

REPATRIATION MEDICAL AUTHORITY

STATEMENT OF REASONS

RE: DECISION NOT TO MAKE STATEMENTS OF PRINCIPLES FOR XEROSTOMIA

Part I	Introduction	3
Part II	Background to the Investigation	3
Part III	Submissions received by the Authority pursuant to section 196F	3
Part IV	Evidence/Information Available to the Repatriation Medical Authority	4
Part V	Disease and injury	4
Part VI	Reasons for the decision	5
Part VII	Decision	6
Part VII	I Bibliography	7

PART I INTRODUCTION

- The Repatriation Medical Authority (the Authority) does not propose to make Statements of Principles under subsections 196B (2) or (3) of the Veterans' Entitlements Act 1986 (the Act) in respect of xerostomia. The Authority published a notice of an investigation into xerostomia in the Commonwealth of Australia Gazette on 13 March 2018.
- 2. Having carried out the investigation as notified, the Authority declares that it does not propose to make a Statement of Principles concerning xerostomia for the purposes of subsection 196B(2) or (3) of the Act. The Authority is of the view that xerostomia is a sign or symptom of an underlying disease, injury or medical treatment. Hence it is not a disease or injury as defined in section 5D of the Act and is not a condition for which a Statement of Principles could be determined.

PART II BACKGROUND TO THE INVESTIGATION

- 3. A request dated 3 January 2018, was received from "a person eligible to make a claim for pension under Part II or Part IV of the *Veterans' Entitlements Act 1986* ('the VEA')", seeking an investigation of xerostomia to find out whether Statements of Principles may be determined concerning the condition. The applicant did not provide any relevant sound medical-scientific evidence in support of the request.
- 4. On 7 February 2018, the Authority agreed to notify an investigation under subsection 196G(1) of the Act to ascertain if Statements of Principles concerning xerostomia could be determined. An investigation notice was placed in the *Commonwealth of Australia Gazette* on 13 March 2018.

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

5. Following notification of its investigation, the Authority received one submission from an organisation eligible to make submissions pursuant to section 196F of the Act as follows:

A submission from the Australian Dental Association (ADA) was received from on 23 July 2018. The submission was in the form of a letter summarising the position of the ADA in relation to xerostomia. The submission provided a reference to one published peer-reviewed article:

• Hopcraft MS, Tan C (2010). Xerostomia: an update for clinicians, Aust Dent J, 55(3): 238-44.

This article refers to a number of medications which can cause xerostomia. In relation to causes of xerostomia other than medications, no specific sound medical-scientific evidence was provided, although the letter listed a number of other risk factors.

PART IV EVIDENCE/INFORMATION AVAILABLE TO THE REPATRIATION MEDICAL AUTHORITY

- 6. The following information was available to the Authority.
 - a) Literature searches were conducted using the Ovid search engine from 1996 to July Week 2 2018, limited to English language. The search terms were: Sjogren's Syndrome/ or sicca.mp. or Xerostomia/ or dry mouth.mp. The search was supplemented by specific searches for xerostomia/dry mouth and various factors of interest, internet searches, manual searches of reference lists and extracts from relevant sections of textbooks.
 - b) A discussion paper prepared by a research officer of the Secretariat for the February 2018 Repatriation Medical Authority meeting.
 - c) A briefing paper dated August 2018 prepared for presentation to the Authority by a research officer of the Secretariat.
 - d) The submission from the Australian Dental Association.

