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

Our Ref : (3) dlm. MDA. 100-1/7/2 Jld 2
Date : 9 May 2022

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 2 YEAR 2022

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

CONTROL OF ORPHANED, OBSOLETE AND DISCONTINUED MEDICAL DEVICE IN HOSPITAL, HEALTHCARE FACILITIES INSTITUTION OR ANY RELATED FACILITIES

PURPOSE

1) The purpose of this circular is to set the implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to control of orphaned, obsolete and discontinued medical device in hospital, healthcare facilities institution or any related facilities in Malaysia.

BACKGROUND

2) Orphaned medical device means an existing medical device in a hospital, healthcare facilities, or any related facilities where the manufacturer or authorized representative has ceased operation.

3) Obsolete medical device means an existing medical device in a hospital, healthcare facilities, or any related facilities which is oudated, or no longer being manufactured due to design changes, evolution of new technologies.

4) Discontinued medical device means an existing medical device in a hospital, healthcare facilities, or any related facilities that is no longer in the distribution.

5) Section 5(1) no medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

6) Section 5(2) any person who contravenes section 5(1) commits an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

7) Section 15 (1) states that no establishment shall import, export or place in the market any registered medical device unless it holds an establishment licence granted under this Act.

8) Section 77, Act 737 states that, the Minister may, if he considers it consistent with the purposes of this Act or in the interest of public health and safety, by order

published in the *Gazette*, exempt any person or medical device from any of the provisions of this Act or any regulations made under this Act for such duration and subject to such conditions as the Minister may specify and he may alter or add the conditions so specified.

9) All medical devices must be registered before being imported, exported or placed in Malaysian market. However, there are orphaned, obsolete and discontinued medical devices which is not registered and still being used in hospitals or healthcare facilities institution. Some of these medical devices can not be registered because unable to comply with registration requirements.

10) Therefore, to ensure that medical services in hospital or healthcare facilities institution are uninterrupted, there is a need to improve the policy to control this medical device.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

11) The Medical Device Authority Meeting No. 2 Year 2022 has decided to set the implementation and enforcement control of orphaned, obsolete and discontinued medical device in hospital, healthcare facilities institution or any related facilities as follows:

a) An orphaned, obsolete and discontinued medical device that has been placed in the market is exempted from medical device registration and establishment licence requirement;

b) The risk of using orphaned, obsolete and discontinued medical device is under the responsibility of establishment, users and healthcare facilities institution;

c) Establishment shall be responsible for post-market issues on any obsolete or discontinued medical device at least in accordance with the projected useful life of the medical device as determined by the manufacturer and comply with the prescribed requirements as stated in registration conditions and Medical Device (Duties and Obligations of Establishments) Regulation 2019; and

d) A user who use orphaned, obsolete and discontinued medical devices are subject to the requirements of Section 43 of Act 737 which states that a user must ensure that medical devices used on a third party are:

   a. Safe and efficacious;
   b. Used in accordance with its intended purpose;
   c. Used in accordance with the manufacturer's instructions; and
   d. Properly installed, tested, commissioned and maintained.

e) An obsolete and discontinued medical device that has not been registered and to be placed in the market still require a valid medical device registration certificate.

12) Establishments/healthcare facility institutions do not need to submit notification application to MDA for orphaned, obsolete and discontinued medical devices that has been placed in the market.

USAGE AND EFFECTIVE DATE

13) With the issuance of this Circular Letter, the Circular Letter of MDA No. 2 Year 2018 (Revision 2) is revoked.

14) This Circular shall be used as part of requirements under Act 737 and shall be effective from the date it is issued.

ENQUIRIES

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

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Thank you

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(TAN SRI DATO' SERI DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia