Asian Harmonization Working Party Technical Committee Leaders Meeting

26 – 27th Feb 2013

Bangkok Thailand

Mrs Joanna Koh
TC Chair
Health Sciences Authority, Singapore

Agenda: Day 1

26 Feb Morning Session (Closed)

No.	Item	Name
1	Opening remarks	Joanna Koh
2	Adoption of the Agenda	Joanna Koh
3	Roll Call	Bryan So
4	AHWP Strategic Framework	Bryan So
5	AHWP Member Economies current status	Bryan So
	Tea Break	
6	Objective of AHWP TC Leaders meeting in Bangkok	Joanna Koh
7	SWOT analysis for AHWP TC	Ali M Al-Dalaan
8	Discussion on the role of Consultants in AHWP	Bryan So All participants
	Lunch	
9	AHWP TC's current status Individual WG work plan discussion (i)WG team members; (ii)Work items (previous and new) (iii)WG update since the Chinese Taipei meeting.	All Participants
10	AHWP/RAPS Conference update	Tran Quan

ASIAN HARMONIZATION WORKING PARTY

Agenda: Day 2

27 Feb 2013 Morning Session (Open)

No.	Item	Name
11	Closed Sessions for TC Leaders and Advisors in own Groups	TC Leaders Advisors
12	Discussion on Roles 1. Role of TC and WGs -Where are we, where are we going? and what can we achieve 2. What we would hope Advisors role to encompass	All Participants Lead by Joanna Miang ,Ali & Bryan
13	Advisors sharing of GHTF experience 1. What are the concrete steps AHWPTC can take to achieve its goals & objectives 2. What role do Advisors see themselves playing in the AHWP TC a. Support to WGs work plans b. Support to WGs to move towards alignment with Strategic Framework	Advisors
14	Upcoming AHWP meetings: (i)AHWP TC meeting (Malaysia) (ii) AHWP main meeting (Malaysia) (iii) AHWP Conference (Malaysia	Bryan So

AHWP Technical Committee Leaders

- TC Chair: Mrs Joanna Koh, Singapore Health Sciences Authority
- TC co-chair (regulator): Eng. Ali M. Al-Dalaan, Saudi Food & Drug Authority
- TC co-chair (non-regulator): Ms Chadaporn TANAKASEMSUB (Miang), Zimmer, Asia Pacific
- TC Secretariat: Prof Jack Wong, Terumo Medical Singapore

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Roll Call

(by Bryan)

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AHWP Technical Committee

WG1: Pre-Market Submission and CSDT

- ~~BAI Huifen~~ (Tentative: WONG Woei Jiuang)
- Alfred KWEK

WG1a: IVDD

- Li-Ling LIU
- Jeffrey CHEN

WG2: Post-Market Surveillance and Vigilance

- Yorkie CHOW
- Saini KULWANT

WG3: Quality Management System

- Ali M AL-DALAAN
- Ee Bin LIEW

WG4: Quality System Audit

- Abdulah AL RASHEED
- Eun Hee CHO

WG5: Clinical Safety/Performance

- ~~Regulator Chair~~(Tentative: Yuwadee PATTANAWONG)
- Sumati RANDEO

WG6: Capacity Building and Regulatory Training

- Rama SETHURAMAN(Tentative: TAN Ming Hao)
- Jack WONG

STG: Medical Device Nomenclature

- YANG Lian Chun
- Carol YAN

ASIAN HARMONIZATION WORKING PARTY

AHWP Technical Committee Advisory Panel

No.	Title / Given Name / Surname	Company
1	Dr Philippe Auclair	Abbott Laboratories
2	Mr Michael Gropp	Medtronic, Inc.
3	Mr Leighton Hansel	Abbott
4	Dr Eamonn Hoxey	J&J
5	Dr Petra Kaars-Wiele	Abbott
6	Mr Greg Leblanc	Cook Canada
7	Dr Peter Linders	Philips Healthcare
8	Mr Benny Ons	BD Europe
9	Mr Grant Ramley	Aseptico Inc
10	Mr Scott Sardeson	3M Health Care

* Surnames in alphabetic order

AHWP Technical Committee Advisory Panel

Dr Philippe Auclair

Senior Director, Regulatory Strategy & Advocary

Abbott Laboratories

- Involved in EMEA
- Post-market Surveillance & Clinical Investigation of EUCOMED
- Secretary of GHTF SG2
- Trainer experiences in various geographies, including EU, South America, North America and Asian Regions
- Third-body assessment procedure (e.g. notified body)
- Auditing experiences with practical manufacturing perspective

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Michael Gropp

Vice President, Global Regulatory Strategy

Medtronic, Inc.

