



**REPORT OF THE 23rd MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)**

MITEC, Kuala Lumpur, Malaysia

25 October 2018

INTRODUCTION

(1) The 23rd Meeting of the Asian Harmonization Working Party (AHWP) was held on 25 Oct 2018 at Kuala Lumpur, Malaysia. The meeting was chaired by Dr. Zamane Abdul Rahman, Chair of AHWP, co-chaired by Mr. Wang Z. S, representative of Mr. Gao Guobiao, Vice-Chair of AHWP (regulatory authority) and Ms. Tran Quan, Vice-Chair of AHWP (industry).

OPENING CEREMONY

(2) Mr. Ahmad Shariff Bin Hambali, Chief Executive Medical Device Authority, Medical Device Authority (MDA), Ministry of Health Malaysia, welcomed all the participants for joining the 23rd AHWP Meeting in Kuala Lumpur.

(3) Mr. Zamane Abdul Rahman, Chair of AHWP, welcomed and thanked all participants for attending the 23rd AHWP Meeting. He extended his thanks and gratitude to the Malaysia MDA for hosting this Meeting. He also thanked the members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting.

ADOPTION OF AGENDA

(4) The agenda was reviewed and the finalized version as in **ANNEX (1)** was adopted with applause.

UPDATES BY AHWP

(5) Ms. Tran Quan, Vice-Chair of AHWP, reported the enhancement of AHWP global partnership, activities with liaisons members, progress of AHWP website enhancement, as well as the status and analysis of the capacity building project with



APACMed and Deloitte.

The presentation on AHWP Updates was appended as **ANNEX (2)**.

UPDATES BY AHWP TECHNICAL COMMITTEE (AHWPTC)

(6) Mr. Ali M. Al-Dalaan, Chair of AHWPTC, reported the highlights of AHWPTC during the past year, including the AHWP TC strategic plan, summary of planned work items of Working Groups for 2018-2020, endorsed guidance documents of WG, the continuous efforts in achieving global harmonization and capacity building projects carried in the past year.

The presentation on AHWPTC Updates was appended as **ANNEX (3)**.

UPDATES BY IMDRF ACTIVITIES

(7) Ms. Wang Xiaoxue, secretariat of IMDRF (entrusted by Dr. Yuan Lin, chair of IMDRF), presented the latest updates on IMDRF activities, including the organization structure, co-operations with AHWP, updates on seven working groups and summary of on-going activities of the current work items.

The presentation on IMDRF Activities Updates was appended as **ANNEX (4)**.

UPDATES BY APEC:

(8) Mr. Fikriansyah Bin Irman, representative of APEC, presented the updates from APEC, including the priority work areas, roadmap to promote regulatory convergence, work of Centre of Excellence (CoE) in building a better harmonization model, report of trainings provided by APEC since 2009, and also RHSC task to achieve regional convergence on regulatory approval procedures for medical products by 2020.

The presentation on updates from APEC was appended as **ANNEX (5)**.

UPDATES BY WHO



(9) Ms. Helena Ardura, Technical Officer of Essential Medicines and Health Products of WHO, presented the WHO work in IVD and Male Circumcision Devices area. Updates included explaining the work of prequalification team in WHO, guidance in draft or published, international harmonization and convergence as well as prequalified male circumcision devices.

The presentation of WHO Updates was appended as **ANNEX (6)**.

UPDATES BY ASEAN AMDC

(10) Mr. Nakorn Tangwanchaoenchai, representative of ASEAN, presented the updates of ASEAN Medical Device Committee (AMDC). Updates included the implementation of AMDD in difference countries and technical assistance and co-operation with dialogue partners.

The presentation of ASEAN AMDC Updates was appended as **ANNEX (7)**.

UPDATES BY PAHWP

(11) Ms. Grace M. Shimwela, from Tanzania Food and Drugs Authority, introduced the nature, structure, members, vision, mission and goal of PAHWP. Progress on alignment of PAHWP with African Medicines Regulatory Harmonization (AMRH) was highlighted. Updates included the vision of PAHWP of a streamlined future, milestones since 2012, AMRH governance framework with PAHWP as well as PAHWP plans for 2018.

The presentation of Updates on PAHWP was appended as **ANNEX (8)**.

UPDATES ON IMDRF STANDARDS WORKING GROUP (SWG)

(12) Mr. Ishikawa Hiroshi, UDI WG member from IMDRF, and Mr. Peter Linders, Chair of ISO/TC 210, introduced the objectives, standards for regulatory, maps to IMDRF essential principles and IMDRF Standards Recognition Survey. Basic overview of ISO/TC 210 was also introduced, with overview on its structure, active work program and key standards.



The presentations were appended as **ANNEX (9) & ANNEX (10)**.

REGULATORY UPDATES BY AHWP MEMBER ECONOMIES

The country regulatory updates were presented by:

- Ms. Salbiah Yaakop, Medical Device Authority, Malaysia,
- Ms. Li Jun, Director of Division of Registration I, Department of MD Registration, NMPA, China,
- Mrs. Eva Zahrah, Directorate General of Pharmaceutical and Medical Device, Ministry of Health, Indonesia
- Mr. Liew Lailing, Senior Regulatory Specialist, Medical Devices Cluster, Health Sciences Authority, Singapore
- Ms. Cheng Ning Wu, Division of Medical Devices and Cosmetics, TFDA, Chinese Taipei
- Mr. Doan Quang Minh, Department of Medical Devices and Construction, MOH, Vietnam (On behalf of Mr. Nguyen Minh Tuan, Director General)
- Ms. Grace M. Shimwela, Tanzania Food and Drugs Authority

for the regulatory updates on medical device of their member economies, including the authorization organization structure, updates on regulations and guidance, requirements for approval, future trends and actions, etc.

