



UPDATE

ASEAN MEDICAL DEVICE COMMITTEE

(AMDC)

ASEAN Medical Device Committee (AMDC)

**Agreement on ASEAN Medical Device Directive (AMDD)
Signed by Ministry of Member states on 21 Nov.,2014**

ARTICLE 14

INSTITUTIONAL ARRANGEMENTS

(1) The AMDC shall be established with the overall responsibility of coordinating, reviewing and monitoring the implementation of this Agreement and shall comprise representatives from the Regulatory Authority of each Member State.

Prev. Meetings

1st	Malaysia	1-2 Dec. 2015
2nd	Indonesia (ASEAN Sec.)	3-4 May 2016
3rd	Brunei Darussalam	8-9 Dec. 2016
4th	Cambodia	19-20 April 2017
5th	Indonesia	4-5 Oct. 2017
6th	Singapore	4-5 April 2018
7 th *	Thailand	6-7 Dec. 2018
8th	Philippines	TBA ...

* Next meeting

Latest Meeting of AMDC

4-5 April, 2018 in Singapore

* Chaired by : Ms. Wong Woei Jiuang , HSA, Singapore
vice-chaired by Mr.Nakorn Tangwancharoenchai, FDA, Thailand

* Attended by representatives from Brunei Darussalam, Cambodia, Indonesia, LaoPDR, Malaysia, Philippines, Singapore, Thailand and the ASEAN Secretariat.

* Representatives from the Pharmaceutical and Medical Device Agency Japan, US Department of Commerce, Duke-NUS Centre of Regulatory Excellence (CoRE) >>> *in part of Technical assistance and cooperation with dialogue partners*

UPDATES ON THE IMPLEMENTATION OF AMDD

No.	Member States	Status
1	Brunei Darussalam	- Medical Device Order submitted for approval and targeting to be fully implemented in 2022
2	Cambodia	- Draft AMDD already submitted to the Council Minister and expected to be ready by 2019
3	Indonesia	- The ratification of AMDD is targeted by the end of 2019. - The current regulation on Medical device is already in line with AMDD
4	Lao PDR	- AMDD has been ratified on 25 May 2015
5	Malaysia	- Mandatory period for Product Registration has started on 1 July,2016 - Final draft of the second part of regulations has been finalized on 6 March,2017. - Target for completion of ratification process by 2019
6	Philippines	- Submission for ratification in 2018 - Implementation of the guideline in 2019
7	Singapore	- Instrument of ratification has been submitted to the ASEAN sec. on 10 Nov 2015 - Has fully implemented AMDD
8	Thailand	- AMDD has already been approved by parliament - Target for ratification of AMDD is expected by 2019

UPDATES ON THE IMPLEMENTATION OF AMDD

- Develop GANTT Chart for Phase Implementation of AMDD ...
including of pre-market, post-market and retification status of MS on implementation of AMDD
- Implement of Guideline on Mandatory Adverse Event :
All MS agreed with the Guideline and will present the status on implementation of this Guideline in next AMDC meeting

TECHNICAL ASSISTANCE AND COOPERATION WITH DIALOGUE PARTNERS

- ❖ Cooperation with Pharmaceutical and Medical Device Agency
(PMDA) , Japan
- ❖ Cooperation with the US Department of Commerce (US DoC)
USA
- ❖ Cooperation with CoRE , Duke-NUS

Date & Venue of next meeting

- The 7th AMDC Meeting will be held in BKK, Thailand on 6-7 December, 2018
 - Related Meetings including : AMDTC (5 Dec.), Regulators Training/Workshop (3-4 Dec.) and Industry Training (6-7 Dec.)





THANK YOU