MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

11 November 2021

[redacted]

By email: [redacted]
Ref: H202114647

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 18 October 2021 for information relating to point of care COVID-19 test kits. You stated:

> *"There was a media release issued on the 22nd April 2020 titled COVID-19 Point of Care Test Kits (COVID-19 Point of Care Test Kits COVID-19 Point of Care Test Kits | Ministry of Health NZ indicating that the importation and sale of all point of care COVID-19 test kits is banned unless they gain approval via Medsafe. The relevant gazette notice states "This notice is valid for one year from the date of publication of this notice" being the same date as the date of the media release, 22nd April 2020.*
>
> *Since the 22nd April 2020, there does not appear to have been any further notice either as a new notice or a notice extending the validity period of the original notice."*

Please find a response to each part of your request below.

1. *Has the 22nd April 2020 notice been either renewed or replaced by a new notice issued in the New Zealand Gazette?*

This is refused under section 18(d) of the Act, as the information requested is publicly available in the below weblinks. The 22 April 2020 notice issued under section 37 of the Medicines Act 1981 ceased to have effect from 22 April 2021.

From that date an Order under the COVID-19 Public Health Response Act 2020 took effect. Information on this is published on the Medsafe website at: www.medsafe.govt.nz/Medicines/policy-statements/COVID19/COVID19PointOfCareTestKits.asp and the Ministry of Health (the Ministry) website at: www.health.govt.nz/news-media/media-releases/covid-19-point-care-test-kits.

A link to the Order follows:
https://legislation.govt.nz/regulation/public/2021/0066/latest/LMS451450.html?search=ts_act%40bill%40regulation%40deemedreg_covid_resel_25_a&p=1

2. *A Covid-19 test kit is an article intended to be used for human beings to diagnose infection with Covid 19 by means other than pharmacological, immunological or metabolic although may be assisted in its function by immunological action. This would indicate that a Covid 19 test kit is a medical device and "approval" of new Covid -19 tests is by notification of the test kit to WAND within 30 days of first sale. Is this correct?*

A COVID-19 test kit is an invitro diagnostic medical device (IVD). There is no pre-market assessment or approval process for medical devices in New Zealand under the current legislative framework. There is a requirement for medical devices (with some exceptions) to be notified to

the Web Assisted Notification of Devices (WAND) database held by Medsafe, as per The Medicines (Database of Medical Devices) Regulations 2003. Notification of a device to the WAND database does not indicate an 'approval' of that device, rather that the legislative requirement to notify has been met. Schedule 1 of these Regulations specifies Exempt medical devices, including *"any diagnostic device that is (i) commonly known as an invitro diagnostic device."* However, Medsafe does encourage suppliers of IVD's to notify these to the WAND database. Further information on medical devices and the WAND database is published on the Medsafe website at: www.medsafe.govt.nz/devices/devices-landing.asp.

3. *If a Covid 19 test kit is not considered to be a medical device with "approval' actioned via notification to WAND, what is a Covid 19 test kit considered to be under the Medicines Act 1981 and what information needs to be submitted to Medsafe in order for the Covid 19 test kit to be approved?*

A COVID-19 test kit is a medical device. There is no approval process for medical devices, and as an IVD, there is no requirement for such to be notified to the WAND database, though such notification is encouraged. The 'approval' referred to in the section 37 notice published under the Medicines Act was an exemption from the import ban in that notice. This notice is no longer in force and has been replaced by an Order under the COVID-19 Public Health Response Act 2020. It is this Order that now prohibits the importation, manufacture, supply, sale, packing or using of these test kits unless the person's activity has been authorised, or the IVD test kits have been exempted from the prohibition. The following link published on the Ministry of Health website includes information on how you can request approval under the current order at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-response-planning/covid-19-epidemic-notice-and-orders#poc-tests

I trust this satisfies 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.

Yours sincerely

Chris James
Group Manager
Medsafe