Specialist Medical Review Council

Declaration and Reasons for Decisions

Section 196W
Veterans' Entitlements Act 1986

Re: Statements of Principles Nos. 75 and 76 of 2015
in respect of myasthenia gravis

Request for Review Declaration No. 29

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles (SoPs) **No. 75** and **No. 76 of 2015** concerning **Myasthenia Gravis**, made under subsection 196B of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under subsection 196W(5) of the VEA:

   DECLARES that there was no sound medical-scientific evidence on which the RMA could have relied to amend either of the SoPs to include a factor or factors for exposure to ionising radiation and the clinical onset and/or clinical worsening of myasthenia gravis.

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REASONS FOR DECISIONS

INTRODUCTION

1. 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 SoPs in respect of a particular kind of injury, disease or death; or

   – a decision of the RMA not to determine, not to amend, SoPs in respect of a particular kind of injury, disease or death.

2. In conducting a review, the Council must review all of the information (and only that information) that was available to the RMA when it made the decision under review. This is information which was actually used by the RMA as opposed to information which 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**.

3. Fundamental to SoPs, and so to a Council review, is the concept of sound medical-scientific evidence (SMSE), as that term is defined in section 5AB(2) of the VEA[1].

4. The information to which the Applicant referred, being information which the RMA advised was new information, that is, information which was not available to the RMA at the relevant time, and so was not considered by the Council in reaching its review decision is listed in **Table 2 of Appendix A**.

5. **Appendix B** sets out further details regarding the composition of the Council for this review and the legislation relating to the making of SoPs.

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[1] The SMSE 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'.

SCOPE OF THIS REVIEW

6. In his application the Applicant sought review of the contents of SoPs **Nos 75 and 76 of 2015 for Myasthenia Gravis.** The Applicant contended that there was SMSE on which the RMA could have relied to amend either or both SoPs in respect to **ionising radiation and onset of Myasthenia Gravis.**

7. The Council, when reviewing the SMSE, must determine whether or not there is SMSE which indicates a reasonable hypothesis connecting the particular injury, disease or death to the relevant service.

8. 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.'[2]

9. 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,[3] i.e. whether the connection is more probable than not.

10. In these Reasons the association for both the reasonable hypothesis test and the balance of probabilities test are respectively referred to as the 'relevant association'.

11. The Council exercises its professional scientific, academic expertise and judgement in weighing the evidence about the relevant association.

Council's decision on the scope of review

12. The Council wrote to both the Applicant and to the Repatriation Commission and Military Rehabilitation and Compensation Commission (the Commissions) advising its decision on the proposed scope of the review and inviting comment. No submissions were received on the proposed scope of the review and therefore the Council decided that it would have particular regard to whether there was SMSE on which the RMA could have relied to amend either or both of the SoPs in the following way:

- the possible inclusion of a factor or factors, as contended, for exposure to ionising radiation and the clinical onset of myasthenia gravis.

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2 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 judgment of Moore J in the *Bey* decision at [33].

3 Relevant service in balance of probabilities statements of principles refers to non-operational service having regard to the various definitions applying to types of 'service' as defined in the VEA and the MRCA.

- the possible inclusion of a factor or factors, as contended, for exposure to ionising radiation and the clinical worsening of myasthenia gravis.

Written and oral submissions

Applicant

13. The Council took into account the submissions made to it, both written and in oral form.

14. In summary, the Applicant, a British Nuclear Test veteran, submitted that studies have found nuclear test veterans were exposed to ionising radiation and that ionising radiation is known to damage cells within the bone marrow. He contended that acetylcholine receptor (AChR) antibodies found in myasthenia gravis come from the bone marrow, and that a logical pathway exists for radiation damaged T-cells to result in AChR antibodies.

15. He also submitted that the US Department of Veterans' Affairs has accepted Myasthenia Gravis as a "Disease subject to presumptive service conditions" for nuclear veterans.

16. The Applicant was critical of the RMA's use of the ionising radiation dosimetry study in Volume 1 of the "Australian Participants in British Nuclear Tests in Australia, Dosimetry and Mortality and Cancer Incidence Study," which he considered to be flawed.

