Strengthening AHWP – Organizational Perspective

Strengthening AHWP – Organizational Perspective

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AHWP Chair

13th AHWP Meeting
NEW DELHI, INDIA • 5-6 November 2008

INTRODUCTION

- AHWP was established as a non-profit organization in 1998
- AHWP is an informal regional forum comprising of both government regulators and industry representatives from member economies in Asia
- AHWP is a Liaison Member of GHTF


AHWP
OUR OBJECTIVES
To forge a common direction for harmonization of medical devices regulation in Asia
To encourage increased understanding on the benefits of harmonization
To facilitate a linkage with GHTF
To encourage active participation by all Asian Economies
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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA


AHWP
OUR OBJECTIVES
To provide a forum for discussion and training, facilitate information exchange, initiate projects and provide platform for implementation of harmonization among regulators and industry groups in Asia
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AHWP
OUR MEMBERS
Myanmar
India
Chinese Taipei
Vietnam
Hong Kong, China
Korea
PR of China
Malaysia
Cambodia
Thailand
Brunei Darussalam
Indonesia
Singapore
Philippines
Kingdom of Saudi Arabia
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AHWP
OFFICE BEARERS & MEMBERS
Chair: Dr M S Pillay, Malaysia (Regulator)
Vice Chair: Dr Davey HAN, China (Industry)
Members: Regulators and industry representatives from Asian Economies
Secretariat: Malaysia
Website: http://www.asiahwp.org
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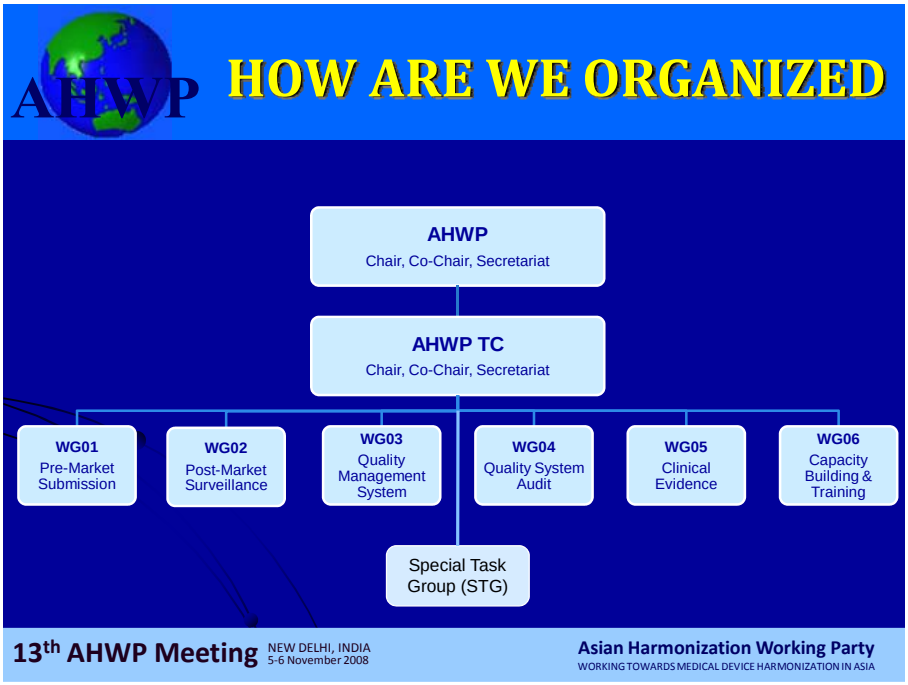
AHWP
HOW ARE WE ORGANIZED
AHWP
Chair, Co-Chair, Secretariat
AHWP TC
Chair, Co-Chair, Secretariat
WG01
Pre-Market Submission
WG02
Post-Market Surveillance
WG03
Quality Management System
WG04
Quality System Audit
WG05
Clinical Evidence
WG06
Capacity Building & Training
Special Task Group (STG)
