

Statement of Principles

concerning

STEATOHEPATITIS
(Reasonable Hypothesis)

(No. 86 of 2022)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

Dated 23 August 2022.

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| The Common Seal of theRepatriation Medical Authoritywas affixed to this instrumentat the direction of: |
| Professor Terence Campbell AMChairperson |

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1. Name

This is the Statement of Principles concerning *steatohepatitis*

 *(Reasonable Hypothesis)* (No. 86 of 2022).

1. Commencement

 This instrument commences on 19 September 2022.

1. Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

1. Repeal

The Statement of Principles concerning steatohepatitis No. 79 of 2013 (Federal Register of Legislation No. F2013L01898) made under subsection 196B(2) of the VEA is repealed.

1. Application

This instrument applies to a claim to which section 120A of the VEA or section 338 of the *Military Rehabilitation and Compensation Act 2004* applies.

1. Schedules

Any item in a Schedule to this Instrument has effect according to its terms.

1. Kind of injury, disease or death to which this Statement of Principles relates
	1. This Statement of Principles is about steatohepatitis and death from steatohepatitis.

Meaning of **steatohepatitis**

* 1. For the purposes of this Statement of Principles, steatohepatitis:
		1. means the presence of fatty change and inflammation of the liver with hepatocyte injury, with or without fibrosis; and
		2. includes alcoholic steatohepatitis and non-alcoholic steatohepatitis; and
		3. excludes:
			1. alpha-1 antitrypsin deficiency;
			2. biliary obstruction;
			3. haemochromatosis; and
			4. Wilson's disease.

Death from **steatohepatitis**

* 1. For the purposes of this Statement of Principles, steatohepatitis,in relation to a person, includes death from a terminal event or condition that was contributed to by the person's steatohepatitis.

Note: ***terminal event*** is defined in the Schedule 1 – Dictionary.

1. Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical‑scientific evidence that indicates that steatohepatitis and death from steatohepatitis can be related to relevant service rendered by veterans, members of Peacekeeping Forces, or members of the Forces under the VEA, or members under the MRCA.

Note: ***MRCA***, ***relevant service*** and ***VEA*** are defined in the Schedule 1 – Dictionary.

1. Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting steatohepatitis or death from steatohepatitis with the circumstances of a person's relevant service:

* 1. having hypertension before the clinical onset of steatohepatitis;
	2. having diabetes mellitus at the time of the clinical onset of steatohepatitis;
	3. being obese at the time of the clinical onset of steatohepatitis;

Note: ***being obese*** is defined in the Schedule 1 – Dictionary.

* 1. having rapid weight loss causing protein-calorie malnutrition within the 18 months before the clinical onset of steatohepatitis;

Note: ***rapid weight loss*** is defined in the Schedule 1 – Dictionary.

* 1. undergoing jejunoileal bypass surgery before the clinical onset of steatohepatitis;
	2. receiving total parenteral nutrition for at least 3 months within the 1 year before the clinical onset of steatohepatitis;

Note: ***total parenteral nutrition*** is defined in the Schedule 1 – Dictionary.

* 1. having dyslipidaemia at the time of the clinical onset of steatohepatitis;

Note: ***dyslipidaemia*** is defined in the Schedule 1 – Dictionary.

* 1. for males, consuming at least 55 kilograms of alcohol within any 5 year period before the clinical onset of steatohepatitis;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

* 1. for females, consuming at least 30 kilograms of alcohol within any 5 year period before the clinical onset of steatohepatitis;

Note: Alcohol consumption is calculated utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

* 1. having hyperuricaemia at the time of the clinical onset of steatohepatitis;

Note: ***hyperuricaemia*** is defined in the Schedule 1 – Dictionary.

* 1. taking irinotecan for at least the 30 days before the clinical onset of steatohepatitis;
	2. taking a drug specified in the Schedule 2 - Drugs of this Instrument, that cannot be ceased or substituted, for at least the 30 days before the clinical onset of steatohepatitis;
	3. taking a drug that cannot be ceased or substituted and which is associated in the individual with:
		1. the development of steatohepatitis within 30 days of first taking the drug; and
		2. the redevelopment of steatohepatitis on rechallenge with the same drug;
	4. inability to obtain appropriate clinical management for steatohepatitis.
1. Relationship to service
	1. The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.
	2. The factor set out in subsection 9(14) applies only to material contribution to, or aggravation of, steatohepatitis where the person's steatohepatitis was suffered or contracted before or during (but did not arise out of) the person's relevant service.
2. Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

* 1. if a factor referred to in section 9 applies in relation to a person; and
	2. that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Schedule 1 - Dictionary

Note: See Section 6

1. Definitions
	1. In this instrument:
		1. ***being obese*** means:
			1. having a Body Mass Index (BMI) of 30 or greater; or
			2. for males, having a waist circumference exceeding 102 centimetres; or
			3. for females, having a waist circumference exceeding 88 centimetres.

Note: ***BMI*** is also defined in the Schedule 1 - Dictionary.

* + 1. ***BMI*** means W/H2 where:
			1. W is the person's weight in kilograms; and
			2. H is the person's height in metres.
		2. ***dyslipidaemia*** means persistently abnormal blood lipid levels, diagnosed by a medical practitioner and evidenced by:
			1. a serum high density lipoprotein cholesterol level less than 1.0 mmol/L; or
			2. a serum low density lipoprotein cholesterol level greater than 4.0 mmol/L; or
			3. a serum triglyceride level greater than or equal to 2.0 mmol/L; or
			4. a total serum cholesterol level greater than 5.5 mmol/L; or
			5. the regular administration of drug therapy to normalise blood lipid levels.
		3. ***hyperuricaemia*** means a serum uric acid level of at least 0.40 mmo/L.
		4. ***MRCA*** means the *Military Rehabilitation and Compensation Act 2004*.
		5. ***rapid weight loss*** means reduction of body mass by at least 20 percent, within a continuous period of no more than 6 months.

Note: Situations which can be associated with rapid weight loss and protein-calorie malnutrition include anorexia nervosa, acute starvation and surgery causing significant diarrhoea or malabsorption (for example, extensive small bowel resection and pancreaticoduodenectomy).

* + 1. ***relevant service*** means:
			1. operational service under the VEA;
			2. peacekeeping service under the VEA;
			3. hazardous service under the VEA;
			4. British nuclear test defence service under the VEA;
			5. warlike service under the MRCA; or
			6. non-warlike service under the MRCA.

Note: ***MRCA*** and ***VEA*** are also defined in the Schedule 1 - Dictionary.

* + 1. ***steatohepatitis***—see subsection 7(2).
		2. ***terminal event*** means the proximate or ultimate cause of death and includes the following:
			1. pneumonia;
			2. respiratory failure;
			3. cardiac arrest;
			4. circulatory failure; or
			5. cessation of brain function.
		3. ***total parenteral nutrition*** means a total nutrient admixture providing calories, amino acids, electrolytes, fluids, minerals, trace elements and vitamins, by the intravenous route.
		4. ***VEA*** means the *Veterans' Entitlements Act 1986*.

Schedule 2 - Drugs

Note: See Section 6, Subsection 9(12)

1. Specified drugs

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| --- | --- | --- |
| 1. amiodarone
 | 1. antiretroviral agents
 | 1. asparaginase
 |
| 1. beta-blockers
 | 1. calcium channel blockers
 | 1. carbamazepine
 |
| 1. cisplatin
 | 1. diethylamino-ethyoxyhexestrol
 | 1. diethylstilbestrol
 |
| 1. estrogen
 | 1. fialuridine
 | 1. fluorouracil
 |
| 1. glucocorticoids
 | 1. linezolid
 | 1. methotrexate
 |
| 1. oxaliplatin
 | 1. pegaspargase
 | 1. perhexiline
 |
| 1. raloxifene
 | 1. rifampicin
 | 1. tamoxifen
 |
| 1. tetracycline antibiotics
 | 1. tianeptine
 | 1. toremifene
 |
| 1. troglitazone
 | 1. valproate
 |  |