



Australian Government

Repatriation Medical Authority

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Our Ref: RMA030/02; RMA144/03;
RMA244/02; RMA346/01;

19 February 2015

RE: NOTIFICATION OF FINDINGS OF INVESTIGATIONS UNDER SECTION 196G OF THE *VETERANS' ENTITLEMENTS ACT 1986*

You may be aware that the Repatriation Medical Authority (the Authority) notified investigations under section 196G of the *Veterans' Entitlements Act 1986* (the Act) concerning the following conditions:

- ***cardiomyopathy***
- ***familial hypertrophic cardiomyopathy***
- ***chicken pox***
- ***malignant neoplasm of the gallbladder***

The Authority had regard to all of the sound medical-scientific evidence available to it, including the sound medical-scientific evidence previously considered. Having regard to the body of sound medical-scientific evidence, the Authority is of the view that the existing Statements of Principles concerning ***cardiomyopathy*** and the existing Statements of Principles concerning ***familial hypertrophic cardiomyopathy*** should be revoked, and new Statements of Principles determined concerning ***cardiomyopathy*** which cover familial hypertrophic cardiomyopathy.

Having regard to both standards of proof, the Authority is of the view that the sound medical-scientific evidence does not support the inclusion of factors as detailed in the attached schedule in the proposed Statements of Principles concerning ***cardiomyopathy***, ***chickenpox*** and ***malignant neoplasm of the gallbladder***.

The Authority considers that the enclosed draft Statements of Principles concerning ***cardiomyopathy***, ***chickenpox*** and ***malignant neoplasm of the gallbladder*** reflect the current sound-medical scientific evidence now available to it after carrying out the investigation as notified.

As the proposed Statements of Principles will not include factors in terms referred to in the attached schedule, the Authority is providing you with the opportunity to make written representations before it proceeds to determine the Statements of Principles under ss196B(2), (3) and (8) of the Act.

Your written representations, including any referenced sound medical-scientific evidence which you may wish to have considered, should be received by the Authority by close of business on 15 May 2015. All representations received will be considered by the Authority at its first meeting after that date and prior to the Authority's determination of new Statements of Principles concerning *cardiomyopathy*, *chickenpox* and *malignant neoplasm of the gallbladder*.

In respect of sound medical-scientific evidence, your attention is drawn to s5AB of the Act where that term is defined as follows:

"Information about a particular kind of injury, disease or death is taken to be sound medical-scientific evidence if:

(a) the information:

- (i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or*
- (ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and*

(b) in the case of information about how that kind of injury, disease or death may be caused - meets the applicable criteria for assessing causation currently applied in the field of epidemiology."

To assist you please find enclosed the following documents:

1. Copies of existing Statements of Principles;
2. Copies of proposed Statements of Principles; and
3. The reference lists of medical-scientific material considered by the Authority for the purposes of these reviews.

If you have any queries on any aspect of this correspondence, I may be contacted by telephone on (07) 3815 9418.

Yours sincerely,



Sandra Pollitt
Deputy Registrar
Repatriation Medical Authority



Statement of Principles

concerning

MALIGNANT NEOPLASM OF THE GALLBLADDER

Instrument No. 67 of 2007 as amended

made under section 196B(2) of the

Veterans' Entitlements Act 1986

This compilation was prepared on 22 July 2011 taking into account Amendment of Statement of Principles concerning MALIGNANT NEOPLASM OF THE GALLBLADDER (*Instrument No. 51 of 2011*)

Prepared by the Repatriation Medical Authority Secretariat, Brisbane

Statement of Principles
concerning

**MALIGNANT NEOPLASM OF THE
GALLBLADDER**

No. 67 of 2007

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 gallbladder No. 67 of 2007.

Determination

2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 36 of 1999 concerning malignant neoplasm of the gallbladder; 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 gallbladder** and **death from malignant neoplasm of the gallbladder**.
 - (b) For the purposes of this Statement of Principles, "**malignant neoplasm of the gallbladder**" means a primary malignancy arising from the cells of the gallbladder. This definition excludes soft tissue sarcoma, carcinoid tumour, non-Hodgkin's lymphoma and Hodgkin's lymphoma.

- (c) Malignant neoplasm of the gallbladder attracts ICD-10-AM code C23.
- (d) In the application of this Statement of Principles, the definition of **"malignant neoplasm of the gallbladder"** 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 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 *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 gallbladder** or **death from malignant neoplasm of the gallbladder** with the circumstances of a person's relevant service is:
 - (a) having cholelithiasis before the clinical onset of malignant neoplasm of the gallbladder; or
 - (b) being a chronic typhoid carrier before the clinical onset of malignant neoplasm of the gallbladder; or
 - (c) having ulcerative colitis before the clinical onset of malignant neoplasm of the gallbladder; or
 - (d) having sclerosing cholangitis before the clinical onset of malignant neoplasm of gallbladder; or
 - (e) having received a cumulative dose of at least 0.1 sievert of ionising radiation to the gallbladder from internal deposition of radioactive nuclides at least five years before the clinical onset of malignant neoplasm of the gallbladder;

- (f) inability to obtain appropriate clinical management for malignant neoplasm of the gallbladder.

