



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
**MALIGNANT NEOPLASM OF THE BILE
DUCT**

No. 70 of 2015

for the purposes of the

Veterans' Entitlements Act 1986
and
Military Rehabilitation and Compensation Act 2004

Title

1. This Instrument may be cited as Statement of Principles concerning malignant neoplasm of the bile duct No. 70 of 2015.

Determination

2. The Repatriation Medical Authority under subsection **196B(3)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 22 of 2007, as amended, concerning malignant neoplasm of the bile duct; and
 - (b) determines in its place this Statement of Principles.

Kind of injury, disease or death

3.
 - (a) This Statement of Principles is about **malignant neoplasm of the bile duct** and **death from malignant neoplasm of the bile duct**.
 - (b) For the purposes of this Statement of Principles, "**malignant neoplasm of the bile duct**" means a primary malignant neoplasm arising from the cells of the intrahepatic or extrahepatic bile duct, including the ampulla of Vater and the cystic duct. This definition excludes soft tissue sarcoma, carcinoid tumour, non-Hodgkin's lymphoma and Hodgkin's lymphoma.

- (c) Malignant neoplasm of the bile duct attracts ICD-10-AM code C22.1 or C24.
- (d) In the application of this Statement of Principles, the definition of "**malignant neoplasm of the bile duct**" is that given at paragraph 3(b) above.

Basis for determining the factors

- 4. On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not 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 or members of the Forces under the VEA, or members under the *Military Rehabilitation and Compensation Act 2004* (the MRCA).

Factors that must be related to service

- 5. Subject to clause 7, at least one of the factors set out in clause 6 must be related to the relevant service rendered by the person.

Factors

- 6. The factor that must exist before it can be said that, on the balance of probabilities, **malignant neoplasm of the bile duct** or **death from malignant neoplasm of the bile duct** is connected with the circumstances of a person's relevant service is:
 - (a) having chronic infestation of the hepatobiliary tract with the liver flukes *Clonorchis sinensis* or *Opisthorchis viverrini* before the clinical onset of malignant neoplasm of the bile duct; or
 - (b) having primary sclerosing cholangitis before the clinical onset of malignant neoplasm of the bile duct; or
 - (c) having ulcerative colitis before the clinical onset of malignant neoplasm of the bile duct; or
 - (d) having cholelithiasis before the clinical onset of malignant neoplasm of the bile duct; or
 - (e) having received a cumulative equivalent dose of at least 0.5 sievert of ionising radiation to the bile ducts at least ten years before the clinical onset of malignant neoplasm of the bile duct; or
 - (f) having cirrhosis of the liver before the clinical onset of malignant neoplasm of the bile duct; or
 - (g) having chronic infection with the hepatitis B virus at the time of the clinical onset of malignant neoplasm of the bile duct; or
 - (h) having chronic infection with the hepatitis C virus at the time of the clinical onset of malignant neoplasm of the bile duct; or
 - (i) having diabetes mellitus for at least five years before the clinical onset of malignant neoplasm of the bile duct; or

- (j) inability to obtain appropriate clinical management for malignant neoplasm of the bile duct.

Factors that apply only to material contribution or aggravation

- 7. Paragraph 6(j) 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 not arising out of) the person's relevant service.

Inclusion of Statements of Principles

- 8. In this Statement of Principles if a relevant factor applies and that factor includes an injury or disease in respect of which there is a Statement of Principles then the factors in that last mentioned Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Other definitions

- 9. For the purposes of this Statement of Principles:

"chronic infection with the hepatitis B virus" means:

- (a) the presence of HBsAg or hepatitis B virus (HBV) deoxyribonucleic acid (DNA), in the absence of IgM Anti-HBc on serological testing; or
- (b) positive serology for hepatitis B plus evidence of chronic hepatitis or other chronic changes on liver biopsy;

"chronic infection with the hepatitis C virus" means:

- (a) positive polymerase chain reaction testing for hepatitis C virus (HCV) ribonucleic acid (RNA);
- (b) the presence of anti-HCV and elevated serum aminotransferase levels, more than six months after evidence of an acute hepatitis C infection; or
- (c) positive serology for hepatitis C plus evidence of chronic hepatitis or other chronic changes on liver biopsy;

"cumulative equivalent dose" means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation-related sources and radiation from nuclear explosions or accidents;

"death from 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;

"ICD-10-AM code" means a number assigned to a particular kind of injury or disease in The International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM), Eighth Edition, effective date of 1 July 2013, copyrighted by the Independent Hospital Pricing Authority, and having ISBN 978-1-74128-213-9;

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

"relevant service" means:

- (a) eligible war service (other than operational service) under the VEA;
- (b) defence service (other than hazardous service and British nuclear test defence service) under the VEA; or
- (c) peacetime service under the MRCA;

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

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

Application

- 10.** This Instrument applies to all matters to which section 120B of the VEA or section 339 of the MRCA applies.

Date of effect

- 11.** This Instrument takes effect from 1 June 2015.

Dated this **first** day of **May**
2015

The Common Seal of the)
Repatriation Medical Authority)
was affixed at the direction of:)



PROFESSOR NICHOLAS SAUNDERS AO
CHAIRPERSON