Commissions

17. The Commissions made a written submission to the Council dated December 2015.

18. In summary, the Commissions submitted that the information that was available to the RMA suggested that ionising radiation exposure may have a role in the development of some forms of autoimmune disease which provides some limited support for the biologically plausibility that there could be a link between ionising radiation exposure and myasthenia gravis. The Commissions contended however, that biological plausibility on its own is not a sufficient basis for the inclusion of a factor in a SOP.

19. The Commissions contended that the information leaves open the possibility of a causal association, but that it does not point to that association.

Council's decisions on the relevant SMSE

20. The Council considered that the SMSE to be assessed 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 SMSE as defined in section 5AB(2) of the VEA being information which:
    a. epidemiologists would consider appropriate to take into account; and
    b. in the Council's view 'touches on' (is relevant to) matters within the scope of review.

21. For the reasons set out below the Council did not consider that there was SMSE with respect to ionising radiation and the clinical onset or clinical worsening of myasthenia gravis.

22. Information which the RMA advised was not available to it at the relevant times was not taken into account by the Council for the purposes of the review, as it could only be considered as 'new information'.

THE COUNCIL'S EVALUATION OF THE SMSE

23. In forming its decisions on the SMSE, the Council brings to bear its scientific expertise and judgement. The Bradford Hill criteria and other tools or criteria appropriate to be taken into account by epidemiologists were applied to the articles as it considered appropriate.

24. The Council also considered any methodological limitations or flaws (including such things as statistical power, control of confounders, bias, exposure assessment methods etc.) in the various articles.

25. For ease of reference, the Bradford Hill criteria (noting that these are not exhaustive) are:

- strength of association
- consistency across investigation
- specificity of the association
- temporal relationship of the association
- biological gradient
- biological plausibility
- coherence
- experiment
- analogy

26. The Council notes that these criteria are not necessary conditions of a cause and effect relationship. They act to provide some circumstantial evidence of such a relationship.

27. The Council considered, but did not focus its evaluation, on those articles that:

- were reviews of available information that the Council has evaluated in these reasons for decisions;

- did not provide data that the Council could draw conclusions on about ionising radiation and myasthenia gravis.

THE COUNCIL'S CONCLUSIONS ON THE RELEVANT SMSE

28. In reaching a decision about the existence or otherwise of a reasonable hypothesis the Council must consider and evaluate all of the SMSE. 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 SMSE in identifying whether the SMSE indicates the relation to the medical condition. Therefore, it is important that the Council considers all information in context. The Council did not consider that there was SMSE concerning ionising radiation and the clinical onset or clinical worsening of myasthenia gravis.

Myasthenia Gravis

29. The RMA defines " Myasthenia Gravis " in the SoPs as:
    a) means an autoimmune neuromuscular disorder characterised by weakness and fatigability of skeletal muscles; and
    b) excludes temporary weakness and fatigability of skeletal muscles due to medication and myasthenia syndromes.

THE COUNCIL'S CONCLUSIONS ON WHETHER THERE SHOULD BE FACTOR(S) FOR, FOR IONISING RADIATION AND THE CLINICAL ONSET OF MYASTHENIA GRAVIS.

30. The Council considered whether there was evidence for ionising radiation causing or worsening myasthenia gravis using the RMA available materials.

31. The Council agreed that there was no SMSE in the pool of information to suggest that ionising radiation can cause or worsen myasthenia gravis.

32. The Council found no SMSE to support an association or biological proven mechanism for ionising radiation causing or worsening myasthenia gravis.

33. The council found no SMSE between ionising radiation exposure of the bone marrow or another tissue and the development or worsening of myasthenia gravis.

34. Ionising radiation has been shown to cause immunosuppression. However the Council found no evidence for ionising radiation up-regulating the immune system, reducing self-tolerance, or causing an autoimmune disease such as myasthenia gravis.

35. As, in the Council's view, the reasonable hypothesis test was not met, the balance of probabilities test necessarily could not be met.