The presentations of country updates were appended as:

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|----------------|--------------|
| Malaysia | : ANNEX (11) |
| China | : ANNEX (12) |
| Indonesia | : ANNEX (13) |
| Singapore | : ANNEX (14) |
| Chinese Taipei | : ANNEX (15) |
| Vietnam | : ANNEX (16) |
| Tanzania | : ANNEX (17) |

UPDATES BY AHWP LIAISON MEMBER - APACMed

(13) Mr. Fredrik Nyberg, representative of APACMed, presented the updates about APACMed current membership, collaboration with AHWP and Deloitte, 2018 Asia



Pacific MedTech Forum, 3rd Asia Pacific Medical Device Regulatory Summit and the upcoming regulatory calendar in 2018.

The presentation of Updates on APACMed was appended as **ANNEX (18)**.

UPDATES BY AHWP LIAISON MEMBER - DITTA

(14) Mr. Naoki Morooka, steering committee member of DITTA, presented the updates about DITTA global presence, structure and governance, achievements on standards, cybersecurity and good refurbishment practice, as well as additional information of APEC LSIF RHSC Medical Devices PWA.

The presentation of Updates on DITTA was appended as **ANNEX (19)**.

UPDATES BY AHWP LIAISON MEMBER – GS1

(15) Mr. Leong Kah Leon, senior executive of GS1, presented the updates about GS1 global system of standards in ensuring visibility, introducing the standards for harmonized implementation of UDI, UDI and GS1 system, new GS1 standards and UDI databases, Global Data Synchronisation Network (GDSN), alignment with global UDI framework and 34th Global GS1 Healthcare Conference.

The presentation of Updates on GS1 was appended as **ANNEX (20)**.

CONFIRMATION OF HOST OF THE 24TH AHWP MEETING

(16) Mr. Zamane Abdul Rahman, Chair of AHWP, declared the confirmation of Sultanate of Oman as the host of the 24th AHWP Annual Meeting, which was supported by AHWP members with applause. Mr. Zamane Abdul Rahman expressed the appreciation on behalf of all AHWP members, to the representative of Sultanate of Oman, for their support on hosting the next meeting, with more details to be announced soon.

REPORT BY SECRETARIAT

(17) Dr. Lawrence Poon, Executive Deputy Secretary General of AHWP, represented



the AHWP Secretariat team to present the work summary for 2017-2018. He reported the summary of secretariat support work done, including:

- Support to AHWP strategic framework towards 2020 “The Foreseeable Harmonization Horizon”
- Support to AHWP Annual Meeting and capacity building project
- Support to the harmonization in key areas based on GHTF principles and AHWP guidance
- Support to the enhancement of AHWP’s global partnership
- Support to the organization of AHWP TC Leaders Meeting and channeling between WG leaders and TC leaders
- Support to the AGMs, management of AHWP reserve/fund in AHWP ASL
- Support to the organizations of secretariat meeting, OC and host of AHWP Annual Meeting
- Support to SADS On-line weekly updates
- Support to AHWP website revamp

The presentation on Secretariat work summary for 2017-2018 was appended as **ANNEX (21)**.

REPORT OF FINANCIAL STATEMENT 2017/2018 AND BUDGET FOR 2018/2019

(18) Dr. Lawrence Poon, Executive Deputy Secretary General of AHWP, presented the financial statement of 2017/2018, with a surplus of US\$237,875.31 as of 30 Sep 2018. The budget for 2018/2019 was presented with estimated income at around US\$293,875.31 and expenditure of around US\$109,436.85. The financial statement of 2017/2018 and the budget of 2018/2019 were agreed and confirmed with applause.

The financial statement and budget was appended as **ANNEX (22)**.

PROPOSED DOCUMENTS FOR RESOLUTION AND ENDORSEMENT

(19) Mr. Ali M. Al-Dalaan, Chair of AHWPTC, announced that the establishment of



the new Work Group 10 for Training. With the discussion in the TC Meeting, TC leaders agreed that the WG 10 would use the competency model as foundation and focus on training. With no objection on the proposed resolution at the meeting, and according to the simple majority rule, Mr. Ali Al-Dalaan declared that the proposed establishment of new Working Group 10 (Training) was endorsed, supported by AHWP members with applause.

(20) Mr. Ali M. Al-Dalaan, Chair of AHWPTC, announced that the PROPOSED “Labelling for In Vitro Diagnostic Medical Devices” was available on AHWP website and completed CALL FOR COMMENTS. With no objection on the proposed document at the meeting, and according to the simple majority rule, Mr. Ali Al-Dalaan declared that the proposed documents was endorsed, supported by AHWP members with applause.

CLOSING REMARKS

(21) Mr. Alfred Kwek, Co-Chair of AHWP TC, presented the closing remarks of the Meeting. He concluded the Meeting by summarizing all the presentations and thanking AHWP and all participants for their contributions. The meeting was adjourned at 17:30 on 25 October 2018.

ACKNOWLEDGEMENT

(22) The participants from over 30 economies expressed their appreciations to the Medical Device Authority, Ministry of Health Malaysia, Malaysia for their hospitality and excellent arrangements for this Meeting.

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