Quarantine (Control of Sale and Use of COVID-19 Home Self-Testing Kit) Regulations

2021

GN No. 109 of 2021

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THE QUARANTINE ACT 2020

Regulations made by the Minister under section 13 of

the Quarantine Act 2020

1. These regulations may be cited as the **Quarantine (Control of Sale and Use of COVID-19 Home** Self-Testing Kit) Regulations 2021.

2. In these regulations —

"Act" means the Quarantine Act 2020;

"COVID-19" means the virus known as the novel coronavirus (2019-nCoV);

"laboratory reagents company" means a company registered with the Ministry to impert laboratory reagents;

"PCR test" means the COVID-19 Polymerase Chain Reaction (PCR) test;

"pharmacy" has the same meaning as in the Pharmacy Act;

"private health institution" has the same meaning as in the Private Health Institutions Act; •

"private laboratory" means a laboratory registered with the Ministry;

"registered medical practitioner" has the same meaning as in the Medical Council Act;

"registered nurse" has the same meaning as in the Nursing Council Act;

"Self-Testing Kit" means the COVID-19 Antigen based test kit with nasal, nasopharyngeal or saliva swabs, as approved by the World Health Organisation, the Food and Drug Administration or the European Union;

"wholesale pharmacy" has the same meaning as in the Pharmacy Act and which holds a written authorisation from the Ministry to import Self-Testing Kits.

- 3. (1) A wholesale pharmacy shall not sell any Self-Testing Kit to any person other than to
 - (a) the Ministry;
 - (b) private health institutions;
 - (c) medical practitioners;

- (d) private laboratories;
- (e) laboratory reagents companies; and
- (f) retail pharmacies.

(2) Every sale of a Self-Testing Kit shall be recorded in a register.

(3) Every user shall keep a record of every Self-Testing Kit that has been used, including the name and contact details of the person on which the Self-Testing Kit has been used.

(4) Where a person is tested to be COVID-19 positive by means of a Self-Testing Kit, the user shall forthwith inform the Quarantine Authority.

4. Any register kept under these regulations shall, on demand, be produced to the Ministry.

5. Any person who contravenes these regulations shall commit an offence and shall, on conviction, be liable to a fine not exceeding 500,000 rupees and to imprisonment for a term not exceeding 5 years.

6. These regulations shall come into operation on 26 May 2021.

Made by the Minister on 26 May 2021.