THE COUNCIL'S ANALYSIS OF THE NEW INFORMATION

36. As mentioned above, in conducting a review, the Council is unable to (and so did not) consider information which was not available to (not before) the RMA at the relevant time. However, having formed the view that there was nothing in the pool of information which pointed to the relevant association, and being mindful of the Applicant's comments, the Council considered whether in its view there was a basis for recommending to the RMA that it undertake a new investigation.

37. The Council has neither the capacity nor the jurisdiction to perform an investigative function, including undertaking a comprehensive literature search. However, Council was not aware of any new information which it could consider on a preliminary basis.

38. The Applicant did refer new information to the Council which it considered to determine whether, in the Council's view, it warranted the Council making any directions or recommendations to the RMA.

39. In the Council's view any such direction or recommendation should only be made by the Council if it formed the view that the new information comprised SMSE as defined in section 5AB(2) of the VEA being information which:

- was information epidemiologists would consider appropriate to take into account; 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 (as appropriate; see paragraphs [9] and [10] above for the relevant associations).

40. New information was provided by the Applicant focusing on the known physiology of B- and T-lymphocytes and their possible role in myasthenia gravis. Although these may suggest a possible role for ionising radiation, these presented materials did not deal with the effect of ionising radiation on autoimmunity or myasthenia gravis. These and other considered materials did not demonstrate an association

between ionising radiation and myasthenia gravis at the level of sound medical or sound epidemiological evidence.

DECISION

41. Having considered the RMA's available materials, the applicant's presented materials, and the Council's further review of peer reviewed literature, the Council found that in relation to the RMA SoPs No. 75 and No. 76 concerning Myasthenia Gravis, there was no SMSE on which the RMA could have relied to amend either of the SoPs to include a factor or factors for exposure to ionising radiation and the clinical onset and/or clinical worsening of myasthenia gravis.

APPENDICES

APPENDIX A:

TABLE 1: MATERIAL BEFORE THE RMA

Australian Government
Repatriation Medical Authority

MYASTHENIA GRAVIS

RMA ID Number	Reference List for # 210 - 2 as at 13 October 2015

71606	Ahmad O, Hafner J (2014). How to treat myasthenia gravis. Australian Doctor, : 23 - 5, 39-41.
73845	Ahmed A, Simmons Z (2008). Drugs which may exacerbate or induce Myasthenia Gravis: A clinician's guide. The Internet Journal of Neurology, 10(2): 10 pages.
40995	Alevizos B, Gatzonis S, Anagnostara Ch (2006). [Letter] Myasthena gravis disclosed by lithium carbonate. J Neuropsychiatry & Clinical Neurosciences, 18(3): 427-429.
73847	Alkhawajah NM, Oger J (2013). Late-onset myasthenia gravis: a review when incidence in older adults keeps increasing. Muscle & Nerve, 48(5): 705-10.
73848	Andersen JB, Heldal AT, Engeland A, et al (2014). Myasthenia gravis epidemiology in a national cohort; combining multiple disease registries. Acta Neurologica Scandinavica, 129(Supp 198): 26-31.
38882	Aragones JM, Bolibar I, Bonfill X, Bufill E, Mummany A, Alonso F, et al (2003). Myasthenia gravis - a higher than expected incidence in the elderly. Neurology, 60: 1024-1026.
73849	Atassi N, Amato AA (2008). Muscle-specific kinase (MuSK) antibody-associated myasthenia gravis after bone marrow transplantation. Muscle & Nerve, 38(2): 1074-5.
38996	Barohn RJ (2003). Standards of measurements in myasthenia gravis. Ann NY Acad Sci, 998: 432-439.
38965	Baron F, Sadzot B, Wang F, Beguin Y (1998). Myasthenia gravis without chronic GVHD after allogeneic bone marrow transplantation. Case report. Bone Marrow Transplantation, 22: 197-200.
39379	Bateman DN, Dyson EH (1986). Quinine toxicity. Adv Drug React Ac Pois Rev, 4: 215-233.
73850	Batocchi AP, Majolini L, Evoli A, et al (1999). Course and treatment of myasthenia gravis during pregnancy. Neurology, 52(3): 447-52.
73142	Berrih-Aknin S, Frenkian-Cuvelier M, Eymard B (2014). Diagnostic and clinical classification of autoimmune myasthenia gravis. J Autoimmun, 48-49(2014): 143-8.
40985	Blanton CL, Sawyer RA (1993). Myasthenia gravis by another name: an elusive imposter. Survey of Ophthalmology, 38(2): 219-226.