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AHWP
OUR WORKING ARMS
AHWP Technical Committee
• Chair: Albert Poon (Hong Kong)
• Co-Chairs: Alfred Kwek (Singapore), Daphne Yeh (Chinese Taipei)
• Acting Secretaries: Jacqueline Monteiro (Singapore), Jack Wong (Hong Kong)
• Representatives from Member Economies
• Resource person by invitation
• 6 Workgroups (WG)
• 1 Special Task Group (STG) on Nomenclature
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AHWP
OUR WORKING ARMS
Work Groups
• WG01: Pre-market Submission
• Chair: Alfred Kwek (Singapore)
• Co-Chair: Daphne Yeh (Chinese Taipei)
• IVDD Co-Chair: Tran Quan (Singapore)
• WG02: Post Market Surveillance
• Chair: Mark Lau (Hong Kong)
• Co-Chair: Chadaporn Tanakasemsub (Hong Kong)
• WG03: Quality Management System - To be determined
• WG04: Quality System Audits - To be determined
• WG05: Clinical Evidence Requirements - To be determined
• WG06: Capacity Building and Regulatory Training
• Chair: Albert Poon (Hong Kong)
• Co-Chair: Jack Wong (Hong Kong)
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AHWP
What do we do
- TERMS OF REFERENCE
To study and recommend ways to harmonize regulations in the Asian region in-line with global harmonization effort and to work in coordination with GHTF, APEC & relevant organizations
To examine the use of quality system requirements around the world and prospects for adopting a quality system standard based on internationally recognized and accepted quality system standard for manufacturing of medical devices
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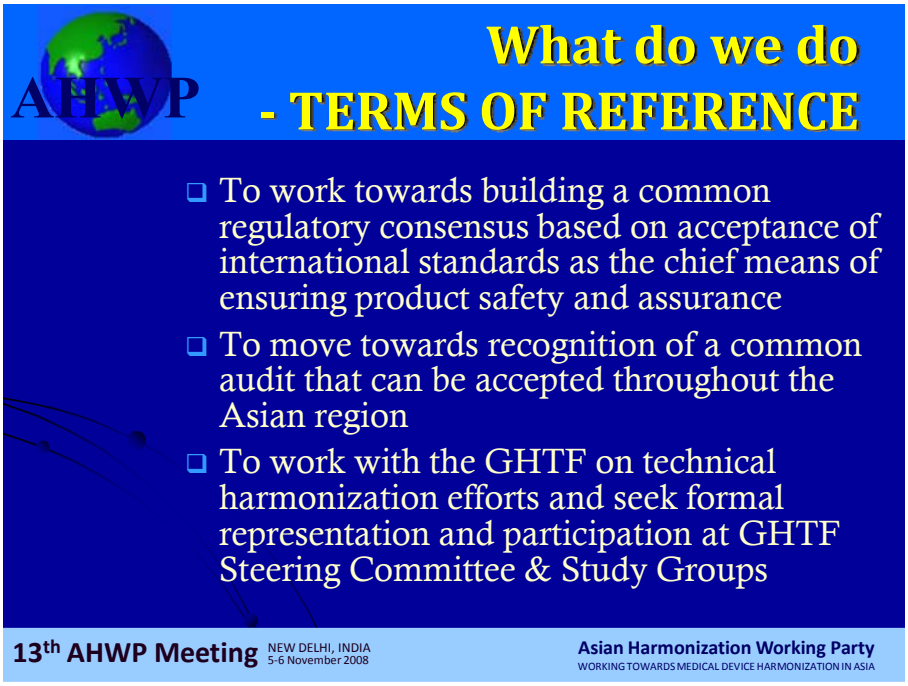
AHWP
What do we do
- TERMS OF REFERENCE
To work towards building a common regulatory consensus based on acceptance of international standards as the chief means of ensuring product safety and assurance
To move towards recognition of a common audit that can be accepted throughout the Asian region
To work with the GHTF on technical harmonization efforts and seek formal representation and participation at GHTF Steering Committee & Study Groups
