

**SUMMARY REPORT OF
THE 1ST MEETING OF THE ASEAN MEDICAL DEVICE COMMITTEE (AMDC)
1 -2 DECEMBER, 2015 at PULLMAN KUALA LUMPUR BANGSAR HOTEL,
KUALA LUMPUR, MALAYSIA**

1. The Meeting was attended by delegates from Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, representative from the ASEAN Secretariat, and representative from the ASEAN Medical Industry, as endorsed by their respective HOD, were also in attendance as observers.
2. The Meeting was officially opened by H.E. Datuk Seri Dr. S. Subramaniam, Minister of Health of Malaysia.
3. The Meeting unanimously elected Mr. Zamane Abdul Rahman, Chief Executive Officer Medical Device Authority, Ministry of Health, Malaysia as the Chair and Ms. Wong Woie Jiuang, Director, Medical Device Branch, Pre-marketing Division, Health Sciences Authority, Singapore as the Co-Chair of AMDC for the period of 2 years.

UPDATES ON THE RECENT DEVELOPMENTS IN ASEAN ECONOMIC INTEGRATION INITIATIVES

4. The ASEAN Secretariat updated the meeting on the outcome of the recent developments in the ASEAN economic integration efforts, in particular the decisions made by the ASEAN Economic Members (AEM), Senior Economic Officials Meeting, and the ASEAN Consultative Committee for Standards and Quality (ACCSQ).
5. The Meeting noted the outcomes and decision from the meeting of the higher ASEAN bodies as follows:

AEC Blueprint 2025

5.1 47th AEM held on 22 August 2015 endorsed in principle the AEC Blueprint 2025. The AEC Blueprint was submitted to AEC Council for final endorsement and subsequently submitted to the High Level Task Force (HLTF) on ASEAN Community Port 2015 (Port 2015 HLTF) for consideration with the rest of document that will comprise the integral document for ASEAN Community 2025 (i.e. Kuala Lumpur Declaration, ASEAN Community Vision 2025, three ASEAN Community Blueprints).

5.2 AEC 2025 is envisioned to be highly integrated and cohesive, competitive, innovative and dynamic; with enhance economic connectivity as well as integration and cooperation across sectors while fostering a more resilient, inclusive, and people-oriented, people-centred community that is integrated into the global economy.

5.3 The AEC Blueprint 2025 was launched at the 27th ASEAN Summit held in November 2015 in Kuala Lumpur, Malaysia.

27th ASEAN Summit

5.4 The 27th ASEAN Summit was held in November 2015 in Kuala Lumpur, Malaysia.

5.5 Kuala Lumpur Declaration on ASEAN 2025: Forging Ahead Together Among Others:

- Adopt the ASEAN Community Vision 2025, the ASEAN Political Security Community Blueprint 2025, the ASEAN Economic Community Blueprint 2025 and the ASEAN Socio-Cultural Community Blueprint 2025.

- Decode that ASEAN 2025 succeeds the Roadmap for ASEAN Community (2009-2015)

44th ACCSQ, 7-11 September 2015, Bangkok, Thailand

Outcome of ACCSQ Strategic Session on Development of ASEAN Standards and conformance Strategic Plan 2016-2025 (1st Draft)

6. The meeting was informed that the ACCSQ Strategic Session of ASEAN Standards and Conformance:

6.1 The ACCSQ has developed 1st Draft of ASEAN Standards and Conformance Strategic Plan 2016 – 2025.

6.2 Six Strategic Thrusts has been agreed to be included in the ACCSQ Strategic Plan 2016 – 2025.

6.3 The ACCSQ will refine further the 1st Draft with assistance from EU ARISE. The final draft is expected to be completed by early December 2015, whereby an ACCSQ Workshop will be held back to back with a Special ACCSQ Meeting to endorse the final draft.

6.4 The final draft will be submitted to SEOM 1/47 Meeting in January 2016 for further endorsement by AEM in February 2016.

Progress of MDPWG

7. The Meeting was informed of the progress of activities of the MDPWG ACCSQ has noted the following progress made by the MDPWG:

7.1 AMDC will be established and all Member States were requested to submit names of their respective Heads of Delegation as well as official delegates for AMDC to the ASEAN Secretariat. MDC will commence its first Meeting in early December 2015.

7.2 Matrix of common interpretation of AMDD will be developed and discussed at the 1st AMDC Meeting. The Matrix will be used as main reference for Member States to transpose AMDD into their national legislation.

7.3 Draft Work Plan for implementation of AMDD has been developed and will be further discussed and finalized at the 1st AMDC Meeting.

7.4 Guidelines on Post Market surveillance to support the implementation of AMDD is being developed and the following documents has been identified for further development; (i) Guidance on Field Safety Corrective Action (FSCA), (ii) Guidance on Complaint Handling, (iii) Guidance on Distribution Records, (iv) Guidance on Medical Device Recalls, and (v) Guidance on Mandatory Problem Reporting.

7.5 US Department of Commerce has indicated its commitment to continue its support to MDPWG for implementation of AMDD.

8. The ASEAN Secretariat briefed the Meeting on the follow-up action taken on matters arising from the 20th MDPWG Meeting which was held on 13-14 August 2015 in Yangon, Myanmar.

9. The Meeting noted the action taken on matter arising from the 20th MDPWG Meeting and agreed discuss the pending issues under the corresponding agenda of the meeting.

OUTCOME FROM THE AMDC HOD WORKSHOP

10. Singapore briefed the Meeting on the outcome of AMDC HOD Workshop held on 30 November 2015 in Kuala Lumpur, Malaysia. The Meeting noted that the draft AMDC Work Plan as well as the draft matrix of AMDD Interpretative Notes were discussed and revised during the Workshop.

Work Plan for ASEAN Medical Device Committee

11. The Meeting discussed and agreed in principle to endorse the draft Work Plan. The Meeting further requested Singapore to fill in the column "Time Frame" in the document. Singapore will circulate the revised Work Plan by 31 January 2016 for review and consideration by Member States.

Interpretative Notes for AMDD

12. The Meeting recalled discussion at the 20th MDPWG Meeting on development of Interpretative Notes for AMDD, in order to assist AMS for transposition of AMDD into their national legislation. Taking into account discussion during AMDC Workshop, the Meeting requested Singapore to refine the draft matrix of Interpretative Notes for AMDD. The revised draft matrix will be presented at the 2nd AMDC Meeting.

Article 9 of AMDD

13. The Meeting noted that AMDC may develop list of relevant technical standards to be recognized by AMDC, whereby medical device that completes with those recognized standards would be considered to be in compliance to Essential Principle referred to in Article 3 of AMDD.

14. The Meeting also noted that the list of relevant technical standards to be developed for Article 9 of AMDD, is a separate list from the list of voluntary standards that previously submitted to ACCSQ WG 1.

Article 17 Para 1 of AMDD

15. The Meeting noted on the concern raised by Chair of RBPWG on Article 17 Para 1 of AMDD, which the consideration may create a non-tariff barrier. Many comments to particular clause, the Meeting discussed and agreed that there is no need to change. Hence, the ASEAN Secretariat can inform the decision of AMDC to the Chair of RBPWG.

Possible Cooperation with Pharmaceutical and Medical Device Agency (PMDA), Japan

16. Singapore informed the Meeting that PMDA, Japan will conduct training on the Use of Standards on Evaluation and Monitoring of Medical Device. The training will be held on 23-24 February 2016 in Singapore. Singapore will circulate the details information and agenda of the Meeting to Member States once she received it from Japan.

17. Thailand informed the Meeting that PMDA, Japan will also conduct training in Bangkok, Thailand tentatively in March 2016. Details information of the training will be circulated to the Member States.

18. The Meeting discussed and agreed to seek consideration of ACCSQ to explore possible cooperation with PMDA, Japan in medical device sector. Taking into account the on-going ACCSQ-METI Japan Dialogue, the Meeting suggested to bring AMDC's proposal to ACCSQ-METI Japan Dialogue for their consideration.

Update on the Implementation of ASEAN Medical Device Directive

Updates on the status of ratification and transposition of the ASEAN Medical Device Directive (AMDD) into national legislation.

19. The Meeting noted the following Status of Member States' ratification as well as action taken at national level towards the implementation of the ASEAN Medical Device as follows:

(Lao PDR is the first Member State who has completed its ratification process. Nevertheless, submission of ratification letter is pending.)

| Member States | Status |
|---------------|---|
| Cambodia | The AMDD is already translated into national language |
| | The current registration guideline has been amended to be in line with the AMDD |
| | Still in the process of ratification, expected to be ready by 2017 |
| | |
| Indonesia | Still in the domestic process for ratification |
| | Based on the new trade law for any international trade agreement has to go through the parliament, hence it needs more time to process the ratification |
| | The ratification of AMDD is targeted by 1 st Quarter of 2017. |
| | |
| Lao PDR | AMDD has been ratified on 25 May 2015 |
| | The original instrument of ratification of AMDD is still being prepared to be sent to the ASEAN Secretariat |

| | |
|-------------|--|
| | Preparation for the implementation of the AMDD is on-going including trainings as well as establishment of medical device regulation |
| Malaysia | The AMDD has been transposed into national legislation |
| | In the midst of Drafting the 2 nd regulation which related to Article 22 of AMDD on Post Market Surveillance. The 2 nd regulation will be gazette in Mid 2016. |
| | Ratification of AMDD is expected by end of 2016 |
| Myanmar | 1 st Draft of Medical Device Law to be established by 2016 |
| | Related requirement will be developed in 2017-2018 |
| | Ratification and Full implementation of AMDD by 2020 |
| Philippines | Awaiting approval for guidance document on implementation of AMDD which is expected by end of 2015 |
| | Ratification of AMDD is expected to be submitted by 2016 |
| Singapore | Instrument of ratification has been submitted to the ASEAN Secretariat |
| | Ready to fully implement AMDD |
| Thailand | The Draft Amendment of Medical Device Act was approved by the Cabinet. The internal procedures have to be done through the Parliament for consideration and approval of this amendment |
| | In the process of ratification AMDD will be submitted to the Parliament for consideration and approval |
| | Preparation for the implementation of AMDD is on-going including activities on capacity building for both regulator and industry |

20. The meeting requested Brunei Darussalam and Viet Nam to share update on their status of ratification and transposition, be submitted by 31 December 2015 through the ASEAN Secretariat.