- Held various engineering, regulatory affairs, quality assurance, and compliance positions
- Experiences in Clinical Research for Vascular Intervention
- Rep. for international affairs and policy to the BOD of AdvaMed
- Chair of Eucomed (Brussels)International Affairs Task Force
- Experiences with GHTF SG1
- Leadership involvement to industry delegation to APEC RHSC
- Involvement in WHO Scientific Advisory Group (clinical trials registry platform project)

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Leighton Hansel

Director, Regulatory Affairs

ABBOTT

- Over 30 yrs of employment by USFDA
- Experiences in Pre-market & post-market
  - Device registration, listing, product code system
  - AE reporting program
- Experiences in Combination Products and UDI
- Eperiences in Compliance management
- Represented FDA, ISO, AdvaMed on various GMDN policy groups
- BOD involvement in AAMI, ANSI ISO Council, and AAMI Committee on Standards Strategy

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Eamonn Hoxey

Vice President, Regulatory Compliance, Medical Devices & Diagnostics

Johnson & Johnson

- Experiences in Quality Management
- Experiences in Regulatory Compliance of Asia Pacific Region and global compliance
- 20yr more experiences in standards preparations
- Chairmanship of ISO/ TC 198
- Chairmanship of ISO/ TC 210

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Petra Kaars-Wiele

Senior Director, International Regulatory Affairs / Division Labeling

ABBOTT

- 30 yrs experiences with Abbott in areas including Regulatory Affairs, Scientific Affairs, and Quality System for IVD products
- Support in addition all IVD MD Divisions (Diabetes Care, Molecular Diagnostics, Point-of-Care)
- Involvements in:-
  - Chairwoman of EDMA Globalization Working Party
  - EUCOMED International Task Force and Blood Safety Working Party
  - RAPS EU Advisory Board, Association of Virology and the German Association of Blood Transfusion
  - GHTF SG1

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Greg Leblanc

Manager, Regulatory Affairs and Quality Systems

Cook Medical / Cook (Canada) Inc.

- Industry association liaison experiences to Canadian regulatory afairs
- Involvement in MEDEC including:-
  - regulatory affairs, government relationship, policy, funding, QS and QS certification etc.
- Member/Vice-Chair of GHTF SG5 since its inception
- Involvement in MEDEC
- Involvement in various committees including:-
  - Regulatory Affairs Steering Committee and subcommittees, Ontario Committee, Federal Affairs Committee, Policy Committee, Value of Technology Committee
- Experiences in scientific research

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Peter Linders

Director Development Global Standards & Regulations

Philips Healthcare

- Involvement in ISO and IEC standards development initiatives
  - ISO/TC 210
  - IEC/TC 62
  - IEC 82304-1 on Medical Software
  - IEC 60601-1 and IEC 62304
- BOD involvement in COCIR
- Chairmanship of COCIR TRAC

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Benny Ons

Director, Regulatory Affairs

BD Europe

- 20yrs more experiences in QA and RA functions
- Regulatory Affairs Committee in the EU industry association EDMA for 10yrs more
- Involvements in GHTF including:-
  - Steering Committee
  - Vice-Chair of SG1 since 2006
  - SG1 IVD subgroup – Chair/Vice-Chair and secretariat since its inception
  - SG5 Clinical Evaluation – linking with IVD subgroup on clinical evidence for IVD MDs

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Grant Ramley

Director, Regulatory Affairs

Aseptico Inc

- Active industry representative to IAF since 2007
- Development of IAF program for ISO 13485 (on QMS)
- Collaboration experiences with GHTF SG4, CABs and Accreditation Body members from every continent
- Representing the Dental Trade Alliance (DTA) since 2001
- Personal experience with the implementation of various MD regulations and standards

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Scott Sardeson

Director, International Regulatory Affairs

3M Health Care

- Former AdvaMed Reps. for GHTF SG3
- Involvements of AHWP activities since 2004
- Involvement in ASEAN Medical Device Products Working Group
- Adjunct Professor for International Regulatory Affairs courses
- Involvement in ISO / TC 210 WG1
- Training experiences in Asia and Latin America

Experiences are intensive and extensive. Only part of them are highlighted here.