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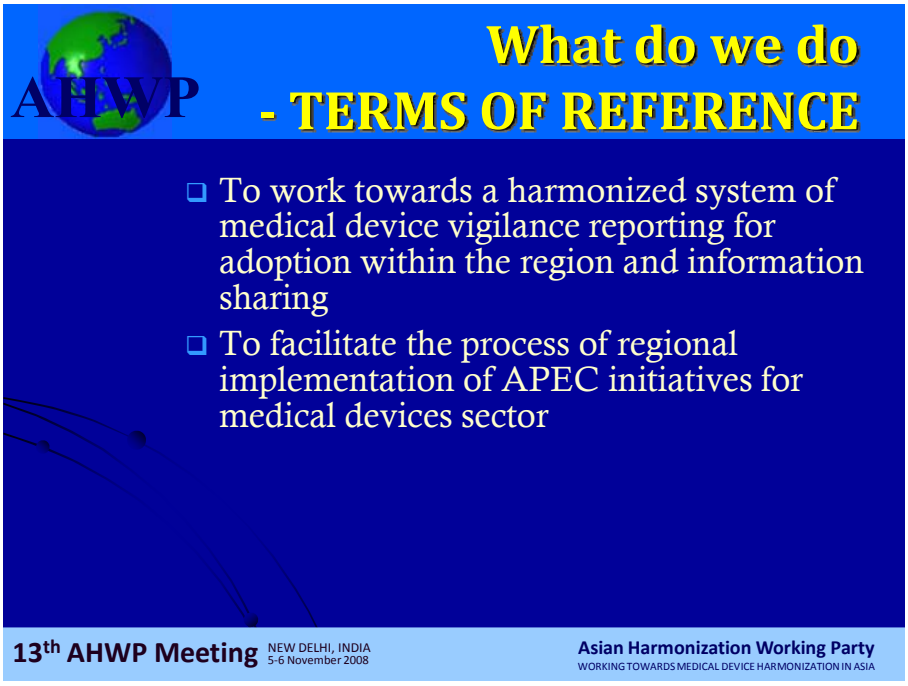
AHWP
What do we do
- TERMS OF REFERENCE
To work towards a harmonized system of medical device vigilance reporting for adoption within the region and information sharing
To facilitate the process of regional implementation of APEC initiatives for medical devices sector
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AHWP
What we want to achieve
HARMONIZED REGULATORY SYSTEM IN ASIA
PRE-MARKET
•Definition
•Nomenclature
•CSDT
•Essential Principles
•Standards
•Quality System
•Clinical evidence
•Conformity Assessment
•.....
PLACEMENT ON MARKET
•Registration/licensing
•Advertisement & claims
•.....
POST-MARKET
Surveillance & vigilance system
•Usage
•Adverse Event Reporting
•Information sharing network
•.....
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AHWP
What we have done/achieved
Comparative study on regulatory systems in Asian Member Economies
Adoption of
GHTF definition of medical device
Medical device classification & classification rules
Nomenclature system
Accepted as a Liaision Member of GHTF
Cooperation/collaboration with international bodies – GHTF, WHO, APEC (ongoing)
Wider participation – Saudi Arabia, South Africa, China, India (new members)
AHWP website as a main communications tool
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AHWP
What we have done/achieved
Recommendations from the Comparative study
Establish a clear & stated national policy as the basis and framework for medical devices regulatory system
Adopt definition classification of medical devices
Use a region-wide nomenclature for medical devices
Establish a comprehensive database and common reporting format to monitor and document adverse incidents
Assist each other in understanding, adapting and adopting GHTF recommendations
Build the capacity of the regulatory authorities & industry players
