

Statement of Principles concerning

FIBROSING INTERSTITIAL LUNG DISEASE No. 53 of 2013

for the purposes of the

Veterans' Entitlements Act 1986 and Military Rehabilitation and Compensation Act 2004

Title

1. This Instrument may be cited as Statement of Principles concerning fibrosing interstitial lung disease No. 53 of 2013.

Determination

- 2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 35 of 2009, as amended by Instrument No. 59 of 2010, Instrument No. 79 of 2011 and Instrument No. 66 of 2012, concerning fibrosing interstitial lung disease; and
 - (b) determines in their place this Statement of Principles.

Kind of injury, disease or death

- 3. (a) This Statement of Principles is about **fibrosing interstitial lung** disease and death from fibrosing interstitial lung disease.
 - (b) For the purposes of this Statement of Principles, "fibrosing interstitial lung disease" means one of a diverse group of lung diseases that are characterised by progressive fibrosis of the pulmonary interstitium with or without chronic inflammation. This definition excludes extrinsic allergic alveolitis, bronchiolitis obliterans organising pneumonia, desquamative interstitial pneumonia, respiratory bronchiolitis-

associated interstitial lung disease and pulmonary manifestations of systemic diseases.

Basis for determining the factors

4. The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that **fibrosing interstitial lung disease** and **death from fibrosing interstitial lung disease** 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 *Military Rehabilitation and Compensation Act 2004* (the MRCA).

Factors that must be related to service

5. Subject to clause 7, at least one of the factors set out in clause 6 must be related to the relevant service rendered by the person.

Factors

- 6. The factor that must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting **fibrosing interstitial lung disease** or **death from fibrosing interstitial lung disease** with the circumstances of a person's relevant service is:
 - (a) smoking at least 15 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of fibrosing interstitial lung disease, and where smoking has ceased, the clinical onset of fibrosing interstitial lung disease has occurred within 30 years of cessation; or
 - (b) inhaling respirable asbestos fibres in an enclosed space:
 - (i) for a cumulative period of at least 1 000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
 - (iii) the first inhalation of asbestos fibres commenced at least five years before the clinical onset of fibrosing interstitial lung disease; or
 - (c) inhaling respirable asbestos fibres in an open environment:
 - (i) for a cumulative period of at least 3 000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
 - (iii) the first inhalation of asbestos fibres commenced at least five years before the clinical onset of fibrosing interstitial lung disease; or
 - (d) inhaling beryllium dust or fumes before the clinical onset of fibrosing interstitial lung disease; or
 - (e) inhaling respirable crystalline silica dust in an enclosed space:

- (i) for a cumulative period of at least 1 500 hours before the clinical onset of fibrosing interstitial lung disease; and
- (ii) at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut or ground, or used in construction, manufacturing, cleaning or blasting; and
- (iii) the first inhalation of respirable crystalline silica dust commenced at least five years before the clinical onset of fibrosing interstitial lung disease; or
- (f) inhaling respirable crystalline silica dust in an open environment:
 - (i) for a cumulative period of at least 3 000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut or ground, or used in construction, manufacturing, cleaning or blasting; and
 - (iii) the first inhalation of respirable crystalline silica dust commenced at least five years before the clinical onset of fibrosing interstitial lung disease; or
- (g) having acute silicosis within the six months before the clinical onset of fibrosing interstitial lung disease; or
- (h) inhaling or intravenously injecting a talc-containing compound or mixture, on more days than not, for a period of at least two years, within the forty years before the clinical onset of fibrosing interstitial lung disease; or
- (i) inhaling respirable coal dust in an enclosed space for a cumulative period of at least 3 000 hours, and the first inhalation of respirable coal dust occurred at least five years before the clinical onset of fibrosing interstitial lung disease; or
- (j) inhaling respirable dust generated from hard metal or diamond-cobalt, while engaged in the manufacture, utilisation, or maintenance of tools composed of hard metal or diamond-cobalt, for a cumulative period of at least 120 hours before the clinical onset of fibrosing interstitial lung disease; or
- (k) developing inflammation of the pulmonary interstitium due to inhalation of toxic gases or fumes within the 12 months before the clinical onset of fibrosing interstitial lung disease; or
- (l) having paraquat poisoning within the six months before the clinical onset of fibrosing interstitial lung disease; or
- (m) inhaling mustard gas within the 20 years before the clinical onset of fibrosing interstitial lung disease; or
- (n) having received a cumulative equivalent dose of at least 0.4 sievert of ionising radiation to the lung at least six months before the clinical onset of fibrosing interstitial lung disease; or