38981	Bolay H, Karabudak R, Varli K, Saribas O (1997). [Letter] Low dose interferon-a is safe in patients with myasthenia gravis. J Neurosurgery and Psychiatry, 62(3): 302-303. Retrieved 8 June 2006, from 302-303
38970	Boneva N, Brenner T, Argov Z (2000). Gabapentin may be hazardous in myasthenia gravis. Muscle & Nerve, 23: 1204-1208.
41419	Booker HE, Chun RWM, Sanguino M (1970). Myasthenia gravis syndrome associated with trimethadione. JAMA, 212(13): 2262-2263.
38977	Bora I, Karli N, Bakar M, Zarifoglu M, turan F, Ogul E (1997). Myasthenia gravis following IFN-a-2a treatment. European Neurology, 38(1): 68.
38963	Borodic G (1998). Myasthenic crisis after botulinum toxin. The Lancet, 352: 1832.
38983	Brogia G, Reynaud L, Gentile I, Cerini R, Ciampi R, Dello Russo M, Piazza M (2001). Myasthenia gravis during low-dose IFN-a therapy for chronic hepatitis C. Journal of Interferon and Cytokine Research, 21: 469-470.
39298	Brumback RA (1981). The Neuromuscular Junction Part II: Myasthenia Gravis. Am Fam Physician, 23(2): 126-133.
41064	Brumlik J, Jacobs RS (1974). Myasthenia gravis associated with diphenylhydantoin therapy for epilepsy. Le Journal Canadien Des Sciences Neurologiques, 1(2): 127-129.
38884	Cartwright MS, Jeffrey DR, Nuss GR, Donofrio PD (2004). Statin-associated exacerbation of myasthenia gravis. Neurology, 63: 2188.
73912	Cavalcante P, Bernasconi P, Mantegazza R (2012). Autoimmune mechanisms in mysathenia gravis. Curr Opin Neurol, 25(5): 621-9.
73631	Cavalcante P, Cufi P, Mantegazza R, et al (2013). Etiology of myasthenia gravis: innate immunity signature in pathological thymus. Autoimmun Rev, 12(9): 863-74.
39014	Ceremuga TE, Yao X-L, McCabe JT (2002). Etiology, mechanisms, and anesthesia implications of autoimmune myasthenia gravis. AANA Journal, 70(4): 301-310.
73851	Chaudhry SA, Vignarajah B, Koren G (2012). Myasthenia gravis during pregnancy. Canadian Family Physician, 58: 1346-9.
39303	Cherasse A, Maillefert J-F, Henlin J-L, Chassard D, Tavernier C (1999). Tiopronin-induced myasthenia. Revue du Rhumatisme (English Edition), 66(4): 238-239.
40869	Ciafaloni E, Massey JM (2004). Myasthenia gravis and pregnancy. Neurol Clin, 22: 771-782.
74100	De Bleecker J, De Reuck J, Quatacker J, et al (1991). Persisting chloroquine-induced myasthenia? Acta Clin Belg, 46(6): 401-6.
73535	Demling RH (2009). Burns and other thermal injuries. Current Diagnosis & Treatment: Surgery, 13th Edition, 14: 1-17. McGraw Hill.
73626	Dilsaver SC (1987). Lithium down-regulates nicotinic receptors in skeletal muscle: cause of lithium associated myasthenic syndrome? J Clin Psychopharmacol, 7(5): 369-70.
38877	Dionisiotis J, Zoukos Y, Thomaides T (2004). [Letter] Development of myasthenia gravis in two patients with multiple sclerosis following interferon B treatment. J Neurol Neurosurg Psychiatry, 75: 1076.
40872	Djelmis J, Sostarko M, Mayer D, Ivanisevic M (2002). Myasthenia gravis in pregnancy: report on 69 cases. Eur J Obstet Gynecol Reprod Biol, 104: 21-25.
74908	Dournon N, Buffet P, Caumes E, et al (2012). Case report: Artesunate for severe acute Plasmodium falciparum infection in a patient with myasthenia gravis. Am J Trop Med Hyg, 87(3): 435-6.