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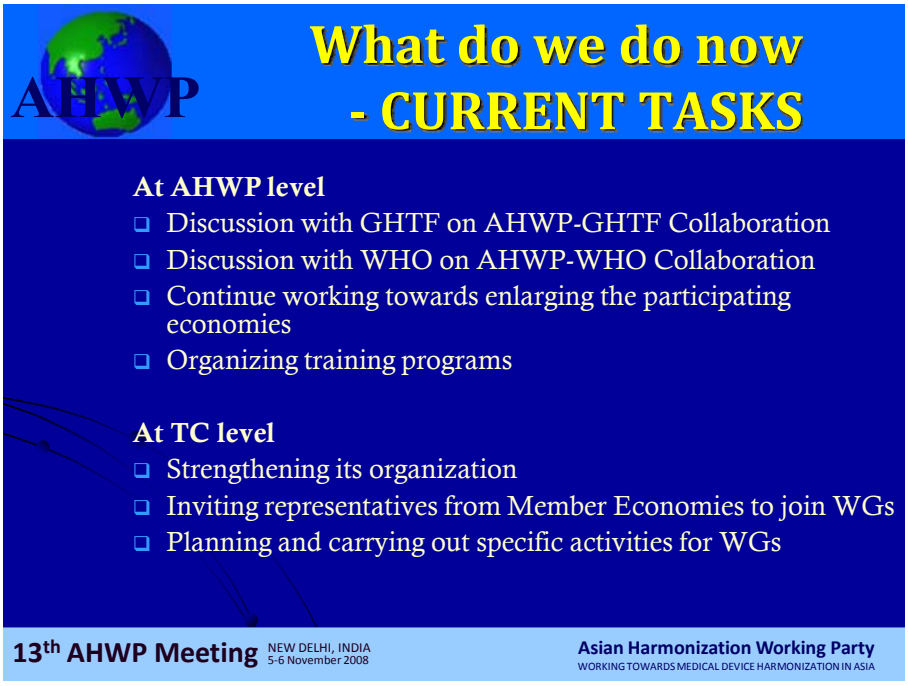
AHWP
What do we do now - CURRENT TASKS
At AHWP level
Discussion with GHTF on AHWP-GHTF Collaboration
Discussion with WHO on AHWP-WHO Collaboration
Continue working towards enlarging the participating economies
Organizing training programs
At TC level
Strengthening its organization
Inviting representatives from Member Economies to join WGs
Planning and carrying out specific activities for WGs
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AHWP
What do we do now
- CURRENT TASKS
Tasks currently undertaken by WGs & STG
WORK GROUP
CURRENT TASK
WG01
CSDT
Conformity Assessment
WG01a
IVDD
WG02
Safety Alert Dissemination System (SADS)
WG03
To be determined
WG04
To be determined
WG05
To be determined
WG06
Diploma in MD Regulation in collaboration with Northeastern University, Boston, USA
STG (Nomenclature)
Special task to resolve nomenclature issue with GMDN
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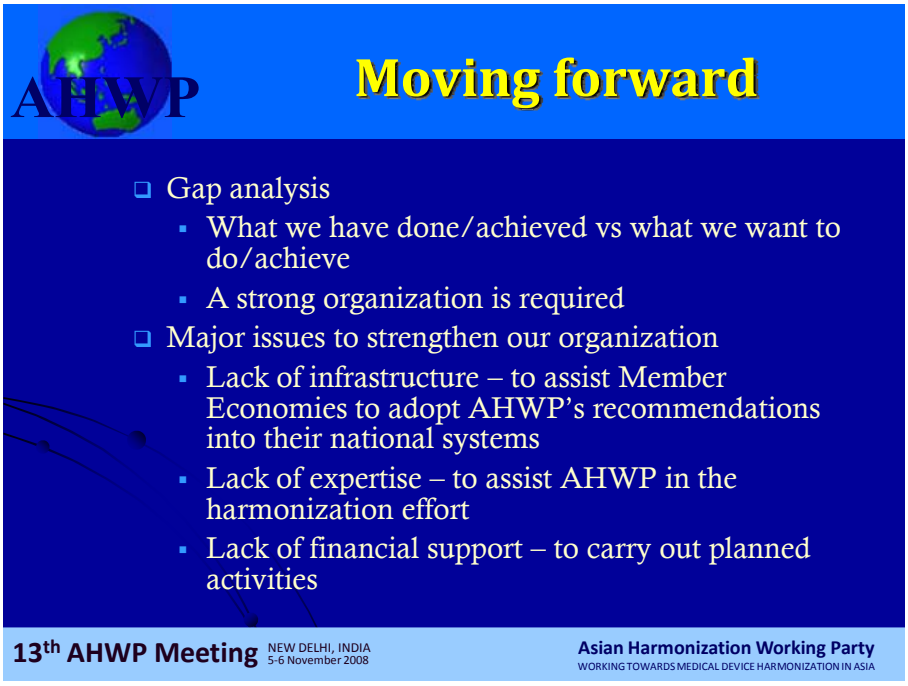
AHWP
Moving forward
Gap analysis
What we have done/achieved vs what we want to do/achieve
A strong organization is required
Major issues to strengthen our organization
Lack of infrastructure – to assist Member Economies to adopt AHWP's recommendations into their national systems
Lack of expertise – to assist AHWP in the harmonization effort
Lack of financial support – to carry out planned activities
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AHWP
Moving forward
- STRENGTHENING AHWP
Enlarge the participating economies
Strengthen TC and WGs
Organize training programs
Establish effective communications network amongst Member Economies
Seek involvement of experts from professional/ international bodies and academia
Seek budgetary and financial support for AHWP activities and programs
Adopt and adapt suitable GHTF recommendations
Assist each other in understanding, adapting and adopting GHTF recommendations
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