Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

REPORT OF THE 20th MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)

Dusit Thani Bangkok, 946 Rama IV Road
Bangkok 10500, Thailand
6 November 2015
DRAFT

INTRODUCTION

(1) The 20th Meeting of the Asian Harmonization Working Party (AHWP) was held on 6 Nov 2015 at Dusit Thani Bangkok, Thailand. The Meeting was chaired by Dr. Hee-Kyo JEONG, Chair of AHWP, co-chaired by Mr. Zamane Abd RAHMAN, Vice-Chair of AHWP (regulatory authority) and Ms. Tran Quan, Vice-Chair of AHWP (industry).

OPENING CEREMONY

(2) Dr. Boonchai Somboonsuk, Secretary General, Thai-FDA welcomed all the participants for joining the 20th AHWP Meeting in Bangkok.

(3) Dr. Jeong, Chair of AHWP, welcomed and thanked all participants for attending the 20th AHWP Meeting. He extended his thanks and gratitude to the Thai-FDA for hosting this Meeting. He also thanked the members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting.

GROUP PHOTO

ADOPTION OF AGENDA

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

ROLL CALL

(5) The roll call was made by AHWP Chair and Vice-chair, AHWPTC Chair and Co-chair, Working Group (WG) and Special Task Group (STG) Chairs and Co-chairs, TC Advisors as well as representatives from AHWP member economies. Over 250 participants attended the 20th AHWP Meeting, with the list of participants as appended in **ANNEX (2)**.

CONFIRMATION OF MINUTES OF THE 19th AHWP MEETING MINUTES

(6) The meeting confirmed the report of the 19th AHWP Meeting, held in Republic of Korea on 18-21 November 2014, as in **ANNEX (3)** without any amendments.

UPDATES BY AHWP

(7) Ms. Tran Quan, Vice-Chair of AHWP, reported the highlights of progresses over the past year in regard to AHWP strategic framework towards 2020, including the new applications for AHWP member economy, the training and capacity building activities, enhancement of AHWP's global partnership with international organizations, progresses in harmonization in key areas as well as the area of focus in 2016.

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

UPDATES BY AHWP TECHNICAL COMMITTEE (AHWPTC)

(8) Mr. Ali, Al-Dalaan, Chair of AHWPTC, reported the highlights of AHWPTC during the past year, including the development and implementation of AHWP guidelines, summary of planned work items of Working Groups for 2015-2017, AHWP Playbook workshop highlights and recommendation from TC Advisors.

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

UPDATES BY IMDRF ACTIVITIES

(9) Mr. Hideyuki Kondo, representative of IMDRF presented the latest updates on IMDRF activities, including the organization structure and membership, IMDRF recently completed and on-going Work Items, final documents issued in 2015 including IMDRF Strategic Plan 2020, and summary of on-going activities of the current work items.

The Presentation on IMDRF Activities Updates was appended as **ANNEX (5)**.

UPDATES BY APEC LSIF-RHSC:

(10) Mr. Lupi Trilaksono, representative of APEC, presented the updates from APEC LSIF-RHSC, including the priority work areas, roadmap to promote regulatory convergence for medical device vigilance which covers a gap analysis (2016-2017) and a safety alerts dissemination study (2017-2018), training and workshop planning and topics (2018-2020), as well as the action item on the concept note by APEC member countries.

The presentation on updates from APEC was appended as **ANNEX (6)**.

UPDATES BY WHO

(11) Ms. Irena Prat, Department of Essential Medicines and Health Products Prequalification Team of WHO, presented the introduction on WHO work in IVD area, updates on the prequalification of IVD programme, model regulatory framework for medical devices including IVDs, WHO national regulatory assessment (NRA) harmonization tool, the way forward as well as the timeline.

The Presentation of WHO Updates was appended as **ANNEX (7)**.

UPDATES BY ASEAN ACCSQ-MDPWG

(12) Mr. Zamane Abdul Rahman, representative of ASEAN, presented the updates of ASEAN ACCSQ-MDPWG, including updates on the signing of AMDD and next steps for ASEAN member states on implementation with the example of Malaysia scenario, the endorsement and amendment of TOR of ASEAN Medical Device Committee (AMDC) and Technical Committee (AMDTC), the agreement on framework for disseminating and sharing of information relating to adverse events as well as the focus on post 2015 activities towards the implementation of AMDD.

The presentation of ASEAN MDPWG Updates was appended as **ANNEX (8)**.

INTRODUCTION AND UPDATES BY IEC

(13) Mr. Dennis Chew, representative of IEC, presented the introduction of IEC, including the nature, scope, the global reach of IEC with 83 national committees and 83 affiliates, membership types, overall structure and the medical field related committees. Dennis also presented the workflow for developing IEC standards six stages for development of an international standard, publications of IEC, how the IEC conformity assessment system relating to medical equipment and its value-added.

The presentation of Updates on IEC was appended as **ANNEX (9)**.

