POLICY UPDATES ON IMPLEMENTATION OF MEDICAL DEVICE REGULATORY CONTROL IN MALAYSIA ACT 737

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ESTABLISHMENT AS AUTHORISED REPRESENTATIVE AND ESTABLISHMENT UNDERTAKING MULTIPLE ACTIVITIES

1) BACKGROUND

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:

- **Establishment as authorised representative for manufacturer having a principal place of business outside Malaysia; and**
- **Establishment undertaking multiple activities**

2) In accordance with Section 2 of Act 737, ”establishment” means-

- 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
- an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia, and such person and authorized representative being –

i. a person domiciled or resident in Malaysia; or

ii. a firm or company constituted under the laws of Malaysia, and carrying on business or practice principally in Malaysia.

3)The authorised representative shall act as representative for manufacturer outside Malaysia 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 product represented by them.

ESTABLISHMENT AS AUTHORISED REPRESENTATIVE

4) To ensure transparent and appropriate implementation of the roles and responsibilities stated above, **the Medical Device Authority Meeting 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 fulfilling condition 4(i) above.

ESTABLISHMENT UNDERTAKING MULTIPLE ACTIVITIES

5) 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.

6) For the above reasons, **the Medical Device Authority Meeting 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;**

Manufacturer
Distributor

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

AR
Distributor
Importer

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

Importer
Distributor

CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICE APPROVED BY RECOGNISED COUNTRIES

1)BACKGROUND

Section 7 of Act 737 requires the carrying out of conformity assessment by the conformity assessment body registered within Section 10 of Act 737. This is a preconditon for having a medical device registered under the Act.

However, there are various medical device which have undergone conformity assessment and approved to be placed in certain recognized countries. The conformity assessment done by the respective countries are similar to the requirements under Act 737.

2)POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

Recognition means adopting conformity assessment and approval of medical devices placed in the market of certain countries. This recognition will prevent a repetition of the process of evaluation and approval granted on a medical device and therefore will simplify, reduce costs and accelerate the registration of medical devices in this country.

CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICE APPROVED BY RECOGNISED COUNTRIES

3) For reasons stated above, **the Medical Device Authority has decided to set the policy for implementation and enforcement as follows:**

i. **To recognize the recognition of conformity assessment and approval of medical devices placed on the market of a particular country;**

ii. **For medical devices that have undergone conformity assessment and approval for placement in the market of the recognized countries, it only needs to undergo a simpler conformity assessment process, which is through the process of verification of evidence-based compliance obtained from the manufacturer of medical device ;**

iii. **The verification process shall be conducted by the conformity assessment body registered under Section 10 of Act 737 in accordance with the procedures as set out in Appendix 1.**

APPENDIX 1:

REGULATORY AUTHORITIES AND NOTIFIED BODIES AND THE APPROVAL TYPES RECOGNIZED BY MDA

Country/Region	Approval Type
(i) Australia	
(i) Canada	
(i) European Union (EU)	
(i) Japan	
(i) United States of America (USA)	
(i) Any other notified bodies	

Appendix 1: The conformity assessment elements and the parameters to be verified for each element

Conformity assessment element	Parameters to be verified
1) Conformity assessment of quality management system	
1) Conformity assessment of post-market surveillance system	(i) (ii
1) Conformity assessment of technical documentation	(i) (ii
1) Declaration of conformity	(i)

EXEMPTION OF MEDICAL DEVICE FROM REGISTRATION

1)BACKGROUND

Section 5, Act 737, requires all medical devices to be registered before they can be imported, exported or placed in the market.

However, some medical devices are low risk, whilst some are custom-made devices needed for use by qualified medical practitioners for his patients or for use in emergency situations or in situations where all conventional treatments have failed, unavailable or unsuitable. Some devices are also only used for the purpose of clinical evaluation, demonstrations or education.

2)POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

Medical devices that is intended to be exempted from the registration requirements are low risk or only limited in its usage therefore it is possible to have a control by means of a notification.

Section 77 of Act 737 provides for Minister to exempt any medical device from any provision of this Act, by order published in the Gazette if it is consistent with the purpose of this Act.

EXEMPTION OF MEDICAL DEVICE FROM REGISTRATION

3)For the above reasons, **the Medical Device Authority has decided to set the policy on implementation and enforcement as follows:**

Exemption from registration under the Medical Device Act 2012 (Act 737) for medical devices in the following categories:

i. **Low-risk medical devices as listed in Appendix 2.**
ii. **Custom-made medical devices for the use of qualified medical practitioners for his patients.**
iii. **Medical devices for the use of qualified medical practitioners in emergency situations or in the events that all conventional treatment has failed, unavailable or unsuitable.**
iv. **Medical devices for the purpose of clinical evaluation, demonstrations or education.**
v. **Although exempt from registration, Medical Device Authority shall be given notification before bringing in the medical device category specified in paragraph (i).**

The exemption in paragraph (i) is made through administrative method before the exemption order is published in the Gazette.

MEDICAL DEVICE FOR THE PURPOSE OF EXPORT AND TRANSIT AND MEDICAL DEVICE FOR IMPORT/EXPORT FROM/TO COUNTRIES WITHOUT DIPLOMATIC TIES WITH MALAYSIA

1)BACKGROUND

Section 5(1) of Act 737, requires all medical devices be registered before they can be imported, exported or placed in the market. However, with regards to medical devices intended for transit only, no registration requirements under the Act 737. Similarly, no specific provision for medical devices imported/exported from/to countries without diplomatic ties with Malaysia.

Section 45 of Act 737 allows an establishment to apply to the Authority for a permit to export a registered medical device.

2)POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

The Medical Device Authority has decided to set the policy implementation and enforcement as follows:

i. **Medical device for export only has to be registered as required by Section 5 of Act 737.**

ii. **For medical device intended for transit, only notification is required.**

iii. **Eksport Permit / *Certificate of Free Sale (CFS)* will not be issued for medical devices to be imported/exported from/to countries without diplomatic ties with Malaysia, such as Israel.**

CERTIFICATION OF GOOD MANUFACTURING PRACTICE (GMP) FOR THE PURPOSE OF OBTAINING ESTABLISHMENT LICENSE

1) BACKGROUND

This policy decisions is relating to GMP certification issued by National Pharmaceutical Control Bureau (NPCB) for the purpose of obtaining establishment license.

In accordance with Regulation 11(1) of the Third Schedule, Conformity Assessment Procedure, Medical Device Regulation 2012, for the purpose of placement of medical device in the market, manufacturer, authorised representative, importers and distributers of medical devices, shall develop, maintain and implement an appropriate quality management system commensurate with the role and function of the establishment and comply with the requirements in the following table:

Type of Establishment	Quality Management System
(a) Manufacturer	ISO 13485 – Medical devices – quality Management System – Requirements for regulatory purposes
(a) Authorised representative	Good Distribution Practice for Medical Devices (GDPMD)
(a) Importer	Good Distribution Practice for Medical Devices (GDPMD)
(a) Distributor	Good Distribution Practice for Medical Devices (GDPMD)

To date, there are some establishment who wish to apply a establishment license using GMP certification issued by NPCB.

CERTIFICATION OF GOOD MANUFACTURING PRACTICE (GMP) FOR THE PURPOSE OF OBTAINING ESTABLISHMENT LICENSE

2) The Medical Device Authority has decided to set the policy implementation and enforcement as follows:

Medical Device Authority (MDA) accepts GMP certification issued by NPCB only in transition period. The transition period is effective from 1st July 2013 until 1st July 2014. Nevertheless, establishment with GMP certification shall obtain the ISO 13485 certification during the transitional period.


Thank You!