Notice Under Section 37 of the Medicines Act 1981

Pursuant to section 37 of the Medicines Act 1981, the Minister of Health hereby prohibits the importation, manufacture, packing, sale, supply or use of any kits and/or other test materials intended for use as point of care testing for COVID-19 infection or for post-infection confirmation using an antigen or antibody detection system unless the particular test kit and/or test materials:

a. has been approved by the Group Manager, Medsafe, Ministry of Health, and
b. the kits and/or test materials are imported, manufactured, packed, sold, supplied with the intention that they are only to be used for testing by a specified category of registered health care professional approved by the Group Manager, Medsafe, Ministry of Health.

This notice does not apply to kits and/or other test materials imported by or supplied to the Institute of Environmental Science and Research, or a designated alternate entity approved by the Group Manager, Medsafe, Ministry of Health.

Note: This notice is valid for one year from the date of publication of this notice.

Dated this 22nd day of April 2020.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

2020-go1737 22-04-2020 15:00