UPDATES BY PAHWP

(14) Ms. Agnes Sitta Kijo, representative of AHWP, introduced the nature, structure, members, vision, mission and goal of PAHWP, and also the updates for PAHWP, including the priority areas of harmonization, activities and updates on attending important international meetings, training conducted, meeting outcomes and

future plans of PAHWP.

The presentation of Updates on PAHWP was appended as **ANNEX (10)**.

UPDATES BY AHWP LIAISON MEMBER - DITTA

(15) Mr. Susumu Uchiyama, representative of DITTA, presented the updates about DITTA new leadership, key achievements in the past three years, outcomes of DITTA Kyoto standards workshop, recommendation on standards to IMDRF, as well as DITTA view on current IMDRF work items, i.e., SAMD, MDSAP, RPS and UDI.

The presentation of Updates on PAHWP was appended as **ANNEX (11)**.

REGULATORY UPDATES BY AHWP MEMBER ECONOMIES

(16) The country regulatory updates were presented by Ms. Yuwadee PATANAWONG, Director of Medical Device Control of Thailand FDA, Mr. Gao Guobiao, Vice Director of Medical Device registration Department, CFDA, Mr. Aseem Sahu, Deputy Drugs Controller in Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health & Family Welfare, India, Mr. Seil Park, Dr. Noor Muhammad Shah, Director Medical Device Division, Drug Regulatory Authority of Pakistan and Dr. Hiiti Sillo, Director General of Tanzania FDA, for the regulatory updates on medical device of their member economies, including authorization organization structure, updates on regulations and guidance, requirements for approval, future trends and actions, etc.

The presentations of country updates were appended as:

Thailand	: **ANNEX (12)**
China	: **ANNEX (13)**
India	: **ANNEX (14)**
Republic of Korea	: **ANNEX (15)**
Pakistan	: **ANNEX (16)**
Tanzania	: **ANNEX (17)**

REPORT BY SECRETARIAT

(17) Mr. Bryan So, Executive Deputy Secretary General of AHWP, represented the AHWP Secretariat Team to present the work summary for 2014-2015. The Secretariat meeting was held in Mar 2015 in Singapore, chaired by Dr. Hee-Kyo Jeong, Chair of AHWP and Dr. Jeong-Rim Lee, Secretary General of AHWP. Key issues discussed during the secretariat meeting included AHWP 3-year plan for 2015-2017, preparation of the 20th AHWP Bangkok Annual Meeting, financial updates on AHWP ASL as well as website enhancement. Bryan reported the summary of secretariat support work done, including the supports to AHWP Strategic Framework Towards 2020" The Foreseeable Harmonization Horizon", the updates of new application of AHWP member economy, the supports to AHWP leadership on promoting global appearance of AHWP, the supports to the organization of AHWP TC Leaders Meeting and channeling between WG leaders and TC leaders, the supports to Annual General Meetings, the management of AHWP reserve/fund in AHWP ASL, the supports the organizations of Secretariat Meeting, OC and host of AHWP Annual Meeting, the updates to AHWP website and SADS On-line System.

(18) Bryan also reported that surplus from AHWP website and AHWP Annual Meeting were pooled into the AHWP reserve/fund under the AHWP ASL account, to be further facilitated the round-trip air tickets and hotel accommodation for invited speakers and the sponsored regulator representatives of AHWP member economies for their attendance to the AHWP Meetings. Bryan further reported the progress of application for tax-exemption under Section 88 of Inland Revenue Ordinance in Hong Kong for AHWP ASL with the support of legal service providers. As an important progress of ASL's charitable status application, the new AOA of ASL proposed by the legal advisor would be endorsed in the AHWP ASL 2015 Annual General Meeting (AGM) later on the same day.

The presentation on Secretariat work summary for 2014-2015 was appended as **ANNEX (18)**.

REPORT OF FINANCIAL STATEMENT 2014/2015 AND BUDGET FOR 2015/2016

(19) Mr. Bryan So, Executive Deputy Secretary General of AHWP, presented the

financial statement of 2014/2015, with a surplus of US$276,775.81 as of 30 Sep 2015. The budget for 2015/2016 was presented with estimated income at around US$445,168.91 and expenditure of around US$290,898.53. The financial statement of 2014/2015, and the budget of 2015/2016 were agreed and confirmed with applause.

The financial statement and budget was appended as **ANNEX (19)**.

PROPOSED DOCUMENTS FOR RESOLUTION AND ENDORSEMENT

(20) Dr. Jeong, Chair of AHWP, announced that the official letter of application for AHWP member economy from Ministry of Health and Sports, Mongolia, and the application form with nominated representatives was received from Mr. Bayarjargal. S, the nominated primary representative from Ministry of Health and Sports, Mongolia. With no objection on the proposed new application at the meeting, and according to the simple majority rule, Dr Jeong declared that Mongolia was endorsed as the 25th member of AHWP, supported by AHWP members with applause.