ASIAN HARMONIZATION WORKING PARTY

Goals of AHWP

To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

ASIAN HARMONIZATION WORKING PARTY

AHWP Strategic Framework

(by Bryan)

AHWP Strategic Framework

Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"

Bryan SO, Executive Deputy Secretary General, AHWP
26-27 Feb 2013
AHWP TC Leaders Meeting
Bangkok

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

ASIAN HARMONIZATION WORKING PARTY

AHWP Strategic Framework

Background and Objective

- **Strategic Objectives:**
  - Continue the momentum built in the past
  - Provide a clear development plan and work targets towards the further enhancement of the capability of AHWP member economies in regulating medical devices, as well as the further strengthening of medical device regulatory harmonization and collaboration activities across the regions
  - Serves as a guiding principles for various AHWP activities

ASIAN HARMONIZATION WORKING PARTY

AHWP Strategic Framework

Background and Objective (Cont.)

- **Background:**
  - Agreed and decision made by leaders at 16th Annual conference in Bali, Indonesia
  - Draft developed and discussed at February AHWP leaders' meeting
  - Revision based on comments received and circulation for leaders' comments between March to June
  - Draft endorsement by AHWP leaders at AHWP TC meeting in June, 2012
  - Further revision between June to Oct, 2012
  - Final draft posted at AHWP website in Oct 2012 for soliciting AHWP members comments
  - Presented in 17th AHWP meeting in Chinese Taipei
  - Call for comment by all AHWP members by Feb 4, 2013

ASIAN HARMONIZATION WORKING PARTY

AHWP Strategic Framework

Framework Elements

- **Element One: AHWP Membership Expansion**
  - Welcome any non-AHWP economic members who shows interest in participating
  - Invite current AHWP economic member who has experience and knowledge on medical device regulation to take leadership role at various levels (AHWP, AHWP TC, working groups) at AHWP
  - Secretariat office offer consistent support to member economies

AHWP Strategic Framework

- **Element Two: Training and Capacity building**

  - Focus on enhance knowledge on medical device, promote understanding of essential elements of medical device regulation, and promote international best practice

  - AHWP offer support to training and capacity building of members economies, in terms of financial and manpower

  - Identify priorities, partners of NGO, regional/international harmonization organizations (e.g. WHO, APEC, RAPS, MTLI, ARPA, and etc.)

  - Develop curriculum and review periodically

  - Promote utilization of advanced technology on training

AHWP Strategic Framework

- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**

  Harmonization in important areas based on availability of GHTF global regulatory model and AHWP guidance:

  - Harmonized definition of the term "medical device" (important in determining what and who are subject to regulation);
  - Registration of manufacturers, distributors, and importers and listing of medical devices marketed;
  - Adopt same risk-based classification of medical devices;
  - Single adverse event reporting and post-marketing surveillance system;
  - Single medical device nomenclature system;
  - Single quality management system requirements, and broader acceptance of quality management system audit report by authorized competent authorities ;
  - Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members ;
  - Acceptance of the same dossier (technical file) template for registration submission (e.g. the CSDT/STED format);
  - Recognition of 'recognized regulatory agencies' registration decisions to expedite evaluation process, etc.

AHWP Strategic Framework

- **Element Four: Working Alongside with APEC and ASEAN to expand beyond regional blocks**
  - APEC strategic framework on regulatory convergence by 2020 was endorsed by 21 economic members in 2011
  - ASEAN will implement AMDD in 2015 to harmonize medical device regulation
  - With common member economies, such efforts will be further leveraged, for example, joint programs on training and capacity building

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AHWP Strategic Framework

- **Element Five: Enhance AHWP's Global Presence**
  - Proactive reach out to international originations, global leaders and experts
  - Establish mechanism for effective interaction and networking:
    - Process of receiving from and providing feedbacks
    - Membership and representation
    - Joint strategic and roadmap development

AHWP Strategic Framework

Indicator of Success

- Increased inclusiveness of AHWP membership
- Enhanced awareness on the robust and effective medical device regulation in improving access, quality and use of medical device
- Adoption or adaption of the GHTF global regulatory model, AHWP and other harmonized international guidance and standards
- Enhanced collaboration among AHWP members, to improve and promote greater efficiency on regulation and use of resource: nomenclature, single post-market surveillance; multi-acceptance of QMS auditing report
- Enhanced global partnership, AHWP's participation at regional/global forums, and joint activities.

