MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
Telephone: 020-2716905/6, 020-3562107
Cellphone: 0733-884411/0720 608811
Fax: 2713409
Email: admin@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

Pharmacy & Poisons Board Hse
Along Lenana Road
P. O. Box 27663-00506
NAIROBI

When replying please quote our ref No:
PPB/REG/GEN/VOL.III/019/20

6th May, 2020

To:

All Marketing Authorization Holders (MAHs)

Thro'

The Local Technical Representatives (LTRs)

RE: PROCEDURE FOR SUBMISSION OF APPLICATIONS FOR EMERGENCY USE AUTHORISATION OF MEDICAL DEVICES/IVDS IN LIGHT OF COVID-19 PANDEMIC

INTRODUCTION

The Pharmacy and Poisons Board ("the Board") is mandated under section 3B of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya (as amended by the Health Laws (Amendment) Act, 2019) to regulate health products and health technologies. This includes the grant or revocation of licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances, which is defined to include medical devices and In-vitro diagnostics (IVDs). Consequently, any company or individual intending to manufacture, distribute (import/export) or wholesale a medical device/IVD pursuant to the provisions of Section 23 and 35A of the Act must be licensed by the Board.

In light of the pandemic and the need to protect the health of the public, the Board has established this procedure as a guide to all persons intending to place on the market any COVID-19 health product and health technology, more specifically medical devices and IVDs.

The procedure shall be read alongside the following guidelines, available on the Board's website:

a) Guidelines for Emergency & Compassionate Use Authorization of Health Products and Technologies (ECUA) dated April 2020;
b) Requirements for Emergency Use Authorisation of Covid-19 Rapid Test Kits (16/4/2020); and
c) Specifications for Personal Protective Equipment and Materials (2/4/2020).

For the avoidance of doubt, this procedure applies to all products intended to be supplied to support the diagnosis or prevention of the spread of COVID-19, such as masks, gloves, antiseptics and disinfectants used on inanimate surfaces in areas of high risk and IVDs used to diagnose COVID-19.

NEW APPLICATION FOR EMERGENCY USE AUTHORIZATION OF MEDICAL DEVICE/IN VITRO DIAGNOSTICS

1. Any individual or company (the *'Applicant'*) may submit an application to the Board for Emergency Use Authorization (EUA) of a medical devise/IVD.

2. An applicant shall submit the common Technical submission document (CSTD)/dossier through a Medical device establishment (referred to as 'Local Authorized Representative') that has a valid Board license for the issuance of EUA or registration.

3. The application forms are available on the Board's website (www.prims.pharmacyboardkenya.org).

4. Reference should be made to the relevant guidelines, found on the Board's website, to provide guidance pertaining to the requirements for Emergency Use Authorisation process.

APPLICATIONS BY LICENCED LOCAL TECHNICAL REPRESENTATIVE

5. Any establishment (*referred to as 'Local Technical Representative'-LTR)* that has a valid Board Wholesale Dealers License may not manufacture, distribute or wholesale medical devices that have not been issued with EUA or registered

6. Local Technical Representative that has a valid Board Wholesale Dealers License may apply to update the product listing and include any medical devices identified to support the diagnosis or prevention of the spread of COVID-19.

7. The LTR that has a valid Board Wholesale Dealers License may not manufacture, distribute or wholesale medical devices, included in the application for emergency use listing, until authorization has been received from the Board to do so.

NOTE: *A Board acknowledgement letter or receipt, acknowledging the submission of an application for the EUA of a medical device will not suffice in lieu of a valid Board license.*

SUBMITTING AN APPLICATION FOR EMERGENCY USE AUTHORISATION OF MEDICAL DEVICE

8. EUA application/s should be submitted via email to the Board (medicaldevices@pharmacyboardkenya.org). Applications for registration may be submitted via website: www. prims.pharmacyboardkenya.org.

NOTE:

i. *An electronically generated letter of acknowledgment of receipt of the application will be sent to the applicant.*
ii. *A Board acknowledgement letter or receipt, acknowledging the submission of an application for the EUA of a medical device will not suffice in lieu of a valid Board license.*

9. The fee for a medical device Emergency Use Authorization application is payable upon application and proof of payment should be submitted together with the completed application.

