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

Our Ref : (22) dlm. MDA. 100-1/7/2
Date : 8 Jun 2017

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 2 YEAR 2017

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

NATIONAL PREPARATION TO RATIFY MINAMATA CONVENTION ON MERCURY

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 requirement to fulfill the obligation towards the Minamata Convention.

BACKGROUND

2) Malaysia has signed the Minamata Convention on 24th September 2014 and must comply with its obligations under this Convention.

3) Among the obligations is compliance with Article 4 of the Convention by not allowing the manufacture, import and export of mercury-added products listed in Part I of Annex A specifically thermometers and sphygmomanometers. For more information about the content is available on the Minamata Convention website http://www.mercuryconvention.org/.

4) Through the convention, several measures have been taken which include initiatives of the World Health Organisation (WHO) *"Free Mercury Healthcare Facilities by 2020"* which aims to end the use of medical devices that contain mercury by 2020.

5) Section 43 of the Medical Devices Act 2012 (Act 737) also provides the need to ensure that the use of medical device is safe and effective.

6) Section 77 of Act 737, provides for the exemption of any person or medical device from any provision of the Act or any regulation made under this Act by the Minister, in the interests of public health and safety, by order published in the Gazette.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

7) **The Medical Device Authority Meeting No. 3/2017 has decided to set the policy for implementation and enforcement to stop the use of *thermometer* and *sphygmomanometer* that contain mercury as follows:**

a) **Importation, exportation and manufacture of medical device which contains mercury need to be phased out by 2020;**

b) **Medical device to be placed in the Malaysian market/imported will not be registered;**

c) **Assessment of the application for registration of existing products will be discontinued;**

d) **Not permitted for import, transit, special access, custom made, education and demonstration;**

e) **Establishment shall inform the Authority of any remaining stocks of medical device containing mercury;**

8) **This method is implemented through administratively before order is published in the Gazette.**

USAGE AND EFFECTIVE DATE

9) 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

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"

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