Statement of Principles concerning sarcoidosis (Reasonable Hypothesis) (No. 59 of 2016)

made under subsection 196B(2) of the

Veterans' Entitlements Act 1986

Compilation No. 1

Compilation date: 28 January 2019

Includes amendments up to: Amendment Statement of Principles concerning sarcoidosis (Reasonable Hypothesis) (No. 13 of 2019) (F2019L00003)

The day of commencement of this Amendment Statement of Principles concerning sarcoidosis is 28 January 2019.

Prepared by the Repatriation Medical Authority Secretariat, Brisbane
About this compilation

This compilation

This is a compilation of the Statement of Principles concerning sarcoidosis (Reasonable Hypothesis) (No. 59 of 2016) that shows the text of the law as amended and in force on 28 January 2019.

The notes at the end of this compilation (the endnotes) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.
Statement of Principles concerning SARCOIDOSIS (Reasonable Hypothesis) (No. 59 of 2016)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the Veterans' Entitlements Act 1986.

Dated 24 June 2016
Statement of Principles concerning Sarcoïdosis (Reasonable Hypothesis) (No. 59 of 2016) Veterans’ Entitlements Act 1986

Compilation No. 1

Compilation date: 28/01/2019

Authorised Version F2019C00013 registered 29/01/2019
1 Name
This is the Statement of Principles concerning sarcoidosis (Reasonable Hypothesis) (No. 59 of 2016).

2 Commencement
This instrument commences on 25 July 2016.

3 Authority
This instrument is made under subsection 196B(2) of the Veterans’ Entitlements Act 1986.

4 Revocation
The Statement of Principles concerning sarcoidosis No. 115 of 2007 made under subsection 196B(2) of the VEA is revoked.

5 Application
This instrument applies to a claim to which section 120A of the VEA or section 338 of the Military Rehabilitation and Compensation Act 2004 applies.

6 Definitions
The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

7 Kind of injury, disease or death to which this Statement of Principles relates
(1) This Statement of Principles is about sarcoidosis and death from sarcoidosis.

Meaning of sarcoidosis

(2) For the purposes of this Statement of Principles, sarcoidosis means a chronic, multisystem disorder characterised in affected organs by an accumulation of T lymphocytes and mononuclear phagocytes, non-caseating epithelioid granulomas, and derangement of the normal tissue architecture.

(3) While sarcoidosis attracts ICD-10-AM code D86, in applying this Statement of Principles the meaning of sarcoidosis is that given in subsection (2).

*Death from sarcoidosis*

(5) For the purposes of this Statement of Principles, sarcoidosis, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's sarcoidosis.

Note: *terminal event* is defined in the Schedule 1 – Dictionary.

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that sarcoidosis and death from sarcoidosis 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 MRCA.

Note: *relevant service* is defined in the Schedule 1 – Dictionary.

9 Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting sarcoidosis or death from sarcoidosis with the circumstances of a person's relevant service:

(1) being treated with a drug from a class of drugs from the specified list of drugs within the five years before the clinical onset of sarcoidosis;

Note: *specified list of drugs* is defined in the Schedule 1 - Dictionary.

(1a) having immunotherapy for cancer or targeted therapy for cancer within the five years before the clinical onset of sarcoidosis;

Note: *immunotherapy for cancer* and *targeted therapy for cancer* are defined in the Schedule 1 - Dictionary.

(2) being treated for human immunodeficiency virus infection with antiretroviral drugs at the time of the clinical onset of sarcoidosis;

(3) being treated with a tumour necrosis factor-α inhibitor at the time of the clinical onset of sarcoidosis;

(3a) having a malignant neoplasm in the ten years before the clinical onset of sarcoidosis;
(4) being obese for at least five years within the 20 years before the clinical onset of sarcoidosis;

Note: being obese is defined in the Schedule 1 - Dictionary.

(5) having received an organ or tissue transplant from a donor with sarcoidosis within the two years before the clinical onset of sarcoidosis;

(6) being treated with a drug from a class of drugs from the specified list of drugs within the five years before the clinical worsening of sarcoidosis;

Note: specified list of drugs is defined in the Schedule 1 - Dictionary.

