



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MALIGNANT NEOPLASM OF THE
GALLBLADDER
(Reasonable Hypothesis)
(No. 36 of 2024)

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

Dated 26 April 2024.

Professor Terence Campbell AM
Chairperson
by and on behalf of
The Repatriation Medical Authority

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1 Name

This is the Statement of Principles concerning *malignant neoplasm of the gallbladder (Reasonable Hypothesis)* (No. 36 of 2024).

2 Commencement

This instrument commences on 28 May 2024.

3 Authority

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

4 Repeal

The Statement of Principles concerning malignant neoplasm of the gallbladder (No. 89 of 2015) (Federal Register of Legislation No. F2015L00921) made under subsections 196B(2) and (8) of the VEA is repealed.

5 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.

6 Definitions

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

7 Kind of injury, disease or death to which this Statement of Principles relates

- (1) This Statement of Principles is about malignant neoplasm of the gallbladder and death from malignant neoplasm of the gallbladder.

Meaning of malignant neoplasm of the gallbladder

- (2) For the purposes of this Statement of Principles, malignant neoplasm of the gallbladder:
- (a) means a primary malignant neoplasm arising from the epithelial cells of the gallbladder; and
 - (b) includes:
 - (i) adenocarcinoma of the gallbladder;
 - (ii) adenosquamous carcinoma of the gallbladder;
 - (iii) carcinoma of the gallbladder;
 - (iv) clear cell carcinoma of the gallbladder;
 - (v) poorly cohesive carcinoma of the gallbladder;

- (vi) squamous cell carcinoma of the gallbladder; and
 - (vii) carcinoma in situ of the gallbladder; and
- (c) excludes:
- (i) soft tissue sarcoma;
 - (ii) malignant neoplasm of the bile duct;
 - (iii) neuroendocrine carcinoma of the gallbladder;
 - (iv) non-Hodgkin lymphoma; and
 - (v) Hodgkin lymphoma.
- (3) While malignant neoplasm of the gallbladder attracts ICD-10-AM code C23, in applying this Statement of Principles the meaning of malignant neoplasm of the gallbladder is that given in subsection (2).
- (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM)*, Tenth Edition, effective date of 1 July 2017, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-296-4.

Death from malignant neoplasm of the gallbladder

- (5) For the purposes of this Statement of Principles, malignant neoplasm of the gallbladder, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's malignant neoplasm of the gallbladder.

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

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that malignant neoplasm of the gallbladder and death from malignant neoplasm of the gallbladder 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.

9 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 malignant neoplasm of the gallbladder or death from malignant neoplasm of the gallbladder with the circumstances of a person's relevant service:

- (1) having cholelithiasis before clinical onset;

- (2) having a chronic biliary infection of *Salmonella typhi* or *Salmonella paratyphi* detected on at least 2 separate occasions, at least a month apart, and within 2 years before clinical onset;

Note: A biliary infection by *Salmonella* can be ascertained by detection of specific antibodies in serum or detection of *Salmonella sp.* in stool samples.
- (3) having primary sclerosing cholangitis before clinical onset;

Note: *primary sclerosing cholangitis* is defined in the Schedule 1 - Dictionary.
- (4) having had an intravascular injection of Thorotrast (thorium dioxide) before clinical onset;
- (5) having porcelain gallbladder before clinical onset;

Note: *porcelain gallbladder* is defined in the Schedule 1 – Dictionary.
- (6) being obese for at least 5 years within the 20 years before clinical onset;

Note: *being obese* is defined in the Schedule 1 – Dictionary.
- (7) being overweight for at least 5 years within the 20 years before clinical onset;

Note: *being overweight* is defined in the Schedule 1 – Dictionary.
- (8) having diabetes mellitus for at least 5 years before clinical onset;
- (9) smoking at least 20 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before clinical onset, and:
 - (a) smoking commenced at least 5 years before clinical onset; and
 - (b) where smoking has ceased, clinical onset has occurred within 20 years of cessation;

Note: *one pack-year* is defined in the Schedule 1 - Dictionary.
- (10) having non-alcoholic fatty liver disease for at least 5 years within the 20 years before clinical onset;
- (11) having chronic infection with hepatitis B or C virus before clinical onset;

Note: *chronic infection with hepatitis B or C virus* is defined in the Schedule 1 - Dictionary.
- (12) being exposed to high levels of dietary aflatoxins, on more days than not, for a period of at least 5 years within the 30 years before clinical onset;

Note: *being exposed to high levels of dietary aflatoxins* is defined in the Schedule 1 – Dictionary.
- (13) inability to obtain appropriate clinical management of malignant neoplasm of the gallbladder before clinical worsening.

10 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 subsections 9(13) applies only to material contribution to, or aggravation of, malignant neoplasm of the gallbladder where the person's malignant neoplasm of the gallbladder was suffered or contracted before or during (but did not arise out of) the person's relevant service.

11 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

In this instrument:

being exposed to high levels of dietary aflatoxins means living or working in a geographic region or country where food items, particularly grains and nuts, are regularly contaminated with high levels of aflatoxins, and consuming these food items as a major part of the diet.

Note: Geographic regions or countries where food items are regularly contaminated with high levels of aflatoxins include sub-Saharan Africa, Southeast Asia, Eastern Mediterranean and China.

being obese means:

- (a) having a Body Mass Index (BMI) of 30 or greater; or
- (b) for males, having a waist circumference exceeding 102 centimetres; or
- (c) for females, having a waist circumference exceeding 88 centimetres.

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

being overweight means having a Body Mass Index (BMI) of 25 or greater.

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

BMI means W/H^2 where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

chronic infection with hepatitis B or C virus means infection with hepatitis B or C virus resulting in a chronic infection of at least six months duration, and which must be confirmed by laboratory testing for hepatitis B or C serological or nucleic acid markers.

malignant neoplasm of the gallbladder—see subsection 7(2).

MRCAs means the *Military Rehabilitation and Compensation Act 2004*.

one pack-year means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

porcelain gallbladder means intramural calcification of the gallbladder commonly associated with chronic cholecystitis.

primary sclerosing cholangitis means an autoimmune disorder characterised by a progressive, inflammatory, sclerosing process in the bile ducts.

relevant service means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

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

terminal event means the proximate or ultimate cause of death and includes the following:

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

VEA means the *Veterans' Entitlements Act 1986*.