NOTE: *Fees may be updated from time to time. The onus is on the Applicant to ensure that payment is made in line with the current fees structures as published in the Government Gazette.*

10. Supportive evidence must be provided for each of the medical devices listed, by the applicant, in the EUA application.

11. The EUA application process will be expedited and will be completed as per the timelines included in the ECUA guidelines but usually within 7 calendar days provided that the applications submitted are complete and meet the requirements and that timely responses are received from applicants where relevant.

DOCUMENTS TO BE ATTACHED TO THE APPLICATION

12. The following documents must be submitted with the application to the Board for EUA of medical device:

a) Cover letter on company letter indicating intention to apply for EUA;
NOTE: *the subject of the letterhead should state: RE: COVID-19 APPLICATION FOR EUA*

b) Proof of Payment (Class A: USD 100 , Class B: USD 100 , Class C: USD 1000 & Class D: USD 1000);

c) Curriculum Vitae of the Authorized Representative;

d) Quality Manual (Manufacturers/Distributors);

e) Supportive evidence for each Class C and Class D medical device:-

i. Comprehensive description of the components of the product (Test Kit), including its unique features for positive and negative controls and ancillary reagents;

ii. Evidence of pre-market authorization or registration for each listed test kit, including COVID-19 Nucleic acid test (NAT) and COVID-19 Rapid Test Kit from a Reference Regulatory Authority from at least one of the six jurisdictions recognized by PPB (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualified by the World Health Organization;

iii. A Certificate of Free Sale confirming evidence that each listed COVID-19 Test Kit is legally sold or distributed in the open market, freely without restriction, and approved/listed by the regulatory authority from the country of origin;

iv. Evidence of ISO13485:2016 certification of the original manufacturer for each listed COVID-19 NAT and Rapid Test Kits;

v. A copy of the Instructions for Use for each listed COVID-19 Test Kit;

vi. A copy of labeling and packaging of each listed COVID-19 Rapid Test Kit;

vii. Evidence of performance of test kits i.e. specificity and sensitivity validation tests. For rapid test kits (antibody test kits) to include determination of IgM (for transient immunity) and IgG (for long term immunity) and the earliest period of antibody detection e.g. One week or three weeks post exposure

to COVID-19. Test kits combining the test of IgM and IgG should be preferred. A two-step test would be encouraged in order to reduce uncertainty. e.g. a two-step ELISA test. A specificity assurance of at least 95% is mandatory; preferably 99%.

viii. Technical document in line with *Guidelines on Submission of Documentation for Registration of Medical Devices*, dated August 2017 based on principles of Common Submission Dossier Template (CSDT) stating what has been carried out in each section-even if it may not be complete.

SCREENING (INTERNAL)

13. The application will be screened and reviewed before being issued with an application number.

14. Any queries arising from screening will be sent electronically to the Applicant as observations.

15. The response will be reviewed. If the screening criteria is met, the application will be issued with an application number.

16. If the screening criteria is not met in the response, the application will be rejected.

EVALUATION (EXPERT REVIEW COMMITTEE)

17. The screened application will be allocated for evaluation and peer review process by the Expert Review Committee. An application shall be allocated for review upon submission of proof of payment.

VALIDATION/VERIFICATION

18. The IVD device is submitted to a qualified ISO 15189-2012 validation licensed laboratories for performance validation against pre-determined specifications (protocol).

19. Validation/verification report shall be submitted and reviewed by the Expert Review Committee.

REVIEW BY THE INTERNAL PPB COMMITTEE

20. A summary of applications that meet evaluation criteria shall be presented to the Technical Committee of the Board for ratification of the recommendations by the Expert Committee.

21. An observation letter will be sent to the applicant in the event that an application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the observation letter.

22. In case of deficiencies, the applicant will be expected to submit additional data as a response to the deficiencies. The response will be peer reviewed by either internal PPB experts or members of Expert Review Committee, as appropriate. If the evaluation criteria is met, then Section 17 shall apply.

23. If the evaluation criteria is not met in the first response, a second observation shall be sent to the applicant.

24. The second response will be peer reviewed as per Section 19. If the evaluation criteria is met, then Section 17 shall apply.

25. If the evaluation criteria is not met after the second response the application shall be rejected.

26. If the application is approved, the EUA shall be granted. A notification of EUA collection will be emailed to the applicant. If application is rejected, the applicant will be required to resubmit a new application.

Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER