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

Our Ref : (34) dlm. MDA. 100-1/7/2
Date : 5 August 2018

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 5 YEAR 2018

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

ADDITIONAL TRANSITION PERIOD FOR MEDICAL DEVICE LABELING

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to transition period for medical device labeling in Malaysia.

BACKGROUND

2) Circular letter of the Medical Device Authority No. 4 Year 2016 had given a transition period of two (2) years for establishments to comply with the requirements of labeling in accordance with the Sixth Schedule of Medical Device Regulations 2012.

3) Section 4(c) Medical Device Act 2012 (Act 737) requires a manufacturer to ensure that a medical device is labelled, packaged and marked in accordance with the prescibed manner.

4) Regulation 16(1) a manufacturer who –

(a) places any registered medical device in the market;

(b) uses or operates any registered medical device to another person; or

(c) uses or operates any registered medical device to another person for the purpose of any investigational testing,

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shall ensure that the medical device is appropriately labelled according to labelling requirements as specified in Sixth Schedule of Medical Device Regulations 2012.

5) The transition period will assist industry to comply with the labeling requirements in accordance with the Six Schedule of Medical Device Regulation 2012 and to implement the labeling of the medical device before the compliance of the labeling requirements is enforced.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Device Authority has decided for implementation of an additional 3 year transition period for establishments to meet the requirments of labeling in accordance with the Sixth Schedule of Medical Device Regulations 2012, commencing from 5th August 2018. The existing labeling shall be applied during the transition period and establishments shall take appropriate action within this transition period to meet the requirements of labeling in accordance with the Sixth Schedule.**

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

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

Chief Executive
Medical Device Authority
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Thank you.

"BERKHIDMAT UNTUK NEGARA"

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