

# Statement of Principles concerning NON-MELANOTIC MALIGNANT NEOPLASM OF THE SKIN (Reasonable Hypothesis) (No. 7 of 2016)

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

Dated 4 March 2016

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

Professor Nicholas Saunders AO

Chairperson

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#### 1 Name

This is the Statement of Principles concerning *non-melanotic malignant neoplasm of the skin (Reasonable Hypothesis)* (No. 7 of 2016).

#### 2 Commencement

This instrument commences on 4 April 2016.

#### 3 Authority

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

#### 4 Revocation

The Statement of Principles concerning non-melanotic malignant neoplasm of the skin No. 81 of 2007, as amended, made under subsections 196B(2) and (8) 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 non-melanotic malignant neoplasm of the skin and death from non-melanotic malignant neoplasm of the skin.

#### Meaning of non-melanotic malignant neoplasm of the skin

- (2) For the purposes of this Statement of Principles, non-melanotic malignant neoplasm of the skin means:
  - (a) a primary malignant neoplasm arising from the cells of the skin;
  - (b) includes non-melanotic malignant neoplasm of the lips and the skin of the external genitalia, squamous cell carcinoma, squamous cell carcinoma in situ (Bowen's disease), basal cell carcinoma and Merkel cell carcinoma; and

(c) excludes non-melanotic malignant neoplasm of the mucosa lining the oral (inner) aspects of the lips and the anogenital mucosa, malignant melanoma of the skin, keratoacanthoma, solar keratosis, Paget's disease of the skin, Kaposi's sarcoma, soft tissue sarcoma, carcinoid tumour, non-Hodgkin's lymphoma and Hodgkin's lymphoma.

#### Death from non-melanotic malignant neoplasm of the skin

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

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 non-melanotic malignant neoplasm of the skin and death from non-melanotic malignant neoplasm of the skin 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 non-melanotic malignant neoplasm of the skin or death from non-melanotic malignant neoplasm of the skin with the circumstances of a person's relevant service:

- (1) being a prisoner of war of Japan before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (2) having sunlight exposure to unprotected skin at the affected site for a cumulative period of at least 2 250 hours while in a tropical area, or having equivalent sunlight exposure in other latitude zones, before the clinical onset of non-melanotic malignant neoplasm of the skin;

Note: *equivalent sunlight exposure in other latitude zones*, *tropical area* and *unprotected skin* are defined in the Schedule 1 - Dictionary.

(3) having ultraviolet radiation exposure to the affected site from an ultraviolet-emitting tanning device on more than ten occasions before the clinical onset of non-melanotic malignant neoplasm of the skin, and where the first exposure occurred more than two years before the clinical onset of non-melanotic malignant neoplasm of the skin;

(4) having at least two episodes of sunburn as specified, at least two years before the clinical onset of non-melanotic malignant neoplasm of the skin:

Note: sunburn as specified is defined in the Schedule 1 - Dictionary.

- (5) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the affected site at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
  - Note: cumulative equivalent dose is defined in the Schedule 1 Dictionary.
- (6) undergoing a course of therapeutic radiation for cancer, where the affected site was in the field of radiation, at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (7) for squamous cell carcinoma of the skin only:
  - (a) smoking at least five pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of non-melanotic malignant neoplasm of the skin, and:
    - (i) smoking commenced at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin; and
    - (ii) where smoking has ceased, the clinical onset of nonmelanotic malignant neoplasm of the skin has occurred within 20 years of cessation;

Note: *pack-years of cigarettes, or the equivalent thereof in other tobacco products* is defined in the Schedule 1 - Dictionary.

(b) having hidradenitis suppurativa involving the affected site, at least six months before the clinical onset of non-melanotic malignant neoplasm of the skin;

Note: hidradenitis suppurativa is defined in the Schedule 1 - Dictionary.

- (c) having chronic lymphoedema involving the affected site within the five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (d) being treated with a BRAF inhibitor at the time of the clinical onset of non-melanotic malignant neoplasm of the skin;
- (e) being treated with voriconazole for a continuous period of at least the four weeks before the clinical onset of non-melanotic malignant neoplasm of the skin; or
- (f) using a hydrochlorothiazide diuretic for a continuous period of at least six months, before the clinical onset of non-melanotic malignant neoplasm of the skin;

- (8) for squamous cell carcinoma of the lip only:
  - (a) smoking at least 2.5 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of non-melanotic malignant neoplasm of the skin, and:
    - (i) smoking commenced at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin; and
    - (ii) where smoking has ceased, the clinical onset of nonmelanotic malignant neoplasm of the skin has occurred within 20 years of cessation;

Note: *lip* and *pack-years of cigarettes, or the equivalent thereof in other tobacco products* are defined in the Schedule 1 - Dictionary.