- (o) undergoing a course of therapeutic radiation for cancer, where the affected lung was in the field of radiation, at least six months before the clinical onset of fibrosing interstitial lung disease; or
- (p) having received ¹³¹Iodine as therapy for widespread pulmonary metastases from a malignant neoplasm of the thyroid, at least six months before the clinical onset of fibrosing interstitial lung disease; or
- (q) having received ⁹⁰Yttrium microspheres as therapy for primary or metastatic liver tumours, at least six months before the clinical onset of fibrosing interstitial lung disease; or
- (r) having acute respiratory distress syndrome within the six months before the clinical onset of fibrosing interstitial lung disease; or
- (s) being treated with a cytotoxic agent for a malignant disease or in association with haematopoietic stem cell transplantation, before the clinical onset of fibrosing interstitial lung disease; or
- (t) being treated with a drug or a drug from a class of drugs from the specified list within the six months before the clinical onset of fibrosing interstitial lung disease; or
- (u) having chronic or recurrent diffuse alveolar haemorrhage before the clinical onset of fibrosing interstitial lung disease; or
- (v) having exogenous lipoid pneumonitis at the time of the clinical onset of fibrosing interstitial lung disease; or
- (w) having tropical pulmonary eosinophilia for at least the six months before the clinical onset of fibrosing interstitial lung disease; or
- (x) smoking at least five pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical worsening of fibrosing interstitial lung disease, and where smoking has ceased, the clinical worsening of fibrosing interstitial lung disease has occurred within five years of cessation; or
- (y) inhaling respirable asbestos fibres:
 - (i) for a cumulative period of at least 1 000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
 - (iii) within the two years before the clinical worsening of fibrosing interstitial lung disease; or
- (z) inhaling beryllium dust or fumes before the clinical worsening of fibrosing interstitial lung disease; or
- (aa) inhaling respirable crystalline silica dust in an enclosed space:
 - (i) for a cumulative period of at least 1 500 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut or ground, or used in construction, manufacturing, cleaning or blasting; and

- (iii) the first inhalation of respirable crystalline silica dust commenced at least five years before the clinical worsening of fibrosing interstitial lung disease; or
- (bb) inhaling respirable crystalline silica dust in an open environment:
 - (i) for a cumulative period of at least 3 000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (ii) at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut or ground, or used in construction, manufacturing, cleaning or blasting; and
 - (iii) the first inhalation of respirable crystalline silica dust commenced at least five years before the clinical worsening of fibrosing interstitial lung disease; or
- (cc) having acute silicosis within the six months before the clinical worsening of fibrosing interstitial lung disease; or
- (dd) inhaling or intravenously injecting a talc-containing compound or mixture, on more days than not, for a period of at least two years, within the forty years before the clinical worsening of fibrosing interstitial lung disease; or
- (ee) inhaling respirable coal dust in an enclosed space for a cumulative period of at least 3 000 hours, and the first inhalation of respirable coal dust occurred at least five years before the clinical worsening of fibrosing interstitial lung disease; or
- (ff) inhaling respirable dust generated from hard metal or diamond-cobalt, while engaged in the manufacture, utilisation, or maintenance of tools composed of hard metal or diamond-cobalt, for a cumulative period of at least 120 hours before the clinical worsening of fibrosing interstitial lung disease; or
- (gg) developing inflammation of the pulmonary interstitium due to inhalation of toxic gases or fumes within the 12 months before the clinical worsening of fibrosing interstitial lung disease; or
- (hh) having paraquat poisoning within the six months before the clinical worsening of fibrosing interstitial lung disease; or
- (ii) inhaling mustard gas within the 20 years before the clinical worsening of fibrosing interstitial lung disease; or
- (jj) having received a cumulative equivalent dose of at least 0.4 sievert of ionising radiation to the lung at least six months before the clinical worsening of fibrosing interstitial lung disease; or
- (kk) undergoing a course of therapeutic radiation for cancer, where the affected lung was in the field of radiation, at least six months before the clinical worsening of fibrosing interstitial lung disease; or
- (II) having received ¹³¹Iodine as therapy for widespread pulmonary metastases from a malignant neoplasm of the thyroid, at least six months before the clinical worsening of fibrosing interstitial lung disease; or