38967	Dowell JE, Moots PL, Stein RS (1999). Myasthenia gravis after allogeneic bone marrow transplantation for lymphoblastic lymphoma. Case report. Bone Marrow Transplantation, 24: 1359-1361.
38475	Drachman DB (1994). Myasthenia Gravis. Medical Progress. New England Jnl Medicine, 330(25): 1797-1810.
38975	Engel WK (2003). [Letter] Reversible ocular myasthenia gravis or mitochondrial myopathy from statins? The Lancet, 361: 85-86.
38984	Evoki A, Di Schino C, Marsili F, Punzi C (2002). Successful treatment of myathenia gravis with tacrolimus. Muscle & Nerve, 25: 111-114.
73523	Farrugia ME, Vincent A (2010). Autoimmune mediated neuromuscular junction defects. Curr Opin Neurol, 23(5): 489-95.
40732	Ferrero S, Pretta S, Nicoletti A, Petrera P, Ragni N (2005). Myasthenia gravis: management issues during pregnancy. Eur J Obstet Gynecol Reprod Biol, 121: 129-138.
38973	Fischer PR, Walker E (2002). Myasthenia and malaria medicines. J Travel Med, 9: 267-268.
40541	Foulks CJ Maj (1981). Myasthenia gravis presenting as laryngeal stridor after exposure to chlorine gas. Southern Medical Journal, 74(11): 1423-1424.
38971	Fraenkel PG, Rutkove SB, Matheson JK, Fowkes M, Cannon ME, Patti M-E, Atkins MB, Gollob JA (2002). Induction of myasthenia gravis, myositis, and insulin-dependent diabetes mellitus by high-dose interleukin-2 in a patient with renal cell cancer. Journal of Immunotherapy, 25(4): 373-378.
38980	Frese A, Bethke F, Ludemann P, Stogbauer F (2000). [Letter] Development of myasthenia gravis in a patient with multiple sclerosis during treatment with glatiramer acetate. J Neurol, 247: 713.
38885	Fujimaki K, Takasaki H, Koharazawa H, Takabayashi M, Yamaji S, et al (2005). Idiopathic thrombocytopenic purpura and myasthenia gravis after fludarabine treatment for chronic lymphocytic leukemia. Leukemia & Lymphoma, 46(7): 1101-1102.
73147	Gale J, Danesh-Meyer HV (2014). Statins can induce myasthenia gravis. J Clin Neurosci, 21(2): 195-7.
73531	Gilhus NE (2012). Myasthenia and the neuromuscular junction. Curr Opin Neurol, 25(5): 523-9.
38879	Goldenberg WD, O'Connor RE (2006). Emergent Management of Myasthenia Gravis. . Retrieved 6 June 2006, from www.emedicine.com/EMERG/topic325.htm
73496	Grover KM, Sripathi N, Elias SB (2012). Muscle-specific kinase-antibody-positive myasthenia gravis after autologous bone marrow transplantation. J Clin Neuromuscul Dis, 13(3): 146-8.
40868	Gurjar M, Jagia M (2005). Successful management of pregnancy-aggravated myasthenic crisis after complete remission of the disease. Aust NZ J Obstet Gynaecol, 45: 331-332.
39382	Gurtubay IG, Morales G, Arechaga O, Gallego J (1999). Development of myasthenia gravis after interferon alpha therapy. Electromyography & Clinical Neurophysiology, 39(2): 75-78.
39302	Gyawali P, Rangedara DC (1999). Iatrogenically revealed myasthenia gravis. IJCP, 53(8): 645.
39442	Halfon P, Levy M, San Marco M, Gerolami V, Khiri H, et al (1996). Myasthenia gravis and hepatitis C virus infection. Journal of Viral Hepatitis, 3(6): 329-332.

