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Ref: MRA 1/8/5 Vol. II (119)

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Attention: All Stakeholders

Dear Sir / Madam,

RE: UPDATE COVID 19 RAPID TEST KITS

The above matter bears reference.

Antigen-based testing kits

As per the latest recommendation from the WHO, the WHO pre-qualified antigen rapid test kits may be used for testing of COVID-19. These have been shown to be more specific and sensitive in the diagnosis of COVID-19. This position has been adopted by BoMRA. Therefore, BoMRA is currently accepting applications for WHO-Prequalified Rapid Antigen Test Kits.

Antibody-based testing kits

Based on the current available science and information, antibody-detecting rapid diagnostic test kits for COVID-19 have low specificity and sensitivity. Therefore, they are not recommended for the diagnosis of COVID-19.

Exemption Procedure

All the entities or individuals who sell, distribute, and import medical devices used in detection, prevention, and control of COVID-19 should apply to BoMRA for Exemption from Registration of Medical devices. Guideline and Forms are available at www.bomra.co.bw, and where applicable for registration.

Your anticipated co-operation is appreciated.

Yours Sincerely

Dr Stephen Ghanie
Chief Executive Officer

Board Of Directors

Mr Duncan Thela (Chairperson) / Dr Mbatshi Mazwiduma / Dr Tiroyaone Mampane / Dr Gaseitsewe Sento / Dr Gontle Moleele / Mr Kagiso Balopi
Ms. Botho Kebabonye Bayendi / Dr Joyce Kgatlwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Letlhogile Modisa / Dr Stephen Ghanie