



Australian Government
Repatriation Medical Authority

EXPLANATORY STATEMENT

**STATEMENT OF PRINCIPLES CONCERNING
MALIGNANT NEOPLASM OF THE GALLBLADDER
(REASONABLE HYPOTHESIS) (NO. 36 OF 2024)**

VETERANS' ENTITLEMENTS ACT 1986
MILITARY REHABILITATION AND COMPENSATION ACT 2004

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

Background

2. The Repatriation Medical Authority (the Authority), under subsection 196B(8) of the *Veterans' Entitlements Act 1986* (the VEA), repeals Instrument No. 89 of 2015 (Federal Register of Legislation No. F2015L00921) determined under subsections 196B(2) and (8) of the VEA concerning **malignant neoplasm of the gallbladder**.
3. The 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 particular kinds of service. The Authority has therefore determined pursuant to subsection 196B(2) of the VEA a Statement of Principles concerning **malignant neoplasm of the gallbladder (Reasonable Hypothesis)** (No. 36 of 2024). This Instrument will in effect replace the repealed Statement of Principles.

Purpose and Operation

4. The Statement of Principles will be applied in determining claims under the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA).
5. The Statement of Principles sets out the factors that must as a minimum exist, and which of those factors must be related to the following kinds of service rendered by a person:
 - operational service under the VEA;
 - peacekeeping service under the VEA;
 - hazardous service under the VEA;
 - British nuclear test defence service under the VEA;
 - warlike service under the MRCA;
 - non-warlike service under the MRCA,

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 that service. The Statement of Principles has been determined for the purposes of both the VEA and the MRCA.

6. This Instrument results from an investigation notified by the Authority in the Government Notices Gazette of 1 November 2022 concerning malignant neoplasm of the gallbladder in accordance with section 196G of the VEA. The investigation involved an examination of the sound medical-scientific evidence now available to the Authority, including the sound medical-scientific evidence it has previously considered.
7. The contents of this Instrument are in similar terms as the repealed Instrument. Comparing this Instrument and the repealed Instrument, the differences include:
 - adopting the latest revised Instrument format, which commenced in 2015;
 - specifying a day of commencement for the Instrument in section 2;
 - revising the definition of 'malignant neoplasm of the gallbladder' in subsection 7(2);
 - revising ICD-10-AM codes for 'malignant neoplasm of the gallbladder' in subsection 7(3);
 - revising the reference to 'ICD-10-AM code' in subsection 7(4);
 - revising the factors in Section 9 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 veteran's relevant service. The revision is required to reflect advances in sound medical scientific evidence that have occurred since the repealed Statement of Principles was made;
 - deleting factor concerning ionising radiation;
 - new factor in subsection 9(4) concerning having had an intravascular injection of Thorotrast (thorium dioxide);
 - new factor in subsection 9(6) concerning being overweight;
 - new factor in subsection 9(10) concerning having non-alcoholic fatty liver disease;
 - new factor in subsection 9(11) concerning having chronic infection with hepatitis B or C virus;
 - new factor in subsection 9(10) concerning being exposed to high levels of dietary aflatoxins;
 - new definitions of 'being exposed to high levels of aflatoxins', 'being overweight', 'BMI', 'chronic infection with hepatitis B or C' and 'one pack-year' in Schedule 1 - Dictionary;
 - revising the definition of 'being obese' in Schedule 1 - Dictionary; and
 - deleting the definitions of 'cumulative equivalent dose' and 'pack-years of cigarettes, or the equivalent thereof in other tobacco products'.

Consultation

8. Prior to determining this Instrument, the Authority advertised its intention to undertake an investigation in relation to malignant neoplasm of the gallbladder in the Government Notices Gazette of 1 November 2022, and circulated a copy of the notice of intention to investigate to a wide range of organisations representing veterans, service personnel and their dependants. The Authority invited submissions from the Repatriation Commission, the Military Rehabilitation and Compensation Commission, organisations and persons referred to in section 196E of the VEA, and any person having expertise in the field. No submissions were received for consideration by the Authority in relation to the investigation.

9. On 22 December 2023, the Authority wrote to organisations representing veterans, service personnel and their dependants regarding the proposed Instrument and the medical-scientific material considered by the Authority. This letter emphasised the deletion of factors relating to *having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the gallbladder at least five years before the clinical onset of malignant neoplasm of the gallbladder*. The Authority provided an opportunity to the organisations to make representations in relation to the proposed Instrument prior to its determination. No submissions were received for consideration by the Authority. No changes were made to the proposed Instrument following this consultation process.

Human Rights

10. This instrument is compatible with the Human Rights and Freedoms recognised or declared in the International Instruments listed in Section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A Statement of Compatibility with Human Rights follows.

Finalisation of Investigation

11. The determining of this Instrument finalises the investigation in relation to malignant neoplasm of the gallbladder as advertised in the Government Notices Gazette of 1 November 2022.

References

12. A list of references relating to the above condition is available on the Authority's website at: www.rma.gov.au. Any other document referred to in this Statement of Principles is available on request to the Repatriation Medical Authority at the following address:

Email: info@rma.gov.au

Post: The Registrar
Repatriation Medical Authority
GPO Box 1014
BRISBANE QLD 4001



Australian Government
Repatriation Medical Authority

Statement of Compatibility with Human Rights

(Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011)

Instrument No.: **Statement of Principles No. 36 of 2024**

Kind of Injury, Disease or Death: **Malignant neoplasm of the gallbladder**

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

1. This Legislative Instrument is determined pursuant to subsection 196B(2) of the *Veterans' Entitlements Act 1986* (the VEA) for the purposes of the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA). Part XIA of the VEA requires the determination of these instruments outlining the factors connecting particular kinds of injury, disease or death with service such being determined solely on the available sound medical-scientific evidence.
2. This Legislative Instrument:-
 - facilitates claimants in making, and the Repatriation Commission and the Military Rehabilitation and Compensation Commission in assessing, claims under the VEA and the MRCA respectively, by specifying the circumstances in which medical treatment and compensation can be extended to eligible persons who have malignant neoplasm of the gallbladder;
 - facilitates the review of such decisions by the Veterans' Review Board and the Administrative Appeals Tribunal;
 - outlines the factors which the current sound medical-scientific evidence indicates must as a minimum exist, before it can be said that a reasonable hypothesis has been raised, connecting malignant neoplasm of the gallbladder with the circumstances of eligible service rendered by a person, as set out in clause 5 of the Explanatory Statement;
 - replaces Instrument No. 89 of 2015; and
 - reflects developments in the available sound medical-scientific evidence concerning malignant neoplasm of the gallbladder which have occurred since that earlier instrument was determined.
3. The Instrument is assessed as being a technical instrument which improves the medico-scientific quality of outcomes under the VEA and the MRCA.

Human Rights Implications

4. This Legislative Instrument does not derogate from any human rights. It promotes the human rights of veterans, current and former Defence Force members as well as other persons such as their dependents, including:
- the right to social security (Art 9, *International Covenant on Economic, Social and Cultural Rights*; Art 26, *Convention on the Rights of the Child* and Art 28, *Convention on the Rights of Persons with Disabilities*) by helping to ensure that the qualifying conditions for the benefit are 'reasonable, proportionate and transparent'¹;
 - the right to an adequate standard of living (Art 11, ICESCR; Art 27, CRC and Art 28, CRPD) by facilitating the assessment and determination of social security benefits;
 - the right to the enjoyment of the highest attainable standard of physical and mental health (Art 12, ICESCR and Art 25, CRPD), by facilitating the assessment and determination of compensation and benefits in relation to the treatment and rehabilitation of veterans and Defence Force members;
 - the rights of persons with disabilities by facilitating the determination of claims relating to treatment and rehabilitation (Art 26, CRPD); and
 - ensuring that those rights "will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status" (Art 2, ICESCR).

Conclusion

This Legislative Instrument is compatible with human rights as it does not derogate from and promotes a number of human rights.

Repatriation Medical Authority

¹ In General Comment No. 19 (The right to social security), the Committee on Economic, Social and Cultural Rights said (at paragraph 24) this to be one of the elements of ensuring accessibility to social security.