MMDA NEWSLETTER

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UPDATES

Update on Status of Conformity Assessment Body

Following the announcement on the MDA website in October 2014 that BSI Services Malaysia Sdn Bhd (BSI) has been suspended as a Conformity Assessment Body with immediate effect, MMDA had received many enquiries from our Members as to whether this is a short term or long term suspension and if the suspension will be lifted.

MMDA communicated the members' request for clarity to MDA. The following are the MDA decision on the suspension of BSI Services Malaysia Sdn Bhd is as follows:

1. *BSI Services Malaysia Sdn is required to conduct corrective action on all the establishment which had been audited by an unregistered auditor and conduct a new audit by an auditor registered under Act 737.*

2. *BSI Services Malaysia Sdn Bhd is required to issue new audit reports for all affected establishment for resubmission to the MDA for the purpose of license application.*

With the above response from MDA, MMDA urge its members to contact BSI Services to for advise on the next steps required if you are impacted with the suspension.

Memorandum to the Ministry of Finance on the Goods and Services Tax (GST) on Medical Devices

MMDA, understanding the concerns faced by the upcoming GST implementation for the medical device industry have been working with Medical Device Authority together with other related associations, namely AMMI and MARGA. A collective Memorandum on the Goods and Services Tax (GST) on Medical Devices was sent to the Ministry of Finance on 19th February 2014.

The Medical device industry associations are collectively recommending that all medical devices and establishments registered with Medical Device Authority (MDA) should be classified as essential items and placed in the zero-rated GST category.

MMDA will continue to follow up with the Department of Customs and the Ministry of Finance accordingly on the status of the recommendation. Members will be updated on the outcome.

President's message

Welcome to all members to our newsletter. As you are aware, we have continuously strived to provide updates to members be it announcements from Medical Device Authority or general information from the Medical device industry.

Our newsletter now carries information from regional meetings to keep members updated and abreast of current developments in the global medical device industry.

In 2014, we have seen some amazing changes both within the association and the industry that we are in - with the implementation of the Medical Device Regulations and a new office for the Association.

You have played an important part in enabling MMDA's proactive approach of engaging with the authorities throughout 2014.

As we move into 2015, the MMDA committee members would like to take this opportunity to wish you and your families a happy and healthy New Year. We look forward to a continuation of this partnership in 2015.

Yong Tuan Heng

December 2014

What's new?

The ASEAN Member states provided updates on the respective status of AMDD implementation during the recent ACCSQ meeting:

Member State	Updates on Implementation of AMDD
Brunei Darussalam	Still drafting the Act for Medical Device and targeted to be finalised by end of December 2014.
Cambodia	New regulations already follow AMDD since 2012. The AMDD has been translated into Khmer language. No local manufacturer in Cambodia.
Indonesia	In the process for ratification. Regulation is being amended to be in line with the AMDD. Has been regulating medical devices since 1991. All information are already uploaded in the website.
Lao PDR	Currently drafting new legislation for transposition and already submitted to the Ministry of Health. Translation has already been done.
Malaysia	Currently conducting awareness raising sessions on AMDD to the industry
Myanmar	In the process of national translation of AMDD into Myanmar language and will be submitted to parliament for approval.
Philippines	In the process of ratification of the AMDD. Two administrative guidelines are being developed and is expected to be approved soon. The implementation of the guidelines will be effective one year from approval date.
Singapore	Already have national regulation which is largely in line with the AMDD. There are some minor amendments required to the Regulations to be further aligned with AMDD
Thailand	Already have the work plans to implement the AMDD, including reclassification of medical devices, CSDT Guidelines for industry, compulsory adverse event reporting system for industry, GDP drafting and translation of AMDD into Thai language
Socialist Republic of Vietnam	Decree on medical device developed since 2012. Targeted to be adopted by next year.

19th ASEAN Consultative Committee on Standards and Quality – Medical Device Product Working Group (ACCSQ-MDPWG) Meeting

7th to 9th December 2014 Bandar Seri Begawan, Negara Brunei Darussalam

The 19th ASEAN consultative committee for standards and quality - medical device product working group met in Bandar Seri Begawan, Brunei Darussalam from 7th -9th December 2014.

The Chair was happy to announce that as of 21 November 2014, all 10 ASEAN Member States have signed the AMDD. A copy of the signed AMDD has been uploaded at the ASEAN Secretariat website at the following link: http://www.asean.org/images/pdf/2014_upload/AMDD%20Signed%20November%202014.pdf

To facilitate smooth implementation of the AMDD, the subsequent steps to be taken include:

- 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;
- Member States to develop milestones towards the completion of their transposition process and submission of instrument of ratification by 2020;
- Request to consider (a) developing Guideline for implementation of AMDD, (b) Implementation of AMDD in phases and (c) Grace period for industries;
- At the future ASEAN Medical Device Committee (AMDC) meeting, Member States to continuously update the status of transposition and ratification;
- AMDC to ensure common interpretation and consistency of translation and transposition of AMDD.

Some of the initial areas which need to be worked on for implementation of AMDD are:

- Common Nomenclature
- Single windows
- Development of guidelines for post market surveillance
- Development of guidance for grouping of medical devices

18th AHWP TC Meeting & 19th AHWP Annual Meeting 18th – 21st November 2014, Seoul, Korea

Updates of the recent Asian Harmonization Working Party (AHWP) meeting in Seoul in November.

- AHWP Chairman

Dr. Hee-Kyo Jeong, DG of Medical Device Evaluation, Korea Ministry of Food and Drug Safety (MFDS)

- AHWP Vice chair

En Zamane Abdul Rahman, CEO Medical Device Authority, Malaysia

- Industry Chair

Ms. Quan Tran, GE Healthcare

- TC Chair

Mr. Ali M AL-SALAAN, Executive Director, Saudi Food and Drug Authority, Kingdom of Saudi Arabia.

- TC Co-chair (regulator)

Dr. Jeong-Rim Lee; Director Cardiovascular Devices Division, MFDS, Republic of Korea.

- TC Co-chair (Industry)

Mr. Alfred Kwek, Regional Director, Government Affairs/HME, Samsung Electronics, Singapore.

The newly elected AHWP Technical Committee members received a 3 year term, while advisors are elected for two years

- Two special working groups were formed for standards and software.
- Training Working Group is removed. In recognition of the importance of training and capacity building, TC will take direct charge.
- The new topics discussed were on regulation of software for medical devices (Japan was a focus country), Unique Device Identifiers, regulator intelligence, and changes in the EU framework for medical devices.
- The AHWP "Playbook" has now been finalized by the Technical Committee, and copies were given to the attendees.
- New member of AHWP: Tanzania.
- Bangladesh is currently interested in joining the AHWP.

Next annual meeting will be in Thailand in 2015