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To: Stakeholders/Applicants

REQUIREMENTS FOR EMERGENCY USE AUTHORISATION OF COVID-19 RAPID TEST KITS

Introduction

1. The Cabinet Secretary for Health, pursuant to Section 35 of the Public Health Act, Cap 242 of the Laws of Kenya, declared the COVID-19 a formidable pandemic disease and as such a public health emergency.

2. Consequently, the Pharmacy and Poisons Board ("the Board") in view of its functions as stipulated under section 3B(2)(e) of the Pharmacy and Poisons Act; and, amended by the Health Laws (Amendment) Act, 2019, has taken deliberate steps towards facilitating expedited access and availability of essential Health Products and Technologies, specifically, the COVID-19 testing kits during this pandemic.

Regulatory Requirements for Covid-19 Rapid Test Kits

3. COVID-19 Rapid Test Kits are classified as Class D Medical Devices according to Classification Rule 1 for IVDs - Detection of transmissible agents posing a high public health risk.

   An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:

   a) To detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

b) *To detect the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation.*

Examples of such tests include: Tests to detect infection by Corona Virus, HIV, HCV, HBV, HTLV. Pyrogenicity tests (Endotoxin Activity Assay).

4. COVID-19 Rapid Test Kits may only be manufactured, imported, exported or wholesaled by establishments that hold a Wholesalers License issued by the Pharmacy and Poisons Board, licensed clinical laboratories or research institutions and manufacturers.

5. Only Class A and Class B Medical Devices and IVDs may be advertised to the public or a lay person.

6. COVID-19 Rapid Test Kits may not be advertised to the public or lay person.

7. COVID-19 Rapid Test Kits are intended for use by professionals only.

8. COVID-19 Rapid Test Kits are not intended for self-testing and may not be sold to the public or lay person.

9. Labelling/packaging of the COVID-19 Rapid Test Kit must contain an indication that the Medical Device or IVD is intended 'for professional use only".

10. Instruction for use of the COVID-19 Rapid Test Kit must contain an indication of the intended user and that the IVD is for in vitro diagnostic use and for "professional use only".

11. Applicants for Emergency Use Authorization of COVID-19 Rapid Test Kits must submit:

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

    b. Evidence of pre-market approval or registration for each listed COVID-19 Rapid Test Kit from at least one of the six jurisdictions recognized by Pharmacy and Poisons Board (South Africa Sahpra, Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualified by the World Health Organization;

    c. A Certificate of Free Sale confirming evidence that each listed COVID-19 Rapid 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;

d. Evidence of ISO13485:2016 certification of the original manufacturer for each listed COVID-19 Rapid Test Kit;

e. A copy of the Instructions for Use for each listed COVID-19 Rapid Test Kit; and,

f. A copy of labelling and packaging of each listed COVID-19 Rapid Test Kit.

12. The applicant must apply to Pharmacy and Poisons Board for approval of any change in the product name or branding on the label/packaging/instruction for use in the listed COVID-19 Rapid Test Kit.

13. The applicant should evaluate the analytical limit of sensitivity and specificity of this product with any Board-recommended reference laboratory. This may lead to updating its labelling to reflect the additional testing.

14. The applicant must demonstrate to have an infrastructure that will enable collection of information on the performance of this product. The applicant will report to the Board any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which they become aware of.

15. NOTE: These products may be referred to by similar names e.g. "COVID-19 POC (Point of Care) Test" or "Corona Self-test"; and, the same requirements are relevant and will be enforced, regardless of the name used.

16. Sale of such IVDs by a license holder to an unauthorized person will be an infringement of the Pharmacy and Poisons' Act and may lead to revocation of the Emergency Use Authorization.

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CHIEF EXECUTIVE OFFICER

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