VERŻJONI ELETTRONIKA

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,831, 11 ta' April, 2022
Taqsima B

L.N. 118 of 2022

MEDICINES ACT
(CAP. 458)

Testing of COVID-19 (Amendment) Regulations, 2022

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, after consultation with the Licensing Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Testing of COVID-19 (Amendment) Regulations, 2022 and these regulations shall be read and construed as one with the Testing of COVID-19 Regulations, hereinafter referred to as the "principal regulations". S.L. 458.61.

Amends regulation 2 of the principal regulations.

2. Regulation 2 of the principal regulations shall be amended as follows:

(a) the definition "Point-of-Care Test for COVID-19" shall be substituted by the following new definition:

" "Point-of-Care Test for COVID-19" means any test that does not require the submission of the test specimen to a laboratory and that is intended to be used to detect and identify the presence of SARS-CoV-2 or any other marking agent related to it, excluding devices for self-testing;"; and

(b) the definition "rapid antigen test" or "RAT" shall be substituted by the following new definition:

" "Rapid Antigen Test" or "RAT" means a rapid diagnostic test suitable as a COVID-19 Test Kit that directly detects the presence or absence of SARS-CoV-2 antigen;".

Amends regulation 3 of the principal regulations.

3. The proviso to sub-regulation (1) of regulation 3 of the principal regulations shall be substituted by the following new proviso:

"Provided that regulation 9 shall not apply to antibody tests and devices for self-testing.".

Substitutes regulation 8 of the principal regulations.

4. Regulation 8 of the principal regulations shall be substituted by the following new regulation:

8. The Authority shall issue its approval or rejection for designated premises and point-of-care tests and Point-of-Care Tests for COVID-19 and devices for self-testing following the consideration of all relevant documents, and any other information as may be deemed necessary in order to ensure fulfilment of the authorisation requirements submitted by the applicant:

Provided that the Authority may, in its own discretion, request additional information and samples it deems necessary for the evaluation of the application.".

Substitutes regulation 10 of the principal regulations.

5. Regulation 10 of the principal regulations shall be substituted by the following new regulation:

"10. The Authority may, where it so deems necessary, restrict market access to COVID-19 Test Kits in the interest of public health and in accordance with the *In Vitro* Diagnostic Medical Devices Regulations S.L. 427.16.:

Provided that COVID-19 Test Kits and devices for self-testing may be made available to the public by distributors in accordance with the standards published by the Superintendent.".

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