tonacchera M, et al (2013). The effect of voluntary iodine prophylaxis in a small rural community: the Pescopagano survey 15 years later. J Clin Endocrinol Metab, 98(3): 1031-9. |
| 65359 | Ahmed R, Al-Shaikh S, Akhtar M (2012). Hashimoto thyroiditis: a century later. Adv Anat Pathol, 19(3): 181-6. |
| 99437 | Alexander EK, Pearce EN, Brent GA, et al (2017). 2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum. Thyroid, 27(3): 315-89. |
| 65360 | Alfaris N, Curiel R, Tabbara S, et al (2010). Autoimmune thyroid disease and Sjogren syndrome. J Clin Rheumatol, 16(3): 146-7. |
| 102784 | American Thyroid Association (2019). Thyroid Function Tests. Retrieved 21 October 2021, from https://www.thyroid.org/wp-content/uploads/patients/brochures/FunctionTests\_brochure.pdf |
| 102783 | Amouzegar A, Kazemian E, Abdi H, et al (2020). Abdominal obesity phenotypes and incidence of thyroid autoimmunity: A 9-year follow-up. Endocr Res, 45(3): 202-9. |
| 101704 | Andersen SL, Olsen J, Wu CS, et al (2014). Smoking reduces the risk of hypothyroidism and increases the risk of hyperthyroidism: evidence from 450,842 mothers giving birth in Denmark. Clin Endocrinol (Oxf), 80(2): 307-14. |
| 99944 | Andersson EM, Scott K, Xu Y, et al (2019). High exposure to perfluorinated compounds in drinking water and thyroid disease. A cohort study from Ronneby, Sweden. Environ Res, 176: 108540. |
| 65908 | Andrade LJ, Atta AM, Atta ML, et al (2011). Thyroid disorders in patients with chronic hepatitis C using interferon-alpha and ribavirin therapy. Braz J Infect Dis, 15(4): 377-81. |
| 66205 | Antonelli A, Ferri C, Fallahi P, et al (2006). Thyroid disorders in chronic hepatitis C virus infection. Thyroid, 16(6): 563-72. |
| 66962 | Antonelli A, Ferri C, Fallahi P, et al (2007). Clinical and subclinical autoimmune thyroid disorders in systemic sclerosis. Eur J Endocrinol, 156(4): 431-7. |
| 101706 | Antonelli A, Ferri C, Pampana A, et al (2004). Thyroid disorders in chronic hepatitis C. Am J Med, 117(1): 10-3. |
| 65350 | Aoki Y (2001). Polychlorinated biphenyls, polychlorinated dibenzo-p-dioxins, and polychlorinated dibenzofurans as endocrine disrupters--what we have learned from Yusho disease. Environ Res, 86(1): 2-11. |
| 62543 | Arisawa K, Takeda H, Mikasa H (2005). Background exposure to PCDDs/PCDFs/PCBs and its potential health effects: a review of epidemiologic studies. J Med Invest, 52(1-2): 10-21. |
| 102516 | Australian Medicines Handbook (2021). Amiodarone. Retrieved 12 October 2021, from https://amhonline.amh.net.au/chapters/cardiovascular-drugs/drugs-arrhythmias/antiarrhythmics/amiodarone |
| 80744 | Australian Radiation Protection and Nuclear Safety Agency (2002). Estimations of Atomic Radiation Exposure in Australian Service Personnel in South West Japan 1946-52, Commonwealth Department of Veterans' Affairs. |
| 80718 | Australian Radiation Protection and Nuclear Safety Agency (2012). Radiation protection: alpha particles. Retrieved 6 February 2017, from http://www.arpansa.gov.au/radiationprotection/basics/alpha.cfm |
| 80721 | Australian Radiation Protection and Nuclear Safety Agency (2012). Radiation protection: Radiation basics - ionising and non ionising radiation. Retrieved 6 February 2017, from http://www.arpansa.gov.au/radiationprotection/basics/ion\_nonion.cfm |
| 80725 | Australian Radiation Protection and Nuclear Safety Agency (2012). Radiation protection: health effects of ionising radiation. Retrieved 6 February 2017, from http://www.arpansa.gov.au/radiationprotection/basics/health\_ion.cfm |
| 80745 | Australian Radiation Protection and Nuclear Safety Agency (2012). Radiation protection: Beta particles. Retrieved 8 February 2017, from http://www.arpansa.gov.au/radiationprotection/basics/beta.cfm |
| 80723 | Australian Radiation Protection and Nuclear Safety Agency (2015). Radiation protection: units of ionising radiation measurement. Retrieved 6 February 2017, from http://www.arpansa.gov.au/RadiationProtection/Basics/units/cfm |
| 80724 | Australian Radiation Protection and Nuclear Safety Agency (2015). Fact sheet: Ionising radiation and health. Retrieved 6 February 2017, from http://arpansa.gov.au/RadiationProtection/Factsheet/is\_ionising.cfm |
| 80726 | Azizova TV, Grigoryeva ES, Haylock RG, et al (2015). Ischaemic heart disease incidence and mortality in an extended cohort of Mayak workers first employed in 1948-1982. Br J Radiol, 88(1054): 20150169. |
| 21386 | Babic Leko M, Gunjaca I, Pleic N, et al (2021). Environmental factors affecting thyroid-stimulating hormone and thyroid hormone levels. Int J Mol Sci, 22(12): 6521. |
| 64577 | Bakhshandeh M, Hashemi B, Mahdavi SR, et al (2012). Evaluation of thyroid disorders during head-and-neck radiotherapy by using functional analysis and ultrasonography. Int J Radiat Oncol Biol Phys, 83(1): 198-203. |
| 102785 | Baranowska-Bik A, Bik W (2020). The association of obesity with autoimmune thyroiditis and thyroid function-possible mechanisms of bilateral interaction. Int J Endocrinol, 2020: 8894792. |
| 85792 | Barroso-Sousa R, Barry WT, Garrido-Castro AC, et al (2018). Incidence of endocrine dysfunction following the use of different immune checkpoint inhibitor regimens: A systematic review and meta-analysis. JAMA Oncol, 4(2): 173-82. |
| 67018 | Bassi V, Marino G, Iengo A, et al (2012). Autoimmune thyroid diseases and Helicobacter pylori: the correlation is present only in Graves's disease. World J Gastroenterol, 18(10): 1093-7. |
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## APPENDIX B: THE CONSTITUTED COUNCIL AND LEGISLATIVE FRAMEWORK OF THE REVIEW