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AHWP Strategic Framework

AHWP Strategic Framework can be found at:

http://www.ahwp.info/index.php?q=node/297

Call for comment closed on Feb 4, 2013

Will become PROPOSED FINAL document in Secretariat Meeting in May 2013

ASIAN HARMONIZATION WORKING PARTY

AHWP Member Economies current status

(by Bryan)

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification According to GHTF	Nomenclature	Essential Principles
1	Abu Dhabi					
2	Brunei	No	No	No	No	No
3	Cambodia	Yes	Yes	Yes, GHTF	No	No
4	Chile	Yes	Yes	Yes	No	Yes
5	China	Yes	No	Yes	No	No
6	Chinese Taipei	Yes	Yes	Yes	Yes	Yes
7	Hong Kong	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, AMDN	Yes, GHTF
8	India	Yes	Yes	Yes	No	Yes
9	Indonesia	Yes, GHTF	Yes, GHTF	Yes	No	Yes, GHTF

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Updates received by 22 Feb 2013

Updates by 2011

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification According to GHTF	Nomenclature	Essential Principles
10	Jordan					
11	Korea	Yes	Yes	Yes	Yes	Yes, KFDA Medical Device Act requirements are equivalent to EPs; include the contents of EPs
12	Laos	Yes	No	Yes	No	No
13	Malaysia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS	Yes, GHTF
14	Myanmar					
15	Pakistan					
16	Philippines	Yes	Yes	Yes	No	No

ASIAN HARMONIZATION WORKING PARTY

Updates received by 22 Feb 2013

Updates by 2011

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification According to GHTF	Nomenclature	Essential Principles
17	Saudi Arabia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS & GMDN	Yes
18	Singapore	Yes, GHTF	Yes	Yes, GHTF	Yes	Yes, GHTF
19	South Africa	Yes	Yes	No	Yes, UMDNS	No
16	Thailand	Yes, GHTF	Yes	Presently No, but being in the procedure of reclassificatio n	Yes, UMDNS& GMDN	Yes
21	State of Kuwait	Yes	No	No	No	Yes
22	Vietnam					
23	Yemen	YES	Yes	No	No	Yes

Updates received by 22 Feb 2013

Updates by 2011

Tea Break

(15 min)

ASIAN HARMONIZATION WORKING PARTY

Meeting Objective of TC Leaders / Advisory Panel to AHWPTC

AHWP Technical Committee

AHWPTC is the executive arm of the Working Party.

It performs the following roles and responsibilities to support the Working Party:

- Execute the Working Party's decisions and resolutions;
- Make recommendations to the AHWP Chair for decisions;
- Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;
- Provide expert opinions and advice;
- Develop technical documents and policy papers;
- Plan and organize meetings, training, seminars, workshops and experience sharing sessions;
- Work with related organizations and participate in their activities; and
- Report on the progress of its activities to the AHWP Meetings.

From: AHWP Terms of Reference

ASIAN HARMONIZATION WORKING PARTY

Objective of TC Leaders / Advisory Panel to AHWPTC Meeting

- To revisit the goals and directions of the TC for in line with AHWP's objectives (and the Strategic Framework) in the light of the formation of the TC Advisory Panel – in the areas of :-
- The work plan of each Work Group
- To strengthen the TC procedures so as to facilitate TC's overall objectives.
- Strengths & Weaknesses identified in last meeting

ASIAN HARMONIZATION WORKING PARTY

SWOT analysis for AHWP TC

(by Ali)

Objectives of the AHWP TC Leaders Meeting (Singapore 2012)

Strength: •Stable working relationship among core team members •Attained certain level of stature •Generous sharing by established member economies, APEC LSIF & GHTF •Legal entity and permanent secretariat office	**Weakness:** •Lacks manufacturing expertise / background •Lacks political commitment to implement •Some member economies have historical controls – difficult to change
Opportunity: •External support (e.g. APEC LSIF) •Some member economies just beginning to regulate (clean white sheet with no baggage) •Tried and tested GHTF fundamentals – flatten learning curve	**Threats:** •GHTF to IMDRF (maintenance of guidance documents) •Loss of core team member •Time – expedite to remain relevant •Implement – need to execute to demonstrate continual funding •Different level of regulatory maturity

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Discussion on the role of Consultants in AHWP

AHWP Membership

AHWP TC Leaders Meeting
26-27 Feb 2013
Bangkok

Bryan SO
AHWP Secretariat

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Content

- Background
- Existing Type of AHWP Membership
  - Regulatory Authority
  - Industry
- Proposed Type of Membership
  - Liaison Member

Background

To support the Framework Element on AHWP's Global Partnership

AHWP should proactively approach international organizations, global leaders and experts, to identify important topics and to establish mechanisms for effective interaction and networking. This could include, but not be limited to:

- a process of receiving from and providing feedback to these organizations;
- membership and representation at these organizations;
- joint strategic planning and roadmap development (especially in the areas of common interest and benefit) including joint conferences and activities, etc.

