

Statement of Principles
concerning

MALIGNANT NEOPLASM OF THE LIVER

No. 21 of 2011

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 liver No. 21 of 2011.

Determination

2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 171 of 1996 concerning malignant neoplasm of the liver; 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 liver** and **death from malignant neoplasm of the liver**.
 - (b) For the purposes of this Statement of Principles, "**malignant neoplasm of the liver**" means a primary malignant neoplasm arising from the hepatocytes. This definition excludes soft tissue sarcoma, carcinoid tumour, malignant neoplasm of the intrahepatic bile duct, non-Hodgkin's lymphoma and Hodgkin's lymphoma.
 - (c) Malignant neoplasm of the liver attracts ICD-10-AM code C22.0.
 - (d) In the application of this Statement of Principles, the definition of "**malignant neoplasm of the liver**" is that given at paragraph 3(b) above.

Basis for determining the factors

4. The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that **malignant neoplasm of the liver** and **death from malignant neoplasm of the liver** 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 *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 as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting **malignant neoplasm of the liver** or **death from malignant neoplasm of the liver** with the circumstances of a person's relevant service is:
 - (a) having chronic infection with the hepatitis B virus before the clinical onset of malignant neoplasm of the liver; or
 - (b) having chronic infection with the hepatitis C virus before the clinical onset of malignant neoplasm of the liver; or
 - (c) having cirrhosis of the liver before the clinical onset of malignant neoplasm of the liver; or
 - (d) drinking at least 110 kilograms of alcohol within any ten year period before the clinical onset of malignant neoplasm of the liver; or
 - (e) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of malignant neoplasm of the liver, and where smoking has ceased, the clinical onset has occurred within 20 years of cessation; or
 - (f) consuming food containing high concentrations of aflatoxins on more days than not, for a period of at least ten years within the 20 years before the clinical onset of malignant neoplasm of the liver; or
 - (g) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the liver at least five years before the clinical onset of malignant neoplasm of the liver; or
 - (h) having type 2 diabetes mellitus for at least the five years before the clinical onset of malignant neoplasm of the liver; or

- (i) being obese for at least the five years before the clinical onset of malignant neoplasm of the liver; or
- (j) using the combined oral contraceptive pill for a continuous period of at least three years before the clinical onset of malignant neoplasm of the liver, and where the use of the combined oral contraceptive pill has ceased, the clinical onset of malignant neoplasm of the liver has occurred within 30 years of cessation; or
- (k) inhaling a cumulative dose of at least 1250 ppm-years of gaseous vinyl chloride at least five years before the clinical onset of malignant neoplasm of the liver; or
- (l) inhaling gaseous vinyl chloride for a cumulative period of at least 5000 hours while working in the production or processing of vinyl chloride monomer or polyvinyl chloride, at least five years before the clinical onset of malignant neoplasm of the liver; or
- (m) having steatohepatitis before the clinical onset of malignant neoplasm of the liver; or
- (n) taking or being treated with anabolic-androgenic steroids for a continuous period of at least three years, and to a cumulative total of at least 14 grams, within the 20 years before the clinical onset of malignant neoplasm of the liver; or
- (o) being treated with immunosuppressive drugs for solid organ transplantation or for stem cell transplantation, for a continuous period of at least two years before the clinical onset of malignant neoplasm of the liver; or
- (p) being infected with human immunodeficiency virus before the clinical onset of malignant neoplasm of the liver; or
- (q) chewing betel quid or areca nut on more days than not, for at least five years before the clinical onset of malignant neoplasm of the liver, and where chewing of betel quid or areca nut has ceased, the clinical onset has occurred within 20 years of cessation; or
- (r) being exposed to arsenic as specified before the clinical onset of malignant neoplasm of the liver, where the first exposure to arsenic occurred at least ten years before the clinical onset of malignant neoplasm of the liver; or
- (s) inability to obtain appropriate clinical management for malignant neoplasm of the liver.

Factors that apply only to material contribution or aggravation

7. Paragraph 6(s) applies only to material contribution to, or aggravation of, malignant neoplasm of the liver where the person's malignant neoplasm of the liver 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:

"alcohol" is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink;

"being exposed to arsenic as specified" means:

- (a) consuming drinking water with an average arsenic concentration of at least 50 micrograms per litre for a cumulative period of at least ten years;
- (b) consuming drinking water resulting in a cumulative total arsenic exposure equivalent to having consumed drinking water containing at least 50 micrograms per litre for at least ten years; or
- (c) having clinical evidence of chronic arsenic toxicity;

"being obese" means an increase in body weight by way of fat accumulation which results in a Body Mass Index (BMI) of thirty or greater.

The $BMI = W/H^2$ and where:

W is the person's weight in kilograms and

H is the person's height in metres;

"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;

"combined oral contraceptive pill" means contraceptive pills containing oestrogen and progestogen;

"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 (Sv). For the purposes of this SOP, 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 liver" 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 liver;

"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), Seventh Edition, effective date of 1 July 2010, copyrighted by the National Centre for Classification in Health, Sydney, NSW, and having ISBN 978 1 74210 154 5;

"immunosuppressive drugs" means drugs or agents administered for the purpose of suppressing immune responses. This definition excludes inhaled or topical steroids;

"pack-years of cigarettes, or the equivalent thereof in other tobacco products" means a calculation of consumption where one pack-year of cigarettes equals twenty tailor-made cigarettes per day for a period of one calendar year, or 7300 cigarettes. One tailor-made cigarette approximates one gram of tobacco or one gram of cigar or pipe tobacco by weight. One pack-year of tailor-made cigarettes equates to 7300 cigarettes, or 7.3 kilograms of smoking tobacco by weight. Tobacco products means either cigarettes, pipe tobacco or cigars smoked, alone or in any combination;

"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) warlike service under the MRCA; or
- (e) non-warlike 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 120A of the VEA or section 338 of the MRCA applies.

Date of effect

11. This Instrument takes effect from 30 March 2011.

Dated this *Twenty-second* day of *March* 2011

The Common Seal of the)
Repatriation Medical Authority)
was affixed to this instrument)
in the presence of:)

KEN DONALD
CHAIRPERSON