The Specialist Medical Review Council

1. The composition of each Review Council changes from review to review depending on the issues relevant to the particular Statement/s of Principles under review. When a review is undertaken three to five Councillors selected by the Convener constitute the Council.
2. The Minister must appoint one of the Councillors to be the Convener. If the Council does not include the Convener, the Convener must appoint one of the Councillors selected for the review to preside at all meetings as Presiding Councillor.
3. The Presiding Councillor (and Convener) for this review was:

**Professor Christian Gericke,** MD, PhD, MPH, MSc, MBA, FRACP, FAFPHM. Professor Gericke’s expertise includes neurology, public health medicine and medical law.

1. The other members of the Council were:

**Professor Kimberly Alexander,** PhD, MEdu, BHlthSc, BNurs, GradCertBus, RN. Professor Alexander’s expertise includes symptom management and epidemiology.

**Dr Richard Arenson,** MBBS, FRACP. Dr Arenson’s expertise includes endocrinology and geriatrics.

**Dr Ian Gardner,** MBBS, MPH, FAFOEM. Dr Gardner’s expertise includes occupational and environmental medicine, public health, toxicology, and biostatistics/epidemiology.

**Dr Kate O’Connor,** MBBS, PhD, FRACP, FRCPA. Dr O’Connor’s expertise includes clinical immunology and immunopathology.

The Legislation

1. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA. Statements of Principles operate as templates. They are determined by the RMA, and set out those criteria (conditions or exposures), known as factors, that must as a minimum exist before it can be said that an injury, disease or death can be connected with service, on either or both of the two statutory tests, the reasonable hypothesis test [[5]](#footnote-5) and the balance of probabilities test. [[6]](#footnote-6) Statements of Principles are ultimately applied by decision-makers in determining individual claims for benefits under the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA). [[7]](#footnote-7)

## APPENDIX C: TABLE 1 List of abbreviations

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| **Abbreviation** | **Term** |
| MRCA | Military Rehabilitation and Compensation Act 2004  |
| RMA | Repatriation Medical Authority |
| SMRC | Specialist Medical Review Council |
| VEA | Veterans' Entitlements Act 1986 |

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1. The sound medical-scientific evidence is a subset of the available information. It comprises those articles which the Council considers:

a) are relevant to the matters within the proposed scope of review, and

b) satisfy the definition in the VEA of 'sound medical-scientific evidence'.

Sound medical-scientific evidence is defined in section 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.

The later requirement is held to mean ‘appropriate to be taken into account by epidemiologists’. [↑](#footnote-ref-1)
2. Section 196B(2) of the VEA sets out the ‘reasonable hypothesis test’:

(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

(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. [↑](#footnote-ref-2)
3. See the full Federal Court decision in *Repatriation Commission v Bey* (1997) 79 FCR 364 which cited with approval these comments from Veterans’ Review Board in *Stacey* (unreported 26 June 1985), all of which were in turn cited with approval in the Moore J decision at [33]. [↑](#footnote-ref-3)
4. Section 196B(3) of the VEA sets out the ‘balance of probabilities test’:

 (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) 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. [↑](#footnote-ref-4)
5. The reasonable hypothesis test is set out in section 196B(2) of the VEA which provides;

 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. [↑](#footnote-ref-5)
6. The balance of probabilities test is set out in section 196B(3) of the VEA which provides:

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. [↑](#footnote-ref-6)
7. See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA. [↑](#footnote-ref-7)