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

Our Ref : (41) dlm. MDA. 100-1/7/2
Date : 15 April 2019

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 1 YEAR 2019

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

POST-MARKET RESPONSIBILITIES FOR MANUFACTURER AND AUTHORIZED REPRESENTATIVE (AR)

PURPOSE

1) The purpose of this circular is to set the implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to post-market responsibilities for manufacturer and authorized representative who have cease business after placing the medical device in the Malaysian market.

BACKGROUND

2) There are 3 situations involving establishment in Malaysia:
   a) AR closed its business and no replacement after placing medical device in the market.
   b) AR closed its business after placing medical device in the market and being replaced by another AR.
   c) Manufacturers closed its business and have no replacement after placing medical device in the market.

3) This will cause problems in the event of a post-market issue such as complaints, incidents and recall of the medical device. The need for accountability for postmarket issues should be developed to ensure that safe and effective medical devices can be controlled.

4) In accordance with Section 38(1), an establishment shall monitor the safety and performance of the medical device manufactured, imported, exported and placed in the market, and put in place a post-market surveillance system as prescribed by minister.

5) Besides that, in accordance with Section 38(2), an establishment shall ensure that any vigilance report of adverse incident involving its medical device in the market is properly recorded and fully evaluated.

6) Refer to both sections 38 (1) and (2), if the manufacturer and AR closed its business or replaced by another AR after placing a medical device in the market, it will cause problem in the event of a post-market issue such as complaints, incident and recall of the medical device. The need for responsibility for post-market issues should be developed in accordance with the purposes of this Act.

7) Section 25(2), the Authority may, at any time after the suspension, revocation, surrender or non-renewal of an establishment license, give such directions to the licensee as it may deem necessary in the interest of public health and safety, and the licensee shall comply with all such directions.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

8) The Medical Device Authority Meeting No 1/2019 has decided to set the implementation and enforcement control of post-market responsibility for manufacturer and authorized representative as follows:

a) AR closed its business and no replacement after placing medical device in the market;

-AR shall be responsible for post-market issues at least in accordance with the projected useful life of the medical device as determined by the manufacturer.

b) AR closed its business after placing medical device in the market and being replaced by another AR;

-The newly appointed AR shall be responsible for post-market issues of the medical device.

c) Manufacturers closed its business and have no replacement after placing medical device in the market;

-The Manufacturer shall be responsible for post-market issues at least in accordance with the projected useful life of the medical device as determined by the manufacturer.

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

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

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Medical Device Authority
Ministry of Health Malaysia
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63000 Cyberjaya, Selangor, MALAYSIA
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Thank you

"BERKHIDMAT UNTUK NEGARA"

(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia