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

Our Ref: (4) dlm. MDA. 100-1/8/5
Date : 22 May 2014

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 1 YEAR 2014

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

ESTABLISHMENT AS AUTHORISED REPRESENTATIVE AND ESTABLISHMENT UNDERTAKING MULTIPLE ACTIVITIES

PURPOSE

1) The purpose of this circular is to set the policy for implemention and enforcement under the Medical Device Act 2012 (Act 737) relating to establishments as authorised representative and establishments undertaking multiple activities.

BACKGROUND

2) To ensure smooth implementation and enforcement of Act 737, the Medical Device Authority has taken the initiative to set the policy on the following issues:

i) establishment as authorised representative for manufacturer having a principal place of business outside Malaysia; and

ii) establishment undertaking multiple activities

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

Establishment as authorised representative

3) In accordance with Section 2 of Act 737, "establishment" means–

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not included a retailer; and

(b) an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being–

(A) a person domiciled or resident in Malaysia; or

(B) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia.

4) The authorised representative shall act as representative for foreign manufacturer relating to any roles and responsibilities under Act 737, including compliance towards duties and obligations of licensees embodied in Section 37-44 of Act 737, for medical device products represented by them.

5) To ensure transparent and appropriate implementation of the roles and responsibilities stated above, **the Medical Device Authority Meeting No. 2/2014 has decided to set the policy on implementation and enforcement as follows:**

i) **Each medical device imported and placed in Malaysian market shall be represented by a single authorised representative; and**

ii) **Manufacturer outside Malaysia having many medical device products to be imported and placed in Malaysia may appoint more than one authorised representative by fullfilling condition 5(i) above.**

Establishment undertaking multiple activities

6) In accordance with Section 15(1) of Act 737, no establishment shall import, export or place in the market any registered medical device unless it holds an establishment license granted under this Act.

7) There are various business models combining different roles/activities in the market. Some establishment conduct all kinds of roles/activities, whilst some other only are committed to a particular role/activity. The requirement of separate license for different roles/activities will increase regulatory cost and this will result in disruption of supply and possible increase in the price of medical device.

8) For the above reasons, **the Medical Device Authority Meeting No. 2/2014 has decided to set the policy on implementation and enforcement as follows:**

i) **establishment that serves as the manufacturer of a medical device may carry out the activities of distributing medical device under a single license;**

ii) **establishment that serves as the Authorized Representative may distribute and import medical device represented to them under a single license;**

iii) **establishment that serves as importer and distributor may carry out the activities of importing and distributing medical device under a single license.**

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

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

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 5, Menara Prisma, No. 26
Jalan Persiaran Perdana, Presint 3
62675 Putrajaya, MALAYSIA
Tel. : (+603) 8892 2400, Fax: (+603) 8892 2500
Email: mdb@mdb.gov.my

Thank you.

"BERKHIDMAT UNTUK NEGARA"

(Y. BHG. DATUK DR. NOOR HISHAM B ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia