



Our Ref : (25) dlm. MDA. 100-1/7/2

Date : 5 March 2018

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 3 YEAR 2017 (REVISION 1)**

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

**IMPLEMENTATION AND ENFORCEMENT OF GUIDELINE FOR REGISTRATION OF
DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATIONS
PRODUCTS**

PURPOSE

1) The purpose of this circular is to set the implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to medical devices that fall under the definition of Combination Product as defined in the Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combinations Products.

BACKGROUND

2) Drug-Medical Device And Medical Device-Drug Combinations Products are required to fulfill the registration requirement set forth by both Medical Device Authority (MDA) and National Pharmaceutical Regulatory Agency (NPRA).

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

3) The Medical Device Authority Meeting No 6/2017 has decided to set the implementation and enforcement of Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combinations Products. The Guideline shall be implemented and enforced as follow:

a) Unregistered Combination Products

- The Guideline is applicable for registration application applied on/after 1st July 2019

- b) **Unregistered Combination Products under evaluation in which application made prior to 1st July 2019**
 - **The Guideline is applicable during the renewal of registration application**

- c) **Registered Combination Products that have been placed on the market**
 - **The Guideline is applicable during the renewal of registration application for products that shall be expiring on/after 1st July 2019**

USAGE AND EFFECTIVE DATE

- 4) This circular shall be enforced from 1st July 2019.

ENQUIRIES

- 5) Any enquiries relating to this circular can be forwarded to:

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Medical Device Authority
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62675 Putrajaya, Malaysia
Tel.: (+603)8892 2400, Fax: (+603) 8892 2500
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Thank you

"BERKHIDMAT UNTUK NEGARA"



(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
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