38958	Harrison's Internal Medicine (2006). Myasthenia gravis and other diseases of the neuromuscular junction: introduction. Harrison's Internal Medicine, 15th Edition, 3 366. McGraw Hill.
38960	He F, Xu H, Qin F, Xu L, Huang J, He X (1998). Intermediate myasthenia syndrome following acute organophosphates poisoning - an analysis of 21 cases. Human & Experimental Toxicology, 17: 40-45.
73497	Hearn J, Tiliakos NA (1986). Myasthenia gravis caused by penicillamine and chloroquine therapy for rheumatoid arthritis. South Med J, 79(9): 1185-6.
73853	Heidarzadeh Z, Mousavi S-A, Ostovan VR, et al (2014). Muscle-specific kinase antibody associated myasthenia gravis after bone marrow transplantation. Neuromuscular Disorders, 24(2014): 148-50.
73856	Hill M, Moss P, Wordsworth P, et al (1999). T cell responses to D-penicillamine in drug-induced myasthenia gravis: recognition of modified DR1 :peptide complexes. J Neuroimmunol, 97(1-2): 146-53.
40871	Hoff JM, Daltveit AK, Gilhus NE (2003). Myasthenia gravis. Consequences for pregnancy, delivery, and the newborn. Neurology, 61: 1362-6.
40634	Hoff JM, Daltveit AK, Gilhus NE (2004). Asymptomatic myasthenia gravis influences pregnancy and birth. Eur J Neurol, 11: 559-562.
40488	Hudson BJ (1988). Positive response to edrophonium in death adder (Acanthophis Antarcticus) envenomation. Aust NZ J Med, 18(6): 792-794.
73894	Huijbers MG, Lipka AF, Plomp JJ, et al (2014). Pathogenic immune mechanisms at the neuromuscular synapse: the role of specific antibody-binding epitopes in myasthenia gravis. J Intern Med, 275(1): 12-26.
39297	Iwase T, Iwase C (2006). Systemic effect of local and small-dose botulinum toxin injection to unmask subclinical myasthenia gravis. Graefe's Arch Clin Exp Ophthalmol, 244: 415-416.
40870	Jackson CE (2003). The effect of myasthenia gravis on pregnancy and the newborn. Neurology, 61: 1459-1460.
73895	Jallouli M, Saadoun D, Eymard B, et al (2012). The association of systemic lupus erythematosus and myasthenia gravis: a series of 17 cases, with a special focus on hydroxychloroquine use and a review of the literature. J Neurol, 259(7): 1290-7.
73896	Jones SC, Sorbello A, Boucher RM (2011). Fluoroquinolone-associated myasthenia gravis exacerbation: evaluation of postmarketing reports from the US FDA adverse event reporting system and a literature review. Drug Saf, 34(10): 839-47.
40733	Juel VC (2004). Myasthenia gravis: management of myasthenic crisis and perioperative care. Seminars in Neurology, 24(1): 75-81.
38959	Kato Y, Naito Y, Narita Y, Kuzuhara S (1997). D-penicillamine-induced myasthenia gravis ina case of eosinophilic fasciitis. Short report. Journal of the Neurological Sciences, 146: 85-86.
38993	Keesey JC (2004). Clinical evaluation and management of myasthenia gravis. Muscle & Nerve, 29: 484-505.
38881	Komal Kumar RN, Patil SA, Taly AB, Nirmala M, Sinha S, Arunodaya GR (2004). Effect of D-penicillamine on neuromuscular junction in patients with Wilson disease. Nuerology, 63: 935-936.
39241	Koski SL, Mackey JR, Mackey DS (1998). Myasthenia gravis post allogeneic bone marrow transplantation revisited. Bone Marrow Transplantation, 22(4): 403-404.