- (b) being exposed to second-hand smoke:
  - (i) for at least 10 000 hours before the clinical onset of nonmelanotic malignant neoplasm of the skin; and
  - (ii) where the first exposure to second-hand smoke commenced at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin; and
  - (iii) where the last exposure to second-hand smoke occurred within the 15 years before the clinical onset of non-melanotic malignant neoplasm of the skin;

Note: being exposed to second-hand smoke is defined in the Schedule 1 - Dictionary.

(c) the oral use of smokeless tobacco on more days than not, for at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin, and where the oral use of smokeless tobacco has ceased, the clinical onset of non-melanotic malignant neoplasm of the skin has occurred within 15 years of cessation;

Note: *smokeless tobacco* is defined in the Schedule 1 - Dictionary.

- (d) chewing betel quid or areca nut on more days than not, for at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin, and where chewing betel quid or areca nut has ceased, the clinical onset of non-melanotic malignant neoplasm of the skin has occurred within 15 years of cessation; or
- (e) drinking at least 100 kilograms of alcohol before the clinical onset of non-melanotic malignant neoplasm of the skin;

Note: alcohol is defined in the Schedule 1 - Dictionary.

- (9) for non-melanotic malignant neoplasm of the skin of the anogenital region only, having lichen sclerosis involving the affected site at the time of the clinical onset of non-melanotic malignant neoplasm of the skin;
- (10) for squamous cell carcinoma of the anogenital skin only, acquiring persistent infection with an oncogenic human papilloma virus before the clinical onset of non-melanotic malignant neoplasm of the skin;
  - Note: oncogenic human papilloma virus is defined in the Schedule 1 Dictionary.
- (11) for non-melanotic malignant neoplasm of the glans penis or prepuce of the penis only, having phimosis for a continuous period of at least two years before the clinical onset of non-melanotic malignant neoplasm of the skin;
  - Note: *phimosis* is defined in the Schedule 1 Dictionary.
- (12) for Merkel cell carcinoma only, being infected with Merkel cell polyomavirus before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (13) being exposed to arsenic as specified before the clinical onset of nonmelanotic malignant neoplasm of the skin, where the first exposure to arsenic occurred at least ten years before the clinical onset of nonmelanotic malignant neoplasm of the skin;
  - Note: being exposed to arsenic as specified is defined in the Schedule 1 Dictionary.
- (14) undergoing solid organ or bone marrow transplantation before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (15) being treated with an immunosuppressive drug within the ten years before the clinical onset of non-melanotic malignant neoplasm of the skin;
  - Note: *immunosuppressive drug* is defined in the Schedule 1 Dictionary.
- (16) having a disease from the specified list of immune-mediated inflammatory diseases before the clinical onset of non-melanotic malignant neoplasm of the skin;
  - Note: *specified list of immune-mediated inflammatory diseases* is defined in the Schedule 1 Dictionary.
- (17) having non-Hodgkin's lymphoma or chronic lymphocytic leukaemia/small lymphocytic lymphoma before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (18) being infected with human immunodeficiency virus before the clinical onset of non-melanotic malignant neoplasm of the skin;

- (19) undergoing PUVA therapy involving the affected site where:
  - (a) the first PUVA treatment commenced at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin; and
  - (b) at least 25 PUVA treatments were administered before the clinical onset of non-melanotic malignant neoplasm of the skin;

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

- (20) having cutaneous contact of the affected site with an agent from the specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons:
  - (a) for a cumulative period of at least 1 500 hours, before the clinical onset of non-melanotic malignant neoplasm of the skin; and
  - (b) the first cutaneous contact occurred at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin;

Note: *specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons* is defined in the Schedule 1 – Dictionary.

- (21) having a scar involving the affected site at the time of the clinical onset of non-melanotic malignant neoplasm of the skin, where the scar is the result of an injury that occurred, or a disease process that commenced, at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (22) having ulceration involving the affected site, for a continuous period of at least six months, within the five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (23) having chronic osteomyelitis involving the affected site within the five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (24) having cutaneous contact with mustard gas at the affected site at least five years before the clinical onset of non-melanotic malignant neoplasm of the skin;
- (25) inability to obtain appropriate clinical management for non-melanotic malignant neoplasm of the skin.

#### 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(25) applies only to material contribution to, or aggravation of, non-melanotic malignant neoplasm of the skin where the person's non-melanotic malignant neoplasm of

the skin 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:

*alcohol* is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

#### being exposed to arsenic as specified means:

- (a) consuming arsenic containing compounds (for example, Fowler's solution) for a cumulative period of at least three months; or
- (b) consuming drinking water with an average arsenic concentration of at least 50 micrograms per litre for a cumulative period of at least two years; or
- (c) inhaling, ingesting or having cutaneous contact with a pesticide containing arsenic, or arsenic in copper smelting operations, for a cumulative period of at least 1 000 hours; or
- (d) having clinical evidence of chronic arsenic toxicity.