PART V DISEASE AND INJURY

7. Section 5D of the Act defines disease and injury relevantly as follows:

disease means:

- (a) any physical or mental ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
- (b) the recurrence of such an ailment, disorder, defect or morbid condition;

but does not include:

- (c) the aggravation of such an ailment, disorder, defect or morbid condition; or
- (d) a temporary departure from:
 - (i) the normal physiological state; or
 - (ii) the accepted ranges of physiological or biochemical measures;

that results from normal physiological stress (for example, the effect of exercise on blood pressure) or the temporary effect of extraneous agents (for example, alcohol on blood cholesterol levels);

[and]

injury means any physical or mental injury (including the recurrence of a physical or mental injury) but does not include:

- (a) a disease; or
- (b) the aggravation of a physical or mental injury.
- 8. The proper meaning of what constitutes a disease or injury for the purposes of determining a Statement of Principles under the VEA is to be determined by the

Authority.¹ In considering these terms, the Authority had regard to ordinary dictionary definitions, medical dictionaries, and its expert knowledge. In determining whether a condition is a disease or injury as defined, the Authority is entitled to have regard to the connotations of the words 'disease or injury' as used and understood in their ordinary meaning.²

9. Being familiar with the ordinary English meanings of the terms that are used in section 5D, the Authority considered whether xerostomia was "a particular kind of injury, disease or death" within the ordinary meaning of those terms. It also relied upon its expert medical knowledge and had regard to internationally agreed concepts in considering whether xerostomia may represent a disease state.

PART VI REASONS FOR THE DECISION

- 10. Xerostomia means the complaint of dry mouth, often accompanied by difficulty eating and swallowing. It may occur in the presence of hyposalivation (abnormally low secretion of saliva), but is not synonymous with hyposalivation.
- 11. Xerostomia (with or without hyposalivation), is a symptom of an underlying disease process involving the salivary glands or a side-effect of a treatment for another disease or injury. Kinds of disease, injuries or circumstances that could result in the symptom of xerostomia include autoimmune disorders such as Sjogren syndrome, radiation therapy involving the salivary glands, damage to the nerve supply to the salivary glands, certain infections, systemic diseases or drugs (especially drugs which have anticholinergic effects).
- 12. In the absence of these underlying disease processes or treatment of an underlying disease or injury, no pathophysiological entity that could form the basis of the reported symptom of xerostomia has been established.
- 13. Xerostomia is a subjective phenomenon, and the sound medical-scientific evidence does not address the issue of how severe the problem must be, or how long a person must experience this symptom, in order that it can be said that he or she has a disease.
- 14. Treatment for xerostomia is available, but treatment is available for many symptoms (for example pain and nausea) and the availability of treatment does not by itself determine whether or not a condition is a disease or injury. Where treatment of the underlying cause is available and effective, the xerostomia will resolve.
- 15. The Statements of Principles for tooth wear and dental caries already include xerostomia as a factor. There are existing Statements of Principles for a range of diseases or injuries that can cause xerostomia, including the Statements of Principles for diabetes mellitus, sleep apnoea, Parkinson's disease, sarcoidosis, hepatitis C, and human immunodeficiency virus. There are also existing Statements of Principles for a

¹ Ryan D, SC (2013) Memorandum. Available at http://www.rma.gov.au/foi/what.htm.

² Comcare v Mooi (1996) 42 ALD 495.

range of diseases or injuries that can cause xerostomia as result of their treatment, including various malignancies of the head and neck (which may be treated with radiation) and various psychiatric conditions (which may be treated with drugs which have anticholinergic side effects).

16. A claim for xerostomia can be determined using existing Statements of Principles for the underlying disease or injury that is causing the xerostomia. If there are no Statements of Principles for the underlying disease or injury, claims can still be lodged with the Department of Veterans' Affairs, and are determined by having regard to available medical opinions.

PART VII DECISION

- 17. The Authority is of the view that xerostomia is a symptom that can arise in a variety of circumstances and is not satisfied on the balance of probabilities that xerostomia is a particular kind of disease or injury within the meaning of section 5D of the Act.
- 18. The Authority declares that it does not propose to make a Statement of Principles concerning xerostomia, for the purposes of subsection 196B(2) or (3) of the Act..

hatan

Professor Nicholas Saunders AO Chairperson Repatriation Medical Authority

26 October 2018

PART VIII BIBLIOGRAPHY

Comcare v Mooi (1996) 42 ALD 495.

Ryan D, SC (2013) Memorandum. Available at http://www.rma.gov.au/foi/what.htm.