སྨན་རིགས་རྒྱུན་བཀོད་དབང་འཛིན།
Drug Regulatory Authority
Royal Government of Bhutan
Thimphu, Bhutan; Post Box No. 1556

DRA/D1/31-Med-Device/21-22/580 **6th April, 2022**

Regulatory Notification

Subject: ***Requirement of Emergency Use Authorization (EUA) for Import, Sale and Distribution of COVID-19 self-test kits***

This has reference to the Ministry of Health letter No. MOH/COVID-19/2021-22/631 dated April 5, 2022 granting policy clearance for the use of COVID-19 antigen self-test kits in the country.

In the interest of public health and in obedience to the Medicines Act, only technical authorization holders *(Market Authorization Holders and Retails Pharmacy with certified Competent Person)* shall be permitted to undertake the sale and distribution of COVID-19 antigen self-test kits since it falls under the category of medicinal products.

The technical authorization holders will be required to obtain an emergency use authorization (EUA) for the products from the Drug Regulatory Authority (DRA) and subsequently the import authorization (IA).

The particulars required for obtaining EUA and IA from DRA can be accessed from our website dra@gov.bt along with the "Guideline for Import, Sale and Distribution, and Use of COVID-19 self-test kits.

We would like to solicit cooperation from all towards ensuring the safety and quality of the COVID-19 self-test kits. The unauthorized sale and distribution of COVID-19 self-test kits shall be dealt with as per the Medicine's Act of the kingdom of Bhutan 2003.

This notification is issued for compliance please.

DRUG REGULATORY AUTHORITY

For any further clarification and queries kindly contact the following focal officials:

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