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13 February 2024

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023034730

Tēnā koe s 9(2)(a)

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 9 January 2024 for information regarding World Health Organization International Health Regulations (WHO IHR) 2005, Annex 6, Vaccination, Prophylaxis and related certificates. You requested:

- 1. Please confirm that the COVID-19 vaccines used in New Zealand were approved for use here by the WHO in accordance with IHR 2005. If so please list all COVID-19 vaccines approved by the WHO for use in New Zealand.*
- 2. If approved for use in New Zealand by the WHO, please confirm if the WHO requested the State to provide evidence of suitability and prophylaxis of the COVID-19 vaccines for use in New Zealand.*
- 3. Please provide evidence of the WHO approval for the use of COVID-19 vaccines in New Zealand.*

Please find a response to these requests below.

Since the beginning of the COVID-19 pandemic, Medsafe has approved five COVID-19 vaccines for use in New Zealand. These are:

- Comirnaty (Pfizer)
- Spikevax (Moderna)
- Janssen COVID vaccine
- Vaxzevria (Astrazeneca)
- Nuvaxovid

These vaccines were approved on the basis of comprehensive information provided by their vaccine sponsor companies. The Medsafe evaluation considered the safety, quality, and efficacy of the vaccines. Three of these vaccines were subsequently made available to New Zealanders. These are Comirnaty, Vaxzevria (subsequently removed from availability), and Nuvaxovid.

Further information on the Medsafe vaccine evaluation and approval process is here: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

Separately, the WHO has a system called the WHO Emergency Use Listing Procedure (EUL) which is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutic products, and in-vitro diagnostics with the aim of expediting the availability of these products during a public health emergency. You can find more about the WHO EUL here: <https://extranet.who.int/prequal/vaccines/emergency-use-listing-procedure>.

The WHO did not request confirmation of the specific vaccines used in New Zealand as this is for the country to determine, and New Zealand used vaccines that were on the WHO list.

In May 2023, the WHO declared that COVID-19 no longer constitutes a public health emergency of international concern (PHEIC). As such, the WHO ceased accepting any new applications (or resubmissions) under the EUL procedure.

A list of the COVID-19 vaccines with WHO Emergency Use Listing are available here: [COVID-19 Vaccines with WHO Emergency Use Listing | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#). All the Medsafe approved COVID-19 vaccines are on the WHO EUL list.

You have also requested:

4. Please confirm that the vaccination certificates issued in New Zealand for COVID-19 are recognised by the WHO as valid as per certificate validity requirements outlined in IHR 2005

Regarding your fourth question, I have interpreted “vaccination certificates” to be the digital international travel COVID-19 vaccination certificate, which New Zealanders can obtain to provide a record of their COVID-19 vaccination(s) for travelling to other countries that have COVID-19 vaccination entry requirements.

In 2021, in the absence of a global standard for digital vaccination certificates, New Zealand aligned its digital international travel COVID-19 vaccination certificate with the European Union Digital COVID-19 Certificate (EUDCC) format. This format was supported by the WHO guidance for developing interoperable digital certificates for COVID-19 vaccination status. For more information about the WHO guidance, please see here: www.who.int/publications/i/item/WHO-2019-nCoV-Digital-certificates-vaccination-2021.1.

Later, following the European Union (EU) acceptance that New Zealand had met its rigorous standards, New Zealand was officially ‘onboarded’ into the EUDCC framework. The EUDCC system eventually became the most widely adopted global standard for COVID-19 vaccination certificates with all EU countries and 51 non-EU countries signing up to the framework. The EU has now transferred the EUDCC to the WHO. You can find out more about that development on this website: www.who.int/initiatives/global-digital-health-certification-network.

The International Certificate of Vaccination or Prophylaxis (ICVP), also referred to as the “yellow card”, is the official, internationally recognised document that travellers use to document proof of vaccination for diseases included in the International Health Regulations (2005) (IHR). Currently, vaccination against yellow fever, and in some instances, polio, must be documented using the ICVP. There is no requirement to use the yellow card to document vaccination against COVID-19.

Amendments to the IHR are currently being negotiated in Geneva and are expected to be considered by the World Health Assembly in May 2024. Draft amendments propose authorising digital vaccination certificates, while still permitting paper certificates. You can find out more about the proposed amendments to the IHR, and have your say here:

<https://consult.health.govt.nz/public-health-agency/proposed-amendments-international-health-regs/>. The consultation is open until 18 February 2024.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā



Dr Andrew Old
Deputy Director-General
Public Health Agency | Te Pou Hauora Tūmatanui