PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Our Ref : (9) dlm. MDA. 100-1/7/2
Date : 15th March 2023

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 1 YEAR 2023

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL DEVICE ACT 2012 (ACT 737):

PERMISSION FOR PLACEMENT IN THE MARKET OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE SELF-TEST KITS

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) regarding the permission for the placement in the market of self-testing kits to detect Human Immunodeficiency Virus (HIV) infection.

BACKGROUND

2) Malaysia has been dealing with the HIV or AIDS epidemic for about three decades since the first case was detected in 1986.

3) The Ministry of Health Malaysia (MOH) has undertaken various efforts to curb HIV/AIDS infection in Malaysia. Efforts are carried out together with Non-Governmental Bodies (NGOs) and corporate bodies through HIV/AIDS prevention, control, treatment and care programs.

4) To enhance efforts towards ending AIDS by 2030, the MOH has introduced HIV self-test (HIVST) as a method of Test and Treat HIV/AIDS to encourage more key populations and their partners undergoing screening and getting treatment.

5) However, since HIV is a serious infectious disease and the HIVST will be handled by the public, MDA should take into account the safety and performance of the HIVST when allowing this medical device to be placed in the Malaysian market in order to preserve the interests of public safety and health.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Devices Authority Meeting No.1 Year 2023 has decided to set the policy for the placement of HIVST in the market subject to certain conditions as follows:**

a) **To guarantee quality, HIVST that does not have approval or registration from recognized countries shall go through a full conformity assessment process, and the test kits must go through performance evaluation in recognized laboratories as follows:**
   i. **National Public Health Laboratory (MKAK), Sungai Buloh;**
   ii. **Institute for Medical Research (IMR), Kuala Lumpur;**
   iii. **Tropical Infectious Diseases Research & Education Centre Laboratory (TIDREC), University of Malaya; or**
   iv. **Other recognized laboratories from time to time.**

b) **The sensitivity of the HIVST kit shall not be less than 99.0% for blood samples and not less than 92.0% for saliva samples. The sensitivity of the HIVST kit means the ability of the test kit to detect HIV 1 and 2 antibodies in a sample of a person infected with HIV.**

c) **The specificity of the HIVST kit shall not be less than 99.0% for both blood and saliva samples. The specificity of the HIVST kit means the ability of the test kit to detect the blood of a person who is free of HIV infection.**

d) **The performance of the HIVST kit mentioned above is by using the method of detecting antibodies and antigens.**

e) **The distribution activities that are allowed to be implemented are as follows:**
   i. **Establishments (authorized representatives or manufacturers) to other establishments (distributors) appointed and licensed (with the scope of in-vitro diagnostics (IVD) in the Good Distribution Practice for Medical Devices (GDPMD) certificate and having a valid Letter of Authorization);**
   ii. **Establishment to public and private healthcare facilities; and**
   iii. **Establishment to NGO(s), specifically for NGOs and its partner organizations that collaborate with the MOH.**

f) **HIVST can only be sold or supplied to the public by:**
   i. **Community pharmacy licensed with the Pharmacy Services Program, MOH;**
   ii. **Public and private healthcare facilities; and**
   iii. **NGO(s) and its partner organizations that collaborate with the MOH.**

HIVST can be sold online by f(i) and (iii). However, deliveries shall be carried out by suitable logistic providers with assurance of safety and performance.

g) **The sale of HIVST by individuals either physically or online is strictly prohibited.**

USAGE AND EFFECTIVE DATE

7) The circular issued shall be used as part of the requirements under Act 737 and this circular shall be effective from the date the *Polisi dan Prosedur Ujian Saringan HIV Kendiri* by the Disease Control Division, MOH is published.

ENQUIRIES

8) Any enquiries relating to this circular can be forwarded to:

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Thank you.

"MALAYSIA MADANI"
"BERKHIDMAT UNTUK NEGARA"

(TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH)
Chairman
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