

28 April 2026

A Goodwin

By email: fyi-request-34390-43635ccb@requests.fyi.org.nz
Ref: H2026081053

Tēnā koe

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 6 April 2026. Please find a response to each part of your request below.

- 1) *At paragraph 310 of the Covid Inquiry Phase 2 report, it is noted that Medsafe recommended a plan to strengthen existing arrangements to monitor COVID-19 vaccine safety. Please provide details of this plan including the document mentioned at footnote 289 – “A COVID-19 Vaccine Safety Surveillance Strategy for New Zealand: Framework Proposal for Discussion, New Zealand Pharmacovigilance Centre – University of Otago (28 September 2020)”*

The document you have requested is attached to this letter as Appendix 1. This is released to you with some information withheld under section 9(2)(g)(ii) of the Act, to protect Ministers, members of organisations, officers, and employees from improper pressure or harassment. Where information is withheld under section 9 of the Act, I have considered the public interest in the release of this information and do not deem it to outweigh the need to withhold it in this case.

- 2) *In reference to paragraph 304 of the Covid Inquiry Phase 2 report, please provide the list of ‘critical terms’ compiled by CARM/Medsafe assessors that they considered should trigger an adverse event report to be reviewed.*

Please refer to Appendix 2 below. Note that this list was not static – items were added and removed over time and therefore, the list may not necessarily be complete or represent the whole monitoring period.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602. Please note that this response, with your personal details removed, may be published on the Ministry website at:

www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe

Appendix 2: List of 'critical terms'

- Abortion spontaneous
- Kawasaki's disease
- Acute kidney injury
- Encephalopathy
- Tachyarrhythmia
- Immune thrombocytopenia
- Haematuria
- Hemorrhagic stroke
- Henoch–Schönlein purpura
- Arterial thrombosis
- Leukocytosis
- Thrombosis
- Guillain–Barré syndrome
- Thrombotic thrombocytopenic purpura
- Myoclonic seizure
- Encephalitis
- Multiple sclerosis
- Squamous cell carcinoma
- Meningioma
- Foetal disorder
- Meningitis bacterial
- Aortic stenosis
- Multisystem inflammatory syndrome
- Cyanosis
- Intestinal necrosis
- Venous thrombosis
- Purpura thrombocytopenic
- Bronchospasm
- Blindness
- Acute disseminated encephalomyelitis
- Transient ischemic attack
- Haemophilia
- Sudden death
- Anaphylactoid reaction
- Respiratory failure
- Serum sickness
- Meningitis viral
- Thromboembolism
- Subarachnoid haemorrhage
- Thromboembolic stroke
- Pulmonary embolism
- Cerebral thrombosis
- Capillary leak syndrome
- Intracranial pressure increased
- Uveitis
- Status epilepticus
- Myeloid leukaemia
- Dermatitis exfoliative
- Neonatal death
- Face oedema
- Vaginal bleeding
- Sjögren's syndrome
- Grand mal convulsions
- Gastrointestinal necrosis
- Tetanus
- Bell's palsy
- Loss of consciousness
- Sudden death
- Seizure
- Leukocytoclastic vasculitis
- Dystonia
- Meningitis
- Bronchospasm aggravated
- Absence seizure
- Haemorrhagic stroke
- Circulatory shock
- Leukaemia
- Lymphatic leukaemia
- Encephalomyelitis
- Amaurosis fugax
- Venous thromboembolism
- Haemorrhage
- Arterial thromboembolism
- Embolism
- Thrombophlebitis
- Myeloid leukaemia
- Tonic-clonic seizure
- Unconsciousness

- Transverse myelitis
- Myocarditis
- Facial palsy
- Myocardial infarction
- Vasculitis
- Respiratory arrest
- Asphyxia
- Shock
- Face oedema
- Foetal distress syndrome
- Sarcoma
- Cerebral venous sinus thrombosis
- Ischaemic stroke
- Anaphylactic shock
- Meningism
- Intussusception
- Death
- Stroke
- Thrombocytopenia
- Peripheral cyanosis
- Pancreatitis
- Aseptic meningitis
- Brain oedema
- Chilblains
- Pulmonary thromboembolism
- Pericarditis
- Facial paralysis
- Foetal hypokinesia
- Sepsis
- Deep vein thrombosis (DVT)
- Stevens–Johnson syndrome
- Polymyalgia rheumatica
- Type 2 diabetes mellitus
- Myasthenia gravis-like syndrome
- Myelitis
- Hypersensitivity vasculitis
- Type 1 diabetes mellitus
- Skin necrosis
- Anaphylaxis
- Coma
- Thrombocytopenic purpura
- Foetal growth restriction
- Ankylosing spondylitis
- Electrocardiogram QT prolonged
- Foetal death
- Convulsions
- Malignant neoplasm
- Oral mucosa blistering
- Liver injury
- Thrombotic stroke
- Erythema multiforme
- Retinopathy
- Systemic lupus erythematosus
- Cardiomyopathy
- Pericardial effusion
- Myelodysplastic syndrome
- Postherpetic neuralgia
- Conversion disorder
- Autoimmune haemolytic anaemia
- Suppressed lactation
- Bronchiectasis
- Cardiomegaly
- Weight increased
- Parkinson's disease
- Bundle branch block
- Tubulointerstitial nephritis
- Exercise tolerance decreased
- Atrioventricular block
- Thyroiditis
- Bacterial endocarditis
- Intestinal ischaemia
- Restless legs syndrome
- Trigeminal neuralgia
- Hypoalbuminaemia
- Menopausal symptoms
- Vitreous detachment
- Hypokalaemia
- Akathisia
- Cardiac sarcoidosis
- Vitiligo
- Aortic dissection
- Postmenopausal haemorrhage
- Sarcoidosis
- Coronary artery disease

- Anhidrosis
- Ejaculation disorder
- Condition aggravated
- Hypophosphataemia
- Congestive cardiomyopathy
- Ruptured aneurysm
- Diverticulitis
- Ectopic pregnancy
- Fasciitis
- Nerve injury