



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MALIGNANT NEOPLASM OF THE
BILE DUCT
(Reasonable Hypothesis)
(No. 53 of 2024)

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

Dated 21 June 2023.

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 bile duct (Reasonable Hypothesis)* (No. 53 of 2024).

2 Commencement

This instrument commences on 23 July 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 bile duct No. 69 of 2015 (Federal Register of Legislation No. F2015L00654) made under subsections 196B(2) and (8) of the VEA is repealed.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 bile duct and death from malignant neoplasm of the bile duct.

Meaning of malignant neoplasm of the bile duct

- (2) For the purposes of this Statement of Principles, malignant neoplasm of the bile duct:
- (a) means a primary malignant neoplasm arising from the epithelial cells of the intrahepatic or extrahepatic bile ducts (including the ampulla of Vater and the cystic duct); and
 - (b) includes:
 - (i) cholangiocarcinoma;
 - (ii) Klatskin tumour (hilar cholangiocarcinoma);
 - (iii) squamous cell carcinoma of the bile duct;
 - (iv) adenosquamous carcinoma of the bile duct;
 - (v) undifferentiated carcinoma of the bile duct;

- (vi) lymphoepithelioma-like cholangiocarcinoma; and
 - (vii) adenocarcinoma of ampulla of Vater; and
- (c) excludes:
- (i) soft tissue sarcoma;
 - (ii) malignant neoplasm of the gallbladder;
 - (iii) neuroendocrine carcinoma of the gallbladder;
 - (iv) non-Hodgkin lymphoma; and
 - (v) Hodgkin lymphoma.
- (3) While malignant neoplasm of the bile duct attracts ICD-10-AM codes, C22.1, C24.0 and C24.1, in applying this Statement of Principles the meaning of malignant neoplasm of the bile duct 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 bile duct

- (5) For the purposes of this Statement of Principles, malignant neoplasm of the bile duct, 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 bile duct.

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 bile duct and death from malignant neoplasm of the bile duct 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 bile duct or death from malignant neoplasm of the bile duct with the circumstances of a person's relevant service:

- (1) having an infestation of the hepatobiliary tract with the liver flukes *Clonorchis sinensis*, *Opisthorchis viverrini* or *Opisthorchis felineus* before clinical onset;

- (2) having primary sclerosing cholangitis before clinical onset;
- (3) having inflammatory bowel disease before clinical onset;
- (4) having cholelithiasis, choledocholithiasis or hepatolithiasis before clinical onset;

Note: Cholelithiasis relates to the formation of stones in the gallbladder, choledocholithiasis relates to stones in the bile ducts, and hepatolithiasis relates to stones in the bile ducts inside the liver.
- (5) having had an injection of Thorotrast (thorium dioxide) before clinical onset;
- (6) having cirrhosis of the liver before clinical onset;
- (7) having chronic infection with the hepatitis B virus at the time of clinical onset;

Note: *chronic infection with hepatitis B virus* is defined in the Schedule 1 – Dictionary.
- (8) having chronic infection with the hepatitis C virus at the time of clinical onset;

Note: *chronic infection with hepatitis C virus* is defined in the Schedule 1 – Dictionary.
- (9) having diabetes mellitus for at least 5 years before clinical onset;
- (10) being obese for at least 5 years within the 20 years before clinical onset;

Note: *being obese* is defined in the Schedule 1 – Dictionary.
- (11) inhaling respirable asbestos fibres in an enclosed space:
 - (a) for a cumulative period of at least 1,000 hours before the clinical onset of malignant neoplasm of the intrahepatic bile duct; and
 - (b) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
 - (c) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the intrahepatic bile duct;

Note: hazardous asbestos fibres (chrysotile (white asbestos), amosite (brown asbestos), crocidolite (blue asbestos)) are an asbestos fibre less than 3 micrometers in diameter and at least 5 micrometers long (with a width to length ratio of greater than 1:3).
- (12) inhaling respirable asbestos fibres in an open environment:
 - (a) for a cumulative period of at least 3,000 hours before the clinical onset of malignant neoplasm of the intrahepatic bile duct; and
 - (b) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
 - (c) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the intrahepatic bile duct;

Note: hazardous asbestos fibres (chrysotile (white asbestos), amosite (brown asbestos), crocidolite (blue asbestos)) are an asbestos fibre less than 3 micrometres in diameter and at least 5 micrometres long (with a width to length ratio of greater than 1:3).

- (13) undergoing solid organ transplantation excluding corneal transplant, at least 5 years before clinical onset;
- (14) smoking at least 30 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before clinical onset, and:
 - (a) smoking commenced at least 5 years before the clinical onset of malignant neoplasm of the bile duct; or
 - (b) where smoking has ceased, the clinical onset of malignant neoplasm of the bile duct has occurred within 20 years of cessation;

Note: *one pack-year* is defined in the Schedule 1 - Dictionary.

- (15) having non-alcoholic fatty liver disease for at least 5 years within the 20 years before clinical onset;
- (16) consuming at least 400 kilograms of alcohol at least 5 years before clinical onset;
- (17) inhaling, ingesting or having cutaneous contact with 1,2-dichloropropane for at least 1,000 ppm-years at least 2 years before clinical onset;

Note: *ppm-years* is defined in the Schedule 1 – Dictionary.

- (18) having an infection with *Helicobacter pylori*, *Helicobacter bilis* or *Helicobacter hepaticus* at least 10 years before clinical onset;
- (19) having IgG4 sclerosing cholangitis before the clinical onset of malignant neoplasm of the bile duct;
- (20) having evidence of infection with Epstein-Barr virus before the clinical onset of lymphoepithelioma-like bile duct cancer;
- (21) inability to obtain appropriate clinical management for malignant neoplasm of the bile duct 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 subsection 9(21) applies only to material contribution to, or aggravation of, malignant neoplasm of the bile duct where the person's malignant neoplasm of the bile duct 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 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.

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 the hepatitis B virus means:

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

chronic infection with the hepatitis C virus means:

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

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

MRCA 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.

ppm-years means parts per million multiplied by years of exposure.

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*.