

ACCSQ-MDPWG

MEETING IN MYANMAR

12-13 AUGUST 2015



ONE VISION, ONE IDENTITY, ONE COMMUNITY

ASEAN MEDICAL DEVICE DIRECTIVE

Update on the Signing of AMDD

- As of August 2015, all 10 AMS have signed the AMDD
- The document has been uploaded in the ASEAN website for public domain

Next Steps

- Establishment of ASEAN Medical Device Committee (AMDC)
- Transposition of AMDD into national legislation
- Ensure the consistency and convergence in translation and transposition process
- Deposit of Instrument of Ratification/Notification to ASEAN Secretariat

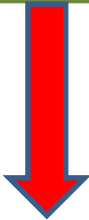
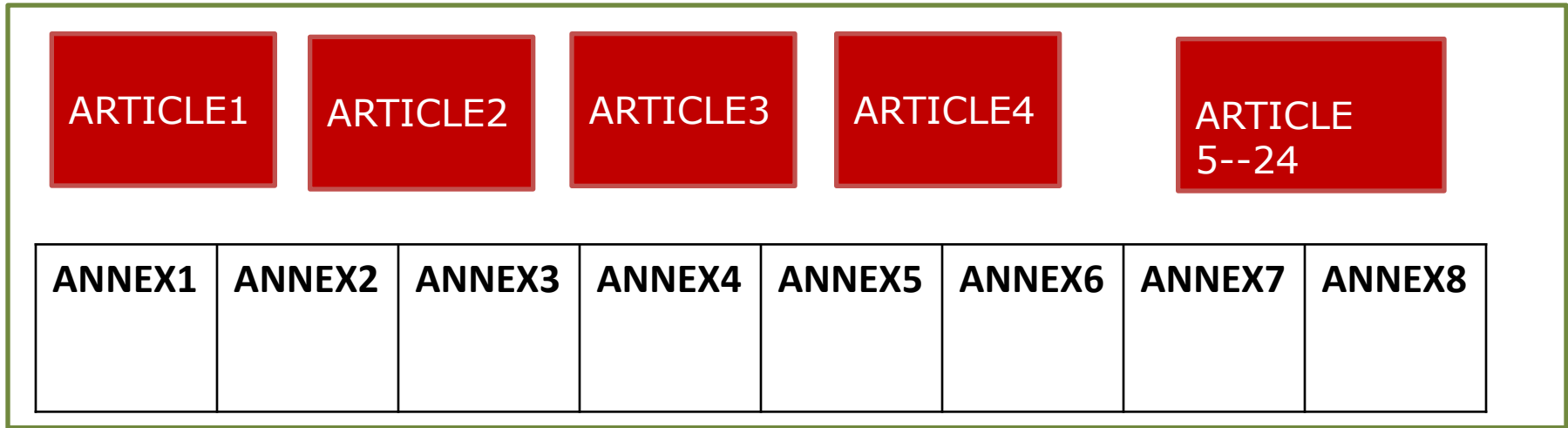
ASEAN MEDICAL DEVICE DIRECTIVE (cont'd)

Next steps (cont'd)

- **Milestone for completion of their transposition process and submission of instrument of ratification by member countries**
- **Requested AMS to consider developing Guideline for implementation of AMDD → Implementation in phases → Grace period for industries**
- **At the ASEAN Medical Device Committee (AMDC) meeting, AMS to continuously update the status of transposition and ratification**
- **AMDC to ensure common interpretation and consistency of translation and transposition of AMDD → Workshop? Engaging Dialogue Partners?**
- **Continuous monitoring of implementation of AMDD**

AMDD CHRONOLOGY (MALAYSIAN SENARIO)

- **AMDD Draft 2007-2012**
- **National Consultation 2012-2013**
- **Revised AMDD Draft- Presentation to Board Meeting-Bil.2/2012**
- **AMDD ver.14 Legal Scrubbing with AGC – 3/7/2013**
- **Legal Scrubbing with ASEAN Legal Division-Final -AMDD ver15: 28 OCT 2013**
- **ACCSQ Endorsement: 1 DEC 2013**
- **SEOM Endorsement :21/22 JAN 2014**
- **ENDORSE BY BOARD FEB 2014, KKM/YBMK APRIL 2014**
- **CABINET APPROVAL JULY 2014**
- **AMDD SIGNED AUGUST 2014**
- **TRANSPOSITION 1.1.2015**



Transpose AMDD into National Laws

National Laws of Member States for Medical Device Control

TOR OF AMDC AND AMDTC

TOR of AMDC

- Noted that the TOR has been endorsed by 42nd ACCSQ Meeting
- Having reviewed Article 14 of AMDD, the HOD agreed to make slight adjustment to the TOR and the revised version was submitted to 43rd ACCSQ Meeting and was endorsed.
- Upon endorsement of TOR by ACCSQ as well as legal advise from ASEAN Legal Division, the 1st AMDC Meeting will be considered to be held in 1-30th November to 2nd December 2015 in Kuala Lumpur

TOR of ASEAN Medical Device Technical Committee (AMDTC)

- The draft TOR of AMDTC was discussed
- AMS to conduct thorough review to the draft and will discuss in detail at the next Meeting



AGREEMENT ON FRAMEWORK FOR DISSEMINATING AND SHARING OF INFORMATION RELATING TO ADVERSE EVENTS ASSOCIATED WITH MEDICAL DEVICE

Guidelines on Post Market Issues

- **HOD agreed to develop a Guidance document on Post Market Surveillance, instead of Agreement. Malaysia will initiate development of this document, by making reference to the Guideline on PMS, developed by EEE sector.**
- **HOD agreed to develop separate Post Market Surveillance Guideline for Medical Device Sector**

POST 2015 ACTIVITIES

- **HOD discussed and agreed that focus on Post 2015 activities for medical device sector will be towards implementation of AMDD**
- **HOD to work on detail Work Plan on Implementation of AMDD, which may include:**
 - **Awareness raising**
 - **Structured way of registration and licensing**
 - **Development of guideline for implementation of AMDD**
 - **Transposition of AMDD into national legislation**
 - **Grace period for industries**
 - **Detail implementation of CSDT**
- **Singapore will develop further detail of Work Plan on Implementation of AMDD. Discussion and endorsement of the Work Plan will be at next Meeting.**

THANK YOU!



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