Factors that apply only to material contribution or aggravation

- 7. Paragraph 6(f) 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 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:

"a chronic typhoid carrier" means a person with evidence of excretion of *Salmonella typhi* in stools or urine (or repeated positive bile or duodenal string cultures) for longer than one year after the onset of acute typhoid fever;

"death from 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;

"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), Fifth Edition, effective date of 1 July 2006, copyrighted by the National Centre for Classification in Health, Sydney, NSW, and having ISBN 1 86487 772 3;

"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;

"sclerosing cholangitis" means a disorder characterised by a progressive, inflammatory, sclerosing and obliterative process in the bile duct;

"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 9 May 2007.

Notes to Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 67 of 2007)

The Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 67 of 2007) in force under section 196B(2) of the *Veterans' Entitlements Act 1986*, as shown in this compilation is amended as indicated in the Tables below.

Table of Instruments

| Title | Date of FRLI registration | Date of commencement | Application, saving or transitional provisions |
|--|----------------------------|----------------------|--|
| <i>Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 67 of 2007)</i> | 2 May 2007 F2007L01192 | 9 May 2007 | |
| <i>Amendment of Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 51 of 2011)</i> | 18 May 2011 F2011L00804 | 25 May 2011 | |

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

| Provision affected | How affected |
|--------------------|-------------------------------|
| Clause 6(e) | rs. Instrument No. 51 of 2011 |



Statement of Principles

concerning

MALIGNANT NEOPLASM OF THE GALLBLADDER

Instrument No. 68 of 2007 as amended

made under section 196B(3) of the

Veterans' Entitlements Act 1986

This compilation was prepared on 22 July 2011 taking into account Amendment of Statement of Principles concerning MALIGNANT NEOPLASM OF THE GALLBLADDER (*Instrument No. 52 of 2011*)

Prepared by the Repatriation Medical Authority Secretariat, Brisbane

Statement of Principles
concerning

**MALIGNANT NEOPLASM OF THE
GALLBLADDER**

No. 68 of 2007

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 gallbladder No. 68 of 2007.

Determination

2. The Repatriation Medical Authority under subsection **196B(3)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 37 of 1999 concerning malignant neoplasm of the gallbladder; 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 gallbladder** and **death from malignant neoplasm of the gallbladder**.
 - (b) For the purposes of this Statement of Principles, "**malignant neoplasm of the gallbladder**" means a primary malignancy arising from the cells of the gallbladder. This definition excludes

soft tissue sarcoma, carcinoid tumour, non-Hodgkin's lymphoma and Hodgkin's lymphoma.

- (c) Malignant neoplasm of the gallbladder attracts ICD-10-AM code C23.
- (d) In the application of this Statement of Principles, the definition of "**malignant neoplasm of the gallbladder**" 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 gallbladder** and **death from malignant neoplasm of the gallbladder** 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 gallbladder** or **death from malignant neoplasm of the gallbladder** is connected with the circumstances of a person's relevant service is:
 - (a) having cholelithiasis before the clinical onset of malignant neoplasm of the gallbladder; or
 - (b) being a chronic typhoid carrier before the clinical onset of malignant neoplasm of the gallbladder; or
 - (c) having ulcerative colitis before the clinical onset of malignant neoplasm of the gallbladder; or
 - (d) having sclerosing cholangitis before the clinical onset of malignant neoplasm of gallbladder; or
 - (e) having received a cumulative dose of at least 0.5 sievert of ionising radiation to the gallbladder from internal deposition of radioactive nuclides at least ten years before the clinical onset of malignant neoplasm of the gallbladder; or

- (f) inability to obtain appropriate clinical management for malignant neoplasm of the gallbladder.

Factors that apply only to material contribution or aggravation

7. Paragraph 6(f) 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 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:

"a chronic typhoid carrier" means a person with evidence of excretion of *Salmonella typhi* in stools or urine (or repeated positive bile or duodenal string cultures) for longer than one year after the onset of acute typhoid fever;

"death from 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;

"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), Fifth Edition, effective date of 1 July 2006, copyrighted by the National Centre for Classification in Health, Sydney, NSW, and having ISBN 1 86487 772 3;

"relevant service" means:

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

"sclerosing cholangitis" means a disorder characterised by a progressive, inflammatory, sclerosing and obliterative process in the bile duct;

"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 9 May 2007.

Notes to Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 68 of 2007)

The Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 68 of 2007) in force under section 196B(3) of the *Veterans' Entitlements Act 1986*, as shown in this compilation is amended as indicated in the Tables below.

Table of Instruments

| Title | Date of FRLI registration | Date of commencement | Application, saving or transitional provisions |
|--|----------------------------|----------------------|--|
| <i>Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 68 of 2007)</i> | 2 May 2007 F2007L001193 | 9 May 2007 | |
| <i>Amendment of Statement of Principles concerning malignant neoplasm of the gallbladder (Instrument No. 52 of 2011)</i> | 18 May 2011 F2011L00802 | 25 May 2011 | |

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

| Provision affected | How affected |
|--------------------|-------------------------------|
| Clause 6(e) | rs. Instrument No. 52 of 2011 |