

Updates from Secretariat & Election of WG7 Co-Chair 17th AHWP TC Meeting

18th AHWP Annual Meeting

4-5 Dec 2013

Kuala Lumpur, Malaysia

Bryan SO

AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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Amendment on WG membership

AHWP House Rules

(Proposed amendments in [blue])

The below new clause 8.E Applications for Joining AHWP is proposed to be added in AHWP House Rules:-

Clause 8 Applications for Joining AHWP

*E. The AHWPTC Working Group membership shall be open to individuals whose work is **based in AHWP member economies in the field of medical device**. Individuals **based in non-AHWP member economies in the field of medical device** who wish to join Working Group Membership **can be accepted as Working Group Advisor(s)**, subject to the final decision of corresponding Working Group Chair and Co-chair. Working Group Chair and Co-chair shall have the rights to nominate, accept and reject the Advisor(s) to his/her Working Group. The number of Advisor(s) to each Working Group **shall not exceed two (2)**.*

Discussed in TC Leaders Meeting, Bangkok, Feb 2013

Next action:

PROPOSED DOCUMENT for resolution on Main Meeting, 5 Dec 2013

Endorsement / Election Arrangements for WG7 Chair, WG7 Co-chair and WG5 Chair

Requirements in AHWP TOR

in regard to office bearers in WGs

Requirements in AHWP TOR

in regard to office bearers in WGs

According to AHWP TOR:

2.4 Working Groups (WGs) and Special Task Groups (STGs)

- A. With the consent of the AHWP Chair, the AHWPTC Chair may create Working Groups and Special Task Groups for carrying out specific tasks and duties of the Technical Committee. Each Group shall have one Chair from the Regulatory Authority and one Co-chair from the Industry.

- B. The AHWPTC Chair may appoint Acting Chairs and Co-chairs to take charge of the newly formed Groups until the next AHWP Meeting in which the Chairs and Co-chairs of the newly formed Groups are elected.

Eligible Voter

According to the AHWP TOR:

Eligible Voter

AHWP Primary
Representative
(Regulatory Authority)

AHWP Primary
Representative
(Industry)

Absent of
AHWP Primary
Representative

AHWP Secondary
Representative
(Regulatory Authority)

AHWP Secondary
Representative
(Industry)

Absent of BOTH
AHWP Primary and
Secondary Representative

AHWPTC Primary
Representative
(Regulatory Authority)

AHWPTC Primary
Representative
(Industry)

Election Requirements in AHWP TOR

According to the AHWP TOR:

- Each Primary AHWPTC Representative shall have one vote at AHWPTC Meeting.
- Nominees with the highest number of votes shall be elected as office bearers.

Voting Procedure

Voting Procedure

1. Introduction of Nominee(s) for Election
2. Distribution of Voting Slips
3. Collection of Voting Slips
4. Counting of Votes
5. Announcement of the name of candidate with the highest number of votes

Voting Instruction (For Voters)

1. Sign on the “List of eligible voters” against the name printed on the list prepared by AHWP Secretariat
2. Receive the Voting Slip from AHWP Secretariat
3. Select only one candidate by putting a “tick” on the Slip
4. Fold the Slip to conceal the vote
5. Put your Slip into the ballot box at the time of collection
6. A blank Slip will be regarded as “given up”
7. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.*

* Adopted from AHWP House Rule Clause 5 on Nominations and Elections of the AHWP/TC Chair/Co-chairs.

Voting Instruction (For Voters)

- The Voting **Slip A** is designed for the election of WG7 Co-chair (Industry)

AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA
Official Website: www.ahwp.info

Voting Slip A

Application of this Voting Slip
This Voting Slip A is designed for the election of **AHWP WG7 Co-Chair (Industry)** at the 18th AHWP Malaysia Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website www.ahwp.info for details), each AHWP Primary Representative shall have one vote at the AHWPTC Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulator) and the AHWP Primary Representative (Industry) of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

Voting Instructions

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

<u>Candidates for AHWP WG7 Co-Chair (Industry)</u>			
Number	1	2	3
Name	Mr. R. Asok Kumar	Mr. Tony Low	Mr. Tony Yip
Member Economy	India	Malaysia	Hong Kong
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted			

Remarks
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

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Eligible Voters:
AHWP Primary Representatives


(if the above are absent):
AHWP Secondary Representatives

(If the above are absent):
AHWPTC Primary Representatives

(If the above are absent):
AHWPTC Secondary Representatives

Voting Instruction (For Voters)

- Correct

<u>Candidates for AHWP WG5 Chair (Regulatory)</u>		
Number	1	2
Name	ABC	EFG
Member Economy	ABC economy	EFG economy
Please put a tick “✓” in either one of the box on the right hand side. Writing other than a “✓” would not be counted		

Voting Instruction (For Voters)

- **INCORRECT (Void)**

<u>Candidates for AHWP WG5 Chair (Regulatory)</u>		
Number	1	2
Name	ABC	EFG
Member Economy	ABC economy	EFG economy
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted	1	

Voting Instruction (For Voters)

- **INCORRECT (Void)**

<u>Candidates for AHWP WG5 Chair (Regulatory)</u>		
Number	1	2
Name	ABC	EFG
Member Economy	ABC economy	EFG economy
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted	X	

Nominee of WG7 Chair

Number of Application Received : One

Nominee of WG7 Chair

Mr. Lupi Trilakson

Head of Section

Medical Device and Household Health Product Certification

Directorate of Medical Devices Production and Distribution

Ministry of Health

Republic of Indonesia



For endorsement

Nominee of WG7 Co-chair

Number of Application Received : Three

Nominee of WG7 Co-chair	Affiliation	Member Economy
Mr. R. Asok Kumar	Vice President (SRAQC) J&J (India)	India
Mr. Tony Low	Conformity Assessment Body / MMPDA	Malaysia
Mr. Tony Yip	Manager of Quality Assurance and Regulatory Affairs, Far East Elekta Limited	Hong Kong



For election

Nominee of WG5 Chair

Number of Application Received : One

Nominee of WG5 Chair

Ms. Yuwadee PATANAWONG

Senior Expert in Medical Device Safety

Medical Device Control Division

Food and Drug Administration

Thailand



For endorsement

Please Vote

1. Select only one candidate for each position by putting a “tick” on the Slip
2. Fold the Slip to conceal the vote
3. Put your Slip into the ballot box at the time of collection
4. A blank Slip will be regarded as “given up”

Collection of Voting Slips

Counting of Votes

Announcement of New Chair and Co-Chair of WG

- Thank You -