Working Plan for Implementation of AMDD

21. The issue has been accommodated in AMDC Work Plan, as discussed under clauses 11 - 19.

Roadmap towards full Implementation of AMDD

22. The Issue has been accommodated in AMDC Work Plan, as discussed under clauses 11-19.

Development of Guidelines on Post Market Surveillance

23. Malaysia, as the lead of ad-hoc group, presented to the Meeting the progress of the development of Guidelines on Post Market Surveillance for Meeting's consideration. The Meeting noted that Guidelines on Post Market Surveillance will consist of five guidance documents, namely:

- i. Guidance on Field Safety Corrective Action (FSCA)
- ii. Guidance on Complaint Handling
- iii. Guidance on Distribution Records
- iv. Guidance on Medical Device Recalls and
- v. Guidance on Mandatory Problem Reporting.

24. The Meeting discussed and requested Member States to review the draft Guidelines and submit their feedback by 31 March 2016.

25. The Meeting further agreed to review in detail the draft guidelines together with any feedback received, at the 2nd AMDC Meeting.

TECHNICAL ASSISTANCE AND COOPERATION WITH DIALOGUE PARTNERS

Cooperation with the US

26. The Meeting recalled discussion with USDOC counterpart during 20th MDPWG Meeting, where by USDOC requested updated survey on training needs among ASEAN Member States towards implementation of AMDD, in order for them to allocate possible technical and funding support. In this regard, the Meeting discussed and agreed to conduct periodic survey on training needs among AMS, to be led by Indonesia.

Plan for Period Survey on Country training needs

27. Indonesia presented to the Meeting the following timeline for first round of periodic survey for training needs:

| Activities | Due Date |
|--|------------------------------|
| Indonesia will circulate the training needs template to AMS based on priority of the training | 31 January 2016 |
| AMS will submit their training need based on the template that has been submitted | 26 February 2016 |
| Indonesia will collect, review and analyze the common interest of training needs and further categorize the training needs | 31 March 2016 |
| The result of analysis by Indonesia will be further submitted to the ASEAN Secretariat | 30 April 2016 |
| ASEAN Secretariat will circulate the result of analysis to AMS | 15 May 2016 |
| Discussion on the result of analysis at the 2 nd AMDC Meeting | 2 nd AMDC Meeting |

28. The Meeting further agreed that the survey on AMS Training needs will be conducted on annual basis.

29. The Meeting discussed and also agreed to explore possible technical and funding support from other Dialogue Partners/Technical Associations/Organizations. In this regard, based on the result of analysis by Indonesia, the 2nd AMDC Meeting will discuss potential technical supports for each identified training/capacity building activities.

Sharing of National Training Activities

30. The Meeting requested Member States to share their national training activities (to be conducted in English) to other Member States, for their consideration and possibility to join.

Regulatory Affairs Professional Society (RAPS)

31. The Expert from Singapore updated to the Meeting on the information related to Regulatory Affairs Professional Society (RAPS).

Other Matters

Establishment of ASEAN Medical Device Technical Committee (AMDC)

32. The Meeting recalled discussion at the 20th MDPWG Meeting, whereby establishment of AMDC will be considered at later stage. In this regard, the draft TOR of AMDC will be further reviewed once the need arise.

Date and Venue of the next meeting

Lao PDR informed the Meeting that she might not be able to host the 2nd AMDC Meeting due to budget constraint.

33. Noting that there is no AMS able to host the 2nd AMDC Meeting, the Meeting further sought consideration from the ASEAN Secretariat to host the 2nd AMDC Meeting in early June 2016.

34. Recalling decision at the 19th MDPWG Meeting on the hosting of future AMDC Meeting, the Meeting discussed and agreed to update the current list as follows:

| No. | Meeting No. | Date | Venue |
|-----|-----------------------|-----------------------------------|-------------------|
| 1 | 1 st AMDC | 1-2 December 2015 | Malaysia |
| 2 | 2 nd AMDC | 1 st week of June 2016 | ASEAN Secretariat |
| 3 | 3 rd AMDC | 2 nd Half 2016 | Brunei Darussalam |
| 4 | 4 th AMDC | 1 st Half 2017 | Cambodia |
| 5 | 5 th AMDC | 2 nd Half 2017 | Indonesia |
| 6 | 6 th AMDC | 1 st Half 2018 | Singapore |
| 7 | 7 th AMDC | 2 nd Half 2018 | Thailand |
| 8 | 8 th AMDC | 1 st Half 2019 | Philippines |
| 9 | 9 th AMDC | 2 nd Half 2019 | Myanmar |
| 10 | 10 th AMDC | 1 st Half 2020 | Viet Nam |
| 11 | 11 th AMDC | 2 nd Half 2020 | Lao PDR |

35. The Meeting requested Member States to observe and consider the above list and share their confirmation at the next AMDC Meeting.

Source: summarized from the slides presentation during the 1st AMDC Meeting