- (mm) having received ⁹⁰Yttrium microspheres as therapy for primary or metastatic liver tumours, at least six months before the clinical worsening of fibrosing interstitial lung disease; or
- (nn) having acute respiratory distress syndrome within the six months before the clinical worsening of fibrosing interstitial lung disease; or
- (oo) being treated with a cytotoxic agent for a malignant disease or in association with haematopoietic stem cell transplantation, before the clinical worsening of fibrosing interstitial lung disease; or
- (pp) being treated with a drug or a drug from a class of drugs from the specified list within the six months before the clinical worsening of fibrosing interstitial lung disease; or
- (qq) having chronic or recurrent diffuse alveolar haemorrhage before the clinical worsening of fibrosing interstitial lung disease; or
- (rr) having exogenous lipoid pneumonitis at the time of the clinical worsening of fibrosing interstitial lung disease; or
- (ss) having tropical pulmonary eosinophilia for at least the six months before the clinical worsening of fibrosing interstitial lung disease; or
- (tt) having gastro-oesophageal reflux disease for at least the five years before the clinical worsening of fibrosing interstitial lung disease; or
- (uu) inability to obtain appropriate clinical management for fibrosing interstitial lung disease.

Factors that apply only to material contribution or aggravation

Paragraphs **6(x)** to **6(uu)** apply only to material contribution to, or aggravation of, fibrosing interstitial lung disease where the person's fibrosing interstitial lung disease was suffered or contracted before or during (but not arising out of) the person's relevant service.

Inclusion of Statements of Principles

8. In this Statement of Principles if a relevant factor applies and that factor includes an injury or disease in respect of which there is a Statement of Principles then the factors in that last mentioned Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Other definitions

9. For the purposes of this Statement of Principles:

"a drug or a drug from a class of drugs from the specified list" means:

- (a) amiodarone;
- (b) azathioprine;
- (c) cetuximab;
- (d) D-penicillamine;
- (e) erlotinib;
- (f) gefitinib;

- (g) gold salts;
- (h) methotrexate;
- (i) mycophenolate mofetil;
- (j) nitrofurantoin;
- (k) panitumumab;
- (1) rituximab;
- (m) sirolimus;
- (n) sulphasalazine;
- (o) tumour necrosis factor alpha antagonists; or
- (p) tocainide;

"acute respiratory distress syndrome" means a clinical syndrome of severe dyspnoea of rapid onset, hypoxaemia, and diffuse pulmonary infiltrates leading to respiratory failure;

"acute silicosis" means a pulmonary disease characterised by basilar filling of alveoli with lipid and proteinaceous exudative material, following exposure to excessive levels of respirable crystalline silica dust over a short time span;

"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;

"death from fibrosing interstitial lung disease" in relation to a person includes death from a terminal event or condition that was contributed to by the person's fibrosing interstitial lung disease;

"diffuse alveolar haemorrhage" means extravasation of blood into the alveoli and interstitium from injury to the pulmonary microcirculation;

"exogenous lipoid pneumonitis" means inflammation of the pulmonary interstitium due to the aspiration or inhalation of oil-based substances;

"hard metal" means material composed predominantly of cobalt and tungsten carbide:

"inhaling beryllium dust or fumes" means having a history of exposure to beryllium dust or beryllium fumes, for a cumulative period of at least 240 hours or clinical evidence of sensitisation to beryllium by positive findings on beryllium lymphocyte proliferation testing of blood or bronchoalveolar lavage fluid:

"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;

"paraquat" means a dipyridilium compound whose dichloride and dimethylsulphate salts are used as contact herbicides;

"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;

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

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function;

"toxic gases or fumes" means toxic agents, including anhydrous ammonia fumes, smoke, oxides of sulphur, oxides of nitrogen, chlorine or phosgene;

"tropical pulmonary eosinophilia" means a disorder which is characterised by pulmonary infiltrations of eosinophils and blood eosinophilia, and is caused by infection with the microfilariae *Wuchereria bancrofti*, *Brugia malayi* or *Dirofilaria immitis*.

Application

10. This Instrument applies to all matters to which section 120A of the VEA or section 338 of the MRCA applies.

Date of effect

11. This Instrument takes effect from 4 September 2013.

Dated this twenty-sixth day of August 2013

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

PROFESSOR NICHOLAS SAUNDERS AO CHAIRPERSON