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21 January 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202200037

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 (the Ministry) on 29 December 2021 for information relating to the four manufacturers of point of care testing in New Zealand.

You requested information on the following:

Any US FDA emergency use authorisations:

Information on In Vitro Diagnostics emergency use authorisations of rapid antigen testing is available on the United States Food and Drug Administration website: www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.

Any UK DHSC approval (phase 3a validation):

The outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 is available from: www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices.

Any MHRA approval or exceptional use authorisation:

A list of medical devices given exceptional use authorisation is available from: www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic/list-of-medical-devices-given-exceptional-use-authorisations.

Any WHO Emergency Use listing of IVDs detecting SARS-CoV-2:

Information on the emergency use listing procedure open for In Vitro Diagnostics is available on the World Health Organization's website: *https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open.*

Any TGA approval for inclusion in the ARTG:

Information on the COVID-19 test kits included in the Australian Register of Theurapeutic Goods us available from: www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia.

Any CE compliance certification.

CE markings are available in the information sheet, packaging of the products or as a certificate.

I trust this information fulfils your request. 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

PP: Jo Pugh

Darryl Carpenter
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COVID-19 Health System Response