All these partnerships would further enhance the extent of regulatory harmonization within the AHWP member economies.

1.2 Membership (A)

The Working Party is a group of experts from Medical Device Regulatory Authorities ("Regulatory Authorities") and the medical device industry including government agencies not Medical Device Regulatory Authorities ("Industry"). Membership is open to those representatives from the Asian and other regions that support the above stated goals. Any economies interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.

1.2 Membership (B)

Upon joining, each member economy should nominate two Primary AHWP Representatives and two Secondary AHWP Representatives, with one each from the Regulatory Authority and one each from the Industry. Representatives from the **Regulatory Authority shall be responsible persons in the development and implementation of medical device regulatory frameworks** while those from the **Industry shall be senior managers from the industry of the member economy such that they could represent the views of both the Regulatory Authority and Industry of their economies.**

AHWP & AHWPTC TOR

1.2 Membership (C)

The Primary and Secondary AHWP Representatives from the Regulatory Authority of a member economy shall be nominated by the medical device regulatory authority of the corresponding government. All organizations from the Industry shall nominate the Primary and Secondary Representatives to subscribe to the AHWP Secretariat. Unless the Secretariat is otherwise informed, the nominated **AHWP Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy**, before subscribing to AHWP Secretariat.

2.2 AHWPTC Membership

The Primary AHWP Representative from the Regulatory Authority shall nominate both the Primary and Secondary AHWPTC Representatives for the Regulatory Authority of his/her economy. The Primary and Secondary AHWPTC Representatives from the Industry should be nominated by the industry representatives of their own economy. Unless the Secretariat is otherwise informed, the nominated AHWPTC Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy, before subscribing to AHWP Secretariat.

1.5 Relationship with Other Parties

The Working Party shall work closely with other international and regional organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.

(Proposed) AHWP Liaison Membership

Background

AHWP pursues to maintain working relationships with other international and regional entities that have a mutual interest in medical device regulatory activities that are directly related to the common goals of nurturing global convergence, leveraging resources and making available safe and effective medical devices globally.

(Proposed) AHWP Liaison Membership

Action

A new clause to be added to the House Rules of AHWP to allow the recruitment of Liaison Member(s) to AHWP.

- *(Remarks: Example of potential liaison members: DITTA, AHC, WHO, etc.)*

(Proposed) AHWP Liaison Membership

Proposed Criteria and Admission Process

1.The Liaison Membership is open to the regional and international organizations who wish to join AHWP and with their goals in-line with the work of AHWP towards harmonization of medical device regulations.

2.Any organization interested in joining AHWP as a Liaison Member shall send their request to AHWP with attention to AHWP Chair and cc AHWP Secretariat at secretariat@ahwp.info.

3.AHWP shall evaluate and determine the suitability of the applying organization for joining AHWP as a Liaison Member.

4.AHWP Chair shall have the rights to reject any AHWP Liaison Membership application.

5.Once the Liaison Membership application is confirmed, an official letter of confirmation from the AHWP Chair will be send via AHWP Secretariat to the new Liaison Member.

(Proposed) AHWP Liaison Membership

Proposed Criteria and Admission Process (Cont')

6.The confirmed Liaison Member shall nominate a representative and subscribe to AHWP Secretariat as the contact person.

7.Liaison Member of AHWP shall have higher priority to co-organizing activities with AHWP.

8.The representative from Liaison Member can be an observer; however, shall not have voting rights in AHWP meetings.

9.The full list of Liaison Members of AHWP as well as the contacts of the corresponding representatives shall be kept by the AHWP Secretariat for record.

10.The list of Liaison Members of AHWP shall also be available at AHWP website.

Discussion
Q&A

Lunch

(Now ~ 13:00)

ASIAN HARMONIZATION WORKING PARTY

WG Reports

Nov 2012 – Feb 2013

(Introduced by Miang)

ASIAN HARMONIZATION WORKING PARTY

18th AHWP Annual Meeting

Updates on 1st AHWP-RAPS Joint Conference

(Introduced by Quan)

ASIAN HARMONIZATION WORKING PARTY

Summary of DAY-1 of TC Leaders Meeting

THANK YOU