Ms.Biziya, Ministrial Advisor, MOH and Sports, Mongolia, also the primary representative (Industry) of Mongolia thanked AHWP & AHWPTC leadership, the local host and Secretariat for guidance and facilitating the application process. He expressed the gratitude to AHWP for welcoming Mongolia as a new member, and presented a short speech on brief introduction of the current medical device regulatory status in Mongolia and the expected MOH and Sports, Mongolia future participations to AHWP activities towards the medical device regulatory harmonization.

(21) Dr. Jeong, Chair of AHWP, announced that the official letter of application for AHWP member economy from Ministry of Health and Social Development, the Republic of Kazakhstan, and the application form with nominated representatives was received from Ms. Gulmira Mukhamejanova, the nominated primary representative from Ministry of Health and Social Development, the Republic of Kazakhstan. With no objection on the proposed new application at the meeting, and according to the simple majority rule, Dr. Jeong declared that Republic of Kazakhstan was endorsed as the 26th member of AHWP, supported by AHWP members with applause.

Ms. Gulmira, Deputy of Director General, MOOH and Social Development, also the primary representative (regulatory authority) of Republic of Kazakhstan thanked AHWP & AHWPTC leadership, the local host and Secretariat for guidance and facilitating the application process. She expressed the gratitude to AHWP for welcoming Republic of Kazakhstan as a new member, and presented a short speech on brief introduction of the current medical device regulatory status in Republic of Kazakhstan and the expected Ministry of Health and Social Development, Republic of Kazakhstan future participations to AHWP activities towards the medical device regulatory harmonization.

(22) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed medical device product submission guidance related document was endorsed, supported by AHWP members with applause.

(23) Dr Jeong, Chair of AHWP, announced that the PROPOSED "White Paper on Regulation of Combination Products – a Review of International Practice" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr Jeong declared that the proposed white paper on regulation of combination products was endorsed, supported by AHWP members with applause.

(24) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. However, concerns were received during the meeting from the floor, and Dr. Jeong thus recommended the proposed document to be further reviewed.

(25) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Guidance document on Qualification of Medical Device Software" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed guidance related document on medical device software was endorsed, supported by AHWP members with applause.

(26) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed adverse event reporting guidance for the medical device manufacturer was endorsed, under the condition that the definition of "Adverse Event" (AE) would be further reviewed by WG and TC. The conditional endorsement was supported by AHWP members with applause.

(27) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Clinical Evaluation" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed clinical evaluation was endorsed, under the condition that the definition of "Adverse Event" (AE) would be further reviewed by WG and TC. The conditional endorsement was supported by AHWP members with applause.

(28) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Clinical Evidence for Medical Device – Key Definitions and Concepts" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and

according to the simple majority rule, Dr. Jeong declared that the proposed clinical evidence for medical device was endorsed, supported by AHWP members with applause.

(29) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Clinical Evidence for IVD Medical Device – Key Definitions and Concept" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed clinical evidence for IVD medical device was endorsed, supported by AHWP members with applause.

(30) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed clinical evidence for IVD medical device was endorsed, supported by AHWP members with applause.

(31) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Distributor Auditing Checklist" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed distributor auditing checklist was endorsed, supported by AHWP members with applause.

(32) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple

majority rule, Dr. Jeong declared that the proposed guidance on regulatory auditing related document was endorsed, supported by AHWP members with applause.

(33) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Regulatory Audit Report Guidance Document" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed guidance on regulatory audit report was endorsed, supported by AHWP members with applause.

(34) Dr. Jeong, Chair of AHWP, announced that the PROPOSED "Guidance for Medical Device Naming Rule" was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Jeong declared that the proposed guidance for medical device naming rule was endorsed, supported by AHWP members with applause.

CONFIRMATION OF HOST OF THE 21ST AHWP MEETING

(35) Dr. Jeong, Chair of AHWP, announced that Philippines had volunteered and expressed the interests in hosting the next AHWP Main Meeting. As there was only a single candidate, Dr. Jeong declared the confirmation of Philippines as the host of the 21st AHWP Annual Meeting, which was supported by AHWP members with applause. Dr. Jeong again expressed the appreciation on behalf of all AHWP members, to the Bureau of Health Devices & Technology, Philippines, for their support on hosting the next meeting, with more details to be announced soon.

The presentation of resolution towards endorsement was appended as **ANNEX (20)**.

CLOSING REMARKS

(36) Dr. Jeong, Chair of AHWP, presented the closing remarks of the Meeting. Dr. Jeong concluded the Meeting by thanking AHWP and all participants for their

contributions and wished them a safe journey home. The meeting was adjourned at 18:00 on 6 November 2015.

ACKNOWLEDGEMENT

(37) The participants from over 30 economies expressed their appreciations to the Food and Drug Administration, Thailand for their hospitality and excellent arrangements for this Meeting.

- END -