(6a) having immunotherapy for cancer or targeted therapy for cancer within the five years before the clinical worsening of sarcoidosis;

Note: immunotherapy for cancer and targeted therapy for cancer are defined in the Schedule 1 - Dictionary.

(7) being treated for human immunodeficiency virus infection with antiretroviral drugs at the time of the clinical worsening of sarcoidosis;

(8) being treated with a tumour necrosis factor-α inhibitor at the time of the clinical worsening of sarcoidosis;

(8a) having a malignant neoplasm in the ten years before the clinical worsening of sarcoidosis;

(9) being obese for at least five years within the 20 years before the clinical worsening of sarcoidosis;

Note: being obese is defined in the Schedule 1 - Dictionary.

(10) inability to obtain appropriate clinical management for sarcoidosis.

10 Relationship to service

(1) The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.

(2) The factors set out in subsections 9(6) to 9(10) apply only to material contribution to, or aggravation of, sarcoidosis where the person's sarcoidosis was suffered or contracted before or during (but did not arise out of) the person's relevant service.
11  Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

(1) if a factor referred to in section 9 applies in relation to a person; and

(2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.
Schedule 1 - Dictionary

Note: See Section 6

1 Definitions

In this instrument:

*being obese* means having a Body Mass Index (BMI) of 30 or greater.

*BMI* means \( W/H^2 \) and where:

- \( W \) is the person's weight in kilograms; and
- \( H \) is the person's height in metres.

*immunotherapy for cancer* means the use of drugs to stimulate a person's own immune system to recognise and destroy cancer cells more effectively.

*MRCA* means the *Military Rehabilitation and Compensation Act 2004*.

*relevant service* means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

Note: *MRCA* and *VEA* are also defined in the Schedule 1 - Dictionary.

*sarcoidosis*—see subsection 7(2).

*specified list of drugs means:*

- (a) BRAF/MEK inhibitors, including vemurafenib, dabrafenib and trametinib;
- (b) immune checkpoint inhibitors, including ipilimumab, pembrolizumab and nivolumab;
- (c) interferons; or
- (d) vaccines used to treat cancer.

*targeted therapy for cancer* means the use of drugs that block the growth and spread of cancer by interfering with specific molecules that are involved in the growth, progression or spread of cancer.

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

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.
VEA means the Veterans' Entitlements Act 1986.
Endnotes

Endnote 1—About the endnotes
The endnotes provide information about this compilation and the compiled law.
The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.
The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.
The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.
If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.
Endnote 2—Abbreviation key

ad = added or inserted
am = amended
amdt = amendment
c = clause(s)
C[x] = Compilation No. x
Ch = Chapter(s)
def = definition(s)
Dict = Dictionary
disallowed = disallowed by Parliament
Div = Division(s)
exp = expires/expired or ceases/ceased to have effect
F = Federal Register of Legislation
gaz = gazette
LA = Legislation Act 2003
LIA = Legislative Instruments Act 2003
(md) = misdescribed amendment can be given effect
(md not incorp) = misdescribed amendment cannot be given effect
mod = modified/modification
No. = Number(s)
o = order(s)
Ord = Ordinance
orig = original
par = paragraph(s)/subparagraph(s)
/sub-subparagraph(s)
pres = present
prev = previous
(prev…) = previously
Pt = Part(s)
reloc = relocated
renum = renumbered
rep = repealed
rs = repealed and substituted
s = section(s)/subsection(s)
Sch = Schedule(s)
Sdiv = Subdivision(s)
SLI = Select Legislative Instrument
SR = Statutory Rules
Sub-Ch = Sub-Chapter(s)
SubPt = Subpart(s)
underlining = whole or part not commenced or to be commenced
## Endnote 3—Legislation history

<table>
<thead>
<tr>
<th>Name</th>
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## Endnote 4—Amendment history

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| Schedule 1 – Dictionary  
  – immunotherapy for cancer | ad. No 13 of 2019 |
| Schedule 1 – Dictionary  
  – specified list of drugs | ad. No 13 of 2019 |
| Schedule 1 – Dictionary  
  – targeted therapy for cancer | ad. No 13 of 2019 |