



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
TOXIC RETINOPATHY
(Reasonable Hypothesis)
(No. 19 of 2018)

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

Dated 2 March 2018

The Common Seal of the
Repatriation Medical Authority
was affixed to this instrument
at the direction of:

A handwritten signature in black ink, appearing to read 'N. Saunders'.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *toxic retinopathy (Reasonable Hypothesis)* (No. 19 of 2018).

2 Commencement

This instrument commences on 2 April 2018.

3 Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

4 Revocation

The Statement of Principles concerning toxic maculopathy No. 39 of 2009 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 toxic retinopathy and death from toxic retinopathy.

Meaning of toxic retinopathy

- (2) For the purposes of this Statement of Principles, toxic retinopathy:
- (a) means pathological changes in the cells of the retina of the eye, in the presence of:
 - (i) sustained vision impairment; and
 - (ii) evidence from the history, physical examination, or diagnostic testing that the pathological changes are caused by a chemical agent; and
 - (b) includes chemically induced chronic cystoid macular oedema, crystalline retinopathy, toxic maculopathy, and peripheral retinal degeneration that does not involve the macula; and

- (c) excludes toxic optic neuropathy, zonal occult outer retinopathy, macular degeneration, retinal detachment and breaks, and retinal photodamage.

Death from toxic retinopathy

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

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 toxic retinopathy and death from toxic retinopathy 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: *MRCA*, *relevant service* and *VEA* are 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 toxic retinopathy or death from toxic retinopathy with the circumstances of a person's relevant service:

- (1) being treated with a quinoline-based drug as specified, before the clinical onset of toxic retinopathy;

Note: *being treated with a quinoline-based drug as specified* is defined in the Schedule 1 - Dictionary.

- (2) being treated with tamoxifen as specified within the one year before the clinical onset of toxic retinopathy;

Note: *being treated with tamoxifen as specified* is defined in the Schedule 1 - Dictionary.

- (3) being treated with an intravitreal or subconjunctival aminoglycoside from the specified list of aminoglycosides, within the seven days before the clinical onset of toxic retinopathy;

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

- (4) being treated with intravitreal fomivirsen or ganciclovir within the 30 days before the clinical onset of toxic retinopathy;

- (5) being treated with intravenous deferoxamine within the seven days before the clinical onset of toxic retinopathy;

- (6) being treated with a phenothiazine from the specified list of phenothiazines for a continuous period of at least the two weeks before the clinical onset of toxic retinopathy;

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

- (7) being treated with daily clofazimine, at an average dose of at least 100 milligrams per day, for a continuous period of at least the three months before the clinical onset of toxic retinopathy;
- (8) being treated with ritonavir for a continuous period of at least the three months before the clinical onset of toxic retinopathy;
- (9) being treated with interferon for a continuous period of at least four weeks, within the three months before the clinical onset of toxic retinopathy;
- (10) being treated with daily topiramate for a continuous period of at least seven days within the 30 days before the clinical onset of toxic retinopathy;
- (11) having iron chelating therapy as specified for a continuous period of at least the four weeks before the clinical onset of toxic retinopathy;

Note: *iron chelating therapy as specified* is defined in the Schedule 1 - Dictionary.

- (12) having haematological or biochemical evidence of poisoning with cobalt at the time of the clinical onset of toxic retinopathy;
- (13) taking oral canthaxanthin supplements or tablets as specified within the five years before the clinical onset of toxic retinopathy;

Note: *taking oral canthaxanthin supplements or tablets as specified* is defined in the Schedule 1 - Dictionary.

- (14) inhaling isopropyl nitrite within the two weeks before the clinical onset of toxic retinopathy;
- (15) using an intravenous drug containing talc within the five years before the clinical onset of toxic retinopathy;
- (16) for cystoid macular oedema only:
 - (a) being treated with daily niacin for a continuous period of at least two weeks, at an average dose of at least 1.5 grams per day, within the three months before the clinical onset of toxic retinopathy;
 - (b) being treated with intravenous paclitaxel or docetaxel within the three months before the clinical onset of toxic retinopathy; or
 - (c) being treated with the thiazolidinedione drugs rosiglitazone or pioglitazone for a continuous period of at least the four weeks before the clinical onset of toxic retinopathy;

Note: *cystoid macular oedema* is defined in the Schedule 1 - Dictionary.

- (17) for cystoid macular oedema only, in an aphakic or pseudophakic eye only:
- (a) being treated with topical adrenaline eye drops, within the three months before the clinical onset of toxic retinopathy; or
 - (b) being treated with latanoprost within the three months before the clinical onset of toxic retinopathy;
- Note: *cystoid macular oedema* and *aphakic or pseudophakic eye* are defined in the Schedule 1 - Dictionary.
- (18) inability to obtain appropriate clinical management for toxic retinopathy.

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 factor set out in subsection 9(18) applies only to material contribution to, or aggravation of, toxic retinopathy where the person's toxic retinopathy 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:

aphakic or pseudophakic eye means an eye without a natural lens, or an eye containing an intraocular lens implant.

being treated with a quinoline-based drug as specified means:

- (a) taking daily chloroquine for a continuous period of at least six months; or
- (b) taking a cumulative dose of chloroquine of at least 100 grams; or
- (c) taking daily hydroxychloroquine for a continuous period of at least five years; or
- (d) taking a cumulative dose of hydroxychloroquine of at least 400 grams; or
- (e) taking daily quinacrine (mepacrine or Atebrin) for a continuous period of at least six months; or
- (f) taking a cumulative dose of quinacrine of at least 20 grams; or
- (g) taking a cumulative dose of at least 1000 mg of mefloquine within a 30 day period.

being treated with tamoxifen as specified means:

- (a) taking daily tamoxifen for a continuous period of at least six months; or
- (b) taking a cumulative dose of tamoxifen of at least 100 grams.

cystoid macular oedema means a painless disorder of the macula, in which disruption of the normal blood-retinal barrier causes the accumulation of fluid within the intracellular spaces of the retina, primarily in the outer plexiform layer.

iron chelating therapy as specified means:

- (a) daily oral deferasirox; or
- (b) daily oral deferiprone; or
- (c) subcutaneous or intramuscular deferoxamine.

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.

specified list of aminoglycosides means:

- (a) amikacin;
- (b) gentamicin;
- (c) kanamycin;
- (d) netilmicin; or
- (e) tobramycin.

specified list of phenothiazines means:

- (a) chlorpromazine;
- (b) thioridazine;
- (c) fluphenazine;
- (d) trifluoperazine; or
- (e) pericyazine.

taking oral canthaxanthin supplements or tablets as specified means:

- (a) daily oral canthaxanthin supplements or tablets for a continuous period of at least six months; or
- (b) having a cumulative dose of at least 15 grams of canthaxanthin.

Note: Canthaxanthin used as a colour additive in foods or drugs is excluded.

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.

toxic retinopathy—see subsection 7(2).

VEA means the *Veterans' Entitlements Act 1986*.