



Australian Government
Repatriation Medical Authority

EXPLANATORY STATEMENT

**STATEMENT OF PRINCIPLES CONCERNING
PULMONARY THROMBOEMBOLISM
(BALANCE OF PROBABILITIES) (NO. 38 OF 2021)**

VETERANS' ENTITLEMENTS ACT 1986
MILITARY REHABILITATION AND COMPENSATION ACT 2004

1. This is the Explanatory Statement to the *Statement of Principles concerning pulmonary thromboembolism (Balance of Probabilities)* (No. 38 of 2021).

Background

2. The Repatriation Medical Authority (the Authority), under subsection 196B(8) of the *Veterans' Entitlements Act 1986* (the VEA), repeals Instrument No. 57 of 2012 (Federal Register of Legislation No. F2012L01798) determined under subsection 196B(3) of the VEA concerning **pulmonary thromboembolism**.
3. The Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that **pulmonary thromboembolism** and **death from pulmonary thromboembolism** can be related to particular kinds of service. The Authority has therefore determined pursuant to subsection 196B(3) of the VEA a Statement of Principles concerning **pulmonary thromboembolism** (Balance of Probabilities) (No. 38 of 2021). This Instrument will in effect replace the repealed Statement of Principles.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 exist, and which of those factors must be related to the following kinds of service rendered by a person:
 - eligible war service (other than operational service) under the VEA;
 - defence service (other than hazardous service and British nuclear test defence service) under the VEA;
 - peacetime service under the MRCA,

before it can be said that, on the balance of probabilities, pulmonary thromboembolism or death from pulmonary thromboembolism is connected 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 29 October 2019 concerning pulmonary thromboembolism 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 reference to 'ICD-10-AM code' in subsection 7(4);
 - revising the factor in subsection 9(2) concerning having superficial vein thrombosis, for clinical onset only;
 - new factor in subsection 9(3) concerning having acute myocardial infarction, for clinical onset only;
 - new factor in subsection 9(4) concerning having heart failure or a thrombus within the right atrium or right ventricle, for clinical onset only;
 - revising the factor in subsection 9(7) concerning being overweight or obese, for clinical onset only;
 - new factor in subsection 9(8) concerning having sleep apnoea, for clinical onset only;
 - revising the factor in subsection 9(9) concerning being pregnant, for clinical onset only;
 - revising the factor in subsection 9(10) concerning having infection with human immunodeficiency virus or hepatitis C virus, for clinical onset only;
 - new factor in subsection 9(11) concerning having infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), for clinical onset only;
 - revising the factor in subsection 9(12) concerning having an autoimmune disease, for clinical onset only;
 - new factor in subsection 9(13) concerning having diabetes mellitus, for clinical onset only;
 - revising the factor in subsection 9(14) concerning having a hypercoagulable state as specified, for clinical onset only;
 - new factor in subsection 9(15) concerning having a kidney disease from the specified list of kidney diseases, for clinical onset only;
 - revising the factor in subsection 9(16) concerning having implantation of an intravenous device, for clinical onset only;
 - revising the factor in subsection 9(17) concerning having surgery requiring a general, spinal or epidural anaesthetic, for clinical onset only;
 - revising the factor in subsection 9(18) concerning having an injury or illness as specified, for clinical onset only, by the inclusion of a note;
 - revising the factor in subsection 9(19) concerning having restricted mobility, for clinical onset only, by the inclusion of a note;
 - revising the factor in subsection 9(20) concerning having a neurological disease that causes loss or impairment of motor function of a limb, for clinical onset only;
 - revising the factor in subsection 9(21) concerning taking a drug from the specified list of drugs, for clinical onset only;

- revising the factor in subsection 9(22) concerning taking combined estrogen-progestogen contraception or taking menopausal hormone therapy as an oral estrogen, or a non-oral estrogen combined with a progestogen, for clinical onset only;
- new factor in subsection 9(23) concerning having smoked tobacco products or cigarettes, where smoking has not permanently ceased, for clinical onset only;
- revising the factor in subsection 9(24) concerning having smoked tobacco products, for clinical onset only;
- revising the factor in subsection 9(25) concerning being at an altitude of at least 3,000 metres, for clinical onset only;
- deleting the factor concerning having a cardiac disease from the specified list, for clinical onset only, as this is now covered by the factors in:
 - subsection 9(3) concerning having acute myocardial infarction, for clinical onset only;
 - subsection 9(4) concerning having heart failure or a thrombus within the right atrium or right ventricle, for clinical onset only;
- deleting the factor concerning experiencing animal envenomation from the bite of a viper, *Crotalinae* spp or *Bitis gabonica*, for clinical onset only, as this now covered by the factor in subsection 9(14) concerning having a hypercoagulable state as specified, for clinical onset only;
- deleting the factor concerning having nephrotic syndrome, or any acute or chronic renal disease requiring dialysis or renal transplantation, for clinical onset only, as this is now covered by the factor in subsection 9(15) concerning having a kidney disease from the specified list of kidney diseases, for clinical onset only;
- deleting the factor concerning immobilisation of the upper or lower limb in a plaster cast or similar restraining device, for clinical onset only, as this is now covered by the factor in subsection 9(18) concerning having an injury or illness as specified, for clinical onset only;
- deleting the factor concerning having chronic bronchitis or emphysema, for clinical onset only;
- deleting the factor concerning having cytomegalovirus infection of new onset, for clinical onset only;
- deleting the factor concerning being an inpatient in a hospital or a resident in a nursing home, for clinical onset only;
- new definitions of 'abnormality of kidney structure or function', 'acute kidney injury', 'being overweight or obese', 'BMI', 'chronic kidney disease', 'cigarettes per day, or the equivalent thereof in other tobacco products', 'hypercoagulable state as specified', 'menopausal hormone therapy', 'MRCA', 'pack-year', 'specified list of drugs', 'specified list of kidney diseases', 'traumatic upper or lower limb amputation' and 'VEA' in Schedule 1 - Dictionary;
- revising the definitions of 'injury or illness as specified' and 'relevant service' in Schedule 1 - Dictionary; and
- deleting the definitions of 'a cardiac disease from the specified list', 'a drug or a drug from a class of drugs from the specified list', 'a hypercoagulable state', 'an autoimmune disease or inflammatory vasculitis from the specified list', 'a neurological disease causing motor impairment', 'being obese', 'having restricted mobility', 'hormone replacement therapy', 'pack-year of cigarettes, or the equivalent thereof in other tobacco products' and 'venous thrombosis'.

8. The Authority has decided to revise the drafting style for factors which contain one or more of the elements of dose, duration, latency and cessation. Section 15AC of the *Acts Interpretation Act 1901* provides that a change to drafting style for the purpose of clearer expression of ideas does not necessarily mean that the ideas themselves have changed. In this Statement of Principles, there have been changes to the format and structure of the factor concerning having smoked tobacco products. The purpose of these revisions is to express the ideas using a clearer drafting style, rather than to change the ideas themselves. Nonetheless, if it is apparent that the ideas themselves have also changed, for example by a change in dose, then the factors should be read accordingly.
9. The Authority has decided to revise the format and structure of the definition of 'pack-year' contained within this Statement of Principles. The purpose of this revision is to express the definition using a clearer drafting style. The main idea of the definition remains unchanged. The intention of this definition is to assist claimants and their representatives with the calculation of the amount of tobacco which may have been smoked over a period of time, in recognition of the difficulties associated with quantifying the gross weight of tobacco which a person may have smoked. One pack-year assumes the smoking of one standard pack of cigarettes, containing 20 cigarettes (or the equivalent in other tobacco products) over a period of one calendar year, that is, 7,300 cigarettes. However, the Authority recognises that the amount of tobacco smoked over a period of time will vary between individuals, and that a person may smoke one pack-year of tobacco in a shorter or longer period of time than one calendar year. Consequently, the definition of 'pack-year' should not be read as imposing a strict requirement that claimants will have smoked precisely 20 cigarettes per day, or 7,300 cigarettes per calendar year.

Consultation

10. Prior to determining this Instrument, the Authority advertised its intention to undertake an investigation in relation to pulmonary thromboembolism in the Government Notices Gazette of 29 October 2019, 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.
11. On 2 November 2020, 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 *being an inpatient in a hospital or a resident in a nursing home for a continuous period of at least seven days, within the three months before the clinical onset of pulmonary thromboembolism, having cytomegalovirus infection of new onset within the six weeks before the clinical onset of pulmonary thromboembolism and having chronic bronchitis or emphysema at the time of the clinical onset of pulmonary thromboembolism*. 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. Minor changes were made to the proposed Instrument following this consultation process.

Human Rights

12. 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

13. The determining of this Instrument finalises the investigation in relation to pulmonary thromboembolism as advertised in the Government Notices Gazette of 29 October 2019.

References

14. 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. 38 of 2021**

Kind of Injury, Disease or Death: **Pulmonary thromboembolism**

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(3) 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 pulmonary thromboembolism;
 - 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 exist before it can be said that, on the balance of probabilities, pulmonary thromboembolism is connected with the circumstances of eligible service rendered by a person, as set out in clause 5 of the Explanatory Statement;
 - replaces Instrument No. 57 of 2012; and
 - reflects developments in the available sound medical-scientific evidence concerning pulmonary thromboembolism 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, ICSECR; 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, ICSECR 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.