38972	Kotani A, Takahashi A, Koga H, Morita R, Fukuyama H, et al (2002). Myasthenia gravis after allogeneic bone marrow transplantation treated with mycophenolate mofetil monitored by peripheral blood OX40+ CD4+ T cells. Eur J Heamatol, 69: 318-320.
39625	Kurian MA, King MD (2003). Antibody positive myasthenia gravis following treatment with carbamazepine - a chance association? Neuropediatrics, 34: 276-277.
41366	Kwan S-Y, Lin J-H, Su M-S (2000). Coexistence of epilepsy, myasthenia gravis and psoriasis vulgaris. Chinese Medical Journal, 63(2): 153-157.
41061	Lacomis D (2005). Myasthenic crisis. Neurocritical Care, 3: 189-194.
73524	Lang B, Vincent A (2009). Autoimmune disorders of the neuromuscular junction. Curr Opin Pharmacol, 9(3): 336-40.
73898	Le Panse R, Berrih-Aknin S (2013). Autoimmune myasthenia gravis: autoantibody mechanisms and new developments on immune regulation. Curr Opin Neurol, 26(5): 569-76.
73525	Leite MI, Jacob S, Viegas S, et al (2008). IgG1 antibodies to acetylcholine receptors in "seronegative" myasthenia gravis. Brain, 131(Pt 7): 1940-52.
38978	Lensch E, Faust J, Nix WA, Wandel E (1966). [Letter] Myasthenia gravis after interferon-alpha treatment. Muscle & Nerve, : 927-8.
38883	Levinson AI, Song D, Gaulton G, Zheng Y (2004). The intrathymic pathogenesis of myasthenia gravis. Clinical & Development Immunology, 11(3/4): 215-220.
39008	Lopez-Cano M, Ponseti-Bosch JM, Espin-Basany E, Sanchez-Garcia JL, Armengol-Carrasco M (2003). Clinical and pathologic predictors of outcome in thymoma-associated myasthenia gravis. Ann Thorac Surg, 76: 1643-9.
38964	Mackey JR, Desai S, Larratt L, Cwik V, Nabholtz J-M (1997). Myasthenia gravis in association with allogeneic bone marrow transplantation: clinical observations, therapeutic implications and review of literature. Case report. Bone Marrow Transplantation, 19: 939-942.
38478	Magni G, Micaglio GF, Lalli R, Bejato L, Candeago MR, Merskey H, Angelini C (1988). Psychiatric disturbances associated with myasthenia gravis. Acta Psychiatr Scand, 77: 443-445.
71607	Manda K, Glasgow A, Paape D, et al (2012). Effects of ionizing radiation on the immune system with special emphasis on the interaction of dendritic and T cells. Front Oncol, article 102, 2: 1-9.
73902	Mao ZF, Yang LX, Mo XA, et al (2011). Frequency of autoimmune diseases in myasthenia gravis: a systematic review. Int J Neurosci, 121(3): 121-9.
39007	Marx A, Muller-Hermelink HK, Strobel P (2003). The role of thymomas in the development of myasthenia gravis. Ann NY Acad Sci, 998: 223-226.
39445	Mase G, Zorzon M, Biasutti E, Vitrani B, Cazzato G, Urban F, Frezza M (1996). [Letter] Development of myasthenia gravis during interferon-a-treatment for anti-HCV positive chronic hepatitis. Journal of Neurology, Neurosurgery, and Psychiatry, 60(3): 348-349.
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TABLE 2: NEW MATERIAL WHICH WAS NOT BEFORE THE RMA

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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. **Professor Lin Fritschi** was the Presiding Councillor for this review. She is Professor of Epidemiology at Curtin University, and a National Health and Medical Research Council Senior Research Fellow. Her research interests include, cancer epidemiology, occupational causes of cancer, and exposure assessment in epidemiological studies**.**

4. **The other members of the Council were:**

– **Dr Rick Tinker,** who is the Director of the Assessment and Advice Section, Australian Radiation Protection and Nuclear Safety Agency. He is responsible for assessing the impact on health of radiation exposures to workers, the public, and the environment in planned, existing, and emergency situations. He has over 20 years' experience in research and measurement of radiation and assessment of health impacts and has played a leading role in advancing radiation protection in Australia.

– **Associate Professor John Worthington** is a Conjoint Associate Professor of UNSW Australia and a Senior Staff Specialist Neurologist at Liverpool Hospital. John's research interests include Stroke and TIA, their prevention, management and outcomes as well as the epidemiology of neurological diseases. He is a co-author of the first Australian epidemiological study of symptomatic Myasthenia Gravis.

The Legislation

5. 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 [4] and the balance of

[4] The reasonable hypothesis test is set out in section 196B(2) of the VEA which provides;

probabilities test. [5] 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). [6]

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.

5 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.

6 See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA.