



Australian Government

Repatriation Medical Authority

REPATRIATION MEDICAL AUTHORITY

STATEMENT OF REASONS

S196B(9) *VETERANS' ENTITLEMENTS ACT 1986*

**DECISION NOT TO AMEND THE CURRENT STATEMENTS OF PRINCIPLES
CONCERNING ROTATOR CUFF SYNDROME FOLLOWING A REVIEW**

STATEMENTS OF PRINCIPLES INSTRUMENT NOS. 100 & 101 OF 2014

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PART I INTRODUCTION

1. The Repatriation Medical Authority (the Authority) has decided not to amend the Statements of Principles concerning rotator cuff syndrome Instrument Nos. 100 & 101 of 2014, under subsection 196B(9) of the *Veterans' Entitlements Act 1986* (the Act), following an investigation which was notified in the *Commonwealth of Australia Gazette* on 9 December 2015.
2. The Authority concluded that the new sound medical-scientific evidence is not sufficient to justify an amendment to Statements of Principles Instrument Nos. 100 & 101 of 2014, already determined in respect of rotator cuff syndrome.

PART II BACKGROUND TO THE INVESTIGATION

3. A request dated 10 October 2015 was received from a veteran seeking a review of the Statements of Principles concerning rotator cuff syndrome with respect to the inclusion of a new factor concerning statins.
4. In support of the request, the applicant provided the following:
 - An excerpt from the Australia Adverse Drug Reactions Bulletin (Vol 27, no.3), listing muscle disorders as one of the reactions associated with statins
 - A published article concerning statins and adverse effects on tendon repair:
Esenkaya I, Unay K. (2012) Tendon, tendon healing, hyperlipidemia and statins. *Muscles Ligaments Tendons J*, Vol 1(4): 169-71.
5. The Authority, under subsection 196B(7A) of the Act, decided to review the contents of the Statements of Principles Instrument Nos. 100 & 101 of 2014, to find out if there was new information in respect of "statins" as a factor in rotator cuff syndrome.
6. The investigation notice was signed by the Chairperson of the Authority on 4 December 2015 and was gazetted in accordance with section 196G of the Act in the *Commonwealth of Australia Gazette* on 9 December 2015. Submissions were invited from persons and organisations wishing to make a submission by 20 May 2016.
7. Statements of Principles Instrument Nos. 100 & 101 of 2014 concerning rotator cuff syndrome did not have any factors relating to "statins".

PART III SUBMISSIONS RECEIVED BY THE AUTHORITY PURSUANT TO SECTION 196F

8. Following notification of its investigation, the Authority did not receive any information from persons eligible to make submissions pursuant to section 196F of the Act.

PART IV EVIDENCE/INFORMATION AVAILABLE TO THE REPATRIATION MEDICAL AUTHORITY

9. The following information was available to the Authority.
 - 9.1. The information supplied by the applicant.
 - 9.2. Literature searches were conducted using the Ovid search engine from 1996 to March Week 2 2016, limited to English language. The search terms were: rotator cuff syndrome, Achilles tendinopathy, epicondylitis, tennis elbow, trochanteric bursitis, gluteal tendinopathy, patellar tendinopathy, tendonitis, tendinopathy OR tendon rupture AND statins or HMG CoA reductase inhibitors. The above search was supplemented by PubMed searches, internet searches, manual searches of reference lists and extracts from relevant sections of textbooks.
 - 9.3. Medical or scientific publications as set out in the bibliography attached hereto.
10. A briefing paper concerning rotator cuff syndrome, Achilles tendinopathy and bursitis, epicondylitis, patellar tendinopathy, and trochanteric bursitis and gluteal tendinopathy prepared for presentation to the Authority by a Medical Researcher of the Secretariat.

PART V SOUND MEDICAL-SCIENTIFIC EVIDENCE

11. The Statements of Principles are determined on the basis of the available "sound medical-scientific evidence" as defined in section 5AB(2) of the Act which states:

*"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."*

PART VI REASONS FOR THE DECISION

12. While the request for the investigation pertained specifically to statins as a cause of rotator cuff syndrome, statins can potentially affect all muscles and tendons. For this reason, and given the limited evidence available specifically concerning statins and rotator cuff syndrome, evidence concerning statins and other tendons was considered relevant to the investigation.
13. A systemic review of four available comparative studies, including two large cohort studies, found no evidence of an increase in risk of tendinopathy or tendon rupture in statin users. One of the studies, a large prospective cohort study, found that statin use was actually associated with a significantly lower risk of developing rotator cuff disease.

14. Tendinitis or tendon rupture has been described in several case reports and a case series of 96 patients. However, statins are often prescribed for people with hypercholesterolaemia and diabetes mellitus, as well as people of older age. As these clinical features are also risk factors for tendon rupture, it is possible that they are the real cause of the associations observed in the case reports.
15. Evidence from animal and mechanistic studies is mixed in terms of negative and positive effects on tendons. Statins may have positive effects on tendons by reducing stored cholesterol, however statins may also increase the risk of tendon rupture by impairing remodelling of the extracellular matrix. Statin treatment reduces Achilles tendon thickness, possibly by reducing inflammation and/or lipid containing macrophages. A study in rats found that statins enhance rotator cuff healing, possibly by stimulating the acute inflammatory phase.
16. Overall, the evidence does not point to a causal association between statin use and rotator cuff syndrome. While there are some case reports of statins and tendonitis or tendon rupture, better quality evidence from comparative studies has not demonstrated an increase in the risk of these outcomes. Chance, bias or confounding are likely to account for the observed associations.

PART VII DECISION

17. At its meeting on 8 June 2016 the Authority decided not to amend the Statements of Principles in respect of rotator cuff syndrome for the purposes of subsections 196B(2), (3) and (8) of the Act as the Authority concluded, for the reasons set out above, that the new sound medical-scientific evidence is not sufficient to justify an amendment to the Statements of Principles already determined in respect of rotator cuff syndrome.



Professor Nicholas Saunders AO
Chairperson
Repatriation Medical Authority

24 June 2016

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