*being exposed to second-hand smoke* means being in an enclosed space and inhaling smoke from burning tobacco products or smoke that has been exhaled by a person who is smoking.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation-related sources and radiation from nuclear explosions or accidents.

equivalent sunlight exposure in other latitude zones means the cumulative hours of sunlight exposure equivalent to that specified for a tropical area, calculated by multiplying the hours of exposure in each latitude zone by the latitude weighting factor for the zone as per the latitude weighting factor schedule and adding together the result for each zone:

#### Latitude weighting factor schedule

Latitude zone	Latitude weighting factor
a latitude between 23° 27' South and 23° 27' North	n 1.0
a latitude from $> 23^{\circ} 27'$ to $35^{\circ}$	0.75
a latitude from $> 35^{\circ}$ to $45^{\circ}$	0.5
a latitude from $> 45^{\circ}$ to $65^{\circ}$	0.25.

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*hidradenitis suppurativa* means a chronic skin disease of the terminal follicular epithelium in the apocrine gland-bearing skin, characterised by comedo-like follicular occlusion, chronic relapsing inflammation, mucopurulent discharge, and progressive scarring.

*immunosuppressive drug* means a drug or an agent which results in substantial suppression of immune responses. This definition includes corticosteroids other than inhaled or topical corticosteroids, drugs used to prevent transplant rejection, tumour necrosis factor- $\alpha$  inhibitors and chemotherapeutic agents used for the treatment of cancer.

*lip* means the lipstick region of the lip and includes the vermilion borders and commissures of the lips.

MRCA means the Military Rehabilitation and Compensation Act 2004.

non-melanotic malignant neoplasm of the skin—see subsection 7(2).

oncogenic human papilloma virus means human papilloma virus type 16, 18 or 33.

pack-years of cigarettes, or the equivalent thereof in other tobacco products means a calculation of consumption where one pack-year of cigarettes equals twenty tailor-made cigarettes per day for a period of one calendar year, or 7 300 cigarettes. One tailor-made cigarette approximates one gram of tobacco or one gram of cigar or pipe tobacco by weight. One pack-year of tailor-made cigarettes equates to 7.3 kilograms of smoking tobacco by weight. Tobacco products mean cigarettes, pipe tobacco or cigars, smoked alone or in any combination.

*phimosis* means a circumferential fibrosis of preputial tissue that leads to narrowing and an inability to retract the penile foreskin over the glans penis.

**PUVA** means photochemotherapy with oral methoxsalen (psoralen) and ultraviolet A radiation

#### 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.

**smokeless tobacco** means tobacco products without combustion or pyrolysis at the time of use, including chewing tobacco and tobacco snuff.

**soot** means a carbonaceous by-product material produced from the incomplete combustion of fossil fuel or other carbon-containing material, including airborne residual pyrolysed fuel particles such as coal, cenospheres, charred wood and petroleum coke.

## specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons means:

- (a) coal tar pitch during paving and roofing;
- (b) concentrated coal tar distillates during coal tar distillation;
- (c) creosote;
- (d) molten bitumen during roofing and mastic-asphalt work;
- (e) shale oil;
- (f) soot during the cleaning of chimneys or flues; or
- (g) untreated or mildly treated mineral oils.

Note: **soot** and **untreated or mildly treated mineral oils** are also defined in the Schedule 1 – Dictionary.

#### specified list of immune-mediated inflammatory diseases means:

- (a) autoimmune hepatitis;
- (b) inflammatory bowel disease;
- (c) psoriasis;
- (d) rheumatoid arthritis;
- (e) sarcoidosis:
- (f) systemic lupus erythematosus; or
- (g) systemic sclerosis.

*sunburn as specified* means painful erythema of the skin of at least 48 hours duration, or blistering of the skin, resulting from exposure to solar ultraviolet radiation.

*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.

*tropical area* means any area between the Tropic of Capricorn (23° 27' South) and the Tropic of Cancer (23° 27' North).

*unprotected skin* means skin that is directly exposed to the sun and is not protected by sunscreen, clothing or other physical barrier.

untreated or mildly treated mineral oils means chemical substances prepared from naturally occurring crude petroleum oil, and which have not been highly or severely refined to remove polycyclic aromatic hydrocarbons by processes of solvent extraction or hydro treatment. This definition includes lubricant products such as engine oils, transmission fluids, gear oils, hydraulic fluids and metalworking fluids; and non-lubricant products such as agricultural spray oils, printing inks, and tyre oil, but excludes cosmetic, pharmaceutical and food products.

VEA means the Veterans' Entitlements Act 1986.