

Election Arrangement for Office Bearers of AHWP and AHWPPTC

8-12 Nov 2011, 16th AHWP Bali Meeting

Mr Bryan SO
AHWP Secretariat



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Nomination Requirement in TOR & House Rules

Requirement on AHWP Main Nominees as according to the AHWP TOR/House Rules:-

- AHWP representatives from Regulatory Authorities can be nominees in the AHWP Chair and AHWP Vice-Chair (Regulatory Authority) elections
- AHWP representatives from the Industry can be nominees in the AHWP Vice-Chair (Industry) election

Nomination Requirement in TOR & House Rules

Requirement on AHWP TC Nominees as according to the TOR/House Rules,

- AHWPTC representatives from Regulatory Authorities can be nominees in the AHWPTC Chair and AHWPTC Co-Chair (Regulatory Authority) elections
- AHWPTC representatives from the Industry can be nominees in the AHWPTC Co-Chair (Industry) election

Nomination Requirement in TOR & House Rules

Requirement on WG/STG Nominees as according to the TOR/House Rules,

- Each Work Group (WG) or STG (Special Task Group) shall have one Chair from the Regulatory Authority and one Co-Chair from the Industry

Nomination Requirement in TOR & House Rules

Supporters to Nominees of AHWP Main Office Bearers

- As according to the Terms of Reference (TOR) and House Rules of AHWP, the support from a minimum of **FIVE** primary representatives of **OTHER** AHWP member economies (i.e. five supporters) were required for each of the nomination of the **AHWP office bearers**, i.e. one AHWP Chair, one AHWP Vice-Chair (Regulatory Authority) and one AHWP Vice-Chair (Industry).
- Each supporter can only support one nominee for each of the position
- Please refer to the AHWP website for more information about the TOR and House Rules of AHWP at www.ahwp.info

Nomination Requirement in TOR & House Rules

Supporters to Nominees of AHWP TC Office Bearers

- As according to the Terms of Reference (TOR) and House Rules of AHWP, the support from a minimum of **FIVE** primary representatives (**NOT** TC Representatives) of **OTHER** AHWP member economies (i.e. five supporter) were required for each of the nomination of the **AHWPTC office bearers**, i.e. one AHWPTC Chair, one AHWPTC Co-Chair (Regulatory Authority) and one AHWPTC Co-Chair (Industry)
- Each supporter can only support one nominee for each of the position
- Please refer to the AHWP website for more information about the TOR and House Rules of AHWP at www.ahwp.info

Nomination Administrative Procedures

AHWP / AHWPTC

- Only the submission of nomination with i) **completely filled form**, ii) **email proof of support** from each of the supporter in nomination form and iii) a brief **CV** (maximum 2 pages in A4 size paper) of the nominee will be processed
- The **AHWP Chair** has the full authority to review the voting rights and validity of the nominee and the supporters as stated in this form, and to reject any application that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in the nomination form

Nomination Administrative Procedures

WG/STG

- Since there was no mentioning of detail mechanism for the nomination of WG/STG Chair and Co-Chair in the TOR and House Rules, the Nomination Form C for WG/STG Chair and Co-Chair is designed **based on the decision made by the AHWPTC on 20 Oct 2011 regarding nomination requirements for WG/STG Chair and Co-Chair**
- A nominee of WG/STG Chair or Co-Chair must be a member of AHWP, and from one of the AHWP member economies
- The nominee may not need to attend the WG/STG Chair or Co-Chair Election
- **Two supporters** are needed, who must either be an AHWP Primary Representative (Regulatory Authority) or AHWP Primary Representative (Industry) or AHWP Secondary Representative (Regulatory Authority) or AHWP Secondary Representative (Industry)


Nomination Administrative Procedures

WG/STG

- Each supporter can only support one nominee for each of the position
- Only the submission of nomination with i) completely filled **Nomination Form C** ii) a brief **CV** (maximum 2 pages in A4 size paper) of the nominee will be processed
- The **AHWPTC Chair** has the full authority to review the voting rights and validity of the nominee, and to reject any application that cannot fulfill the requirements as stated in the Nomination Form

Nomination Form A

- AHWP Chair
- AHWP Vice-Chair (Regulatory Authority)
- AHWP Vice-Chair (Industry)



To : AHWP Secretariat (secretariat@ahwp.info)

Nomination Form A

(For AHWP Chair and Vice-Chairs)

As according to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website for more information about the TOR and House Rules of AHWP at www.ahwp.info), the support from a minimum of FIVE primary representatives of other AHWP member economies (i.e. five supporters) were required for each of the nomination of the AHWP office bearers, i.e. one AHWP Chair, one AHWP Vice-Chair (Regulatory Authority) and one AHWP Vice-Chair (Industry).

PART 1 – Type of Nomination

The below filled nomination is for the election of the following post of AHWP in the 16th AHWP Bali Meeting : - (Please select by ticking either ONE of the following boxes)

☐ AHWP Chair
☐ AHWP Vice-Chair (Regulatory Authority)
☐ AHWP Vice-Chair (Industry)

PART 2 – Nominee's Information and Signatory

Name of Nominee : _____
 Job Title of Nominee : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

This is to confirm that I am eligible^a to be nominated and agreed to be nominated for the above position as stated in Part 1 of this nomination form. I will submit my CV to the Secretariat at secretariat@ahwp.info together with this completely filled form before the deadline of 28 Oct 2011. I understand that the AHWP Secretariat would review the completeness of this application, and might request supplement information to support my application, otherwise my application would be rejected.

^a Eligible as according to the TOR and House Rules of AHWP, with highlights also provided in Part 4 of this nomination form

(Signature of the Nominee)

PART 3 – Supporters' Information

Supporter ONE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter TWO

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter THREE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter FOUR

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter FIVE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

PART 4 – Instructions of Submission and Remarks

a) According to the House Rules, AHWP representatives from regulatory authorities can be nominees in the AHWP Chair and AHWP Vice-Chair (Regulatory Authority) elections. AHWP representatives from the Industry can be nominees in the AHWP Vice-Chair (Industry) election.

b) Each supporter in Part 3 of this nomination form can only support one nominee for each of the position as stated in Part 1 of this nomination form. According to the House Rules, supporters from the same member economy of the nominee is NOT accepted.


c) Only the submission of nomination with i) completely filled form, ii) email proof of support from each of the supporters in Part 3 of this form, and iii) a short CV (maximum 2 pages in A4 size report) of the nominee will be processed. The submission should reach the AHWP Secretariat at "secretariat@ahwp.info" on or before 23:59pm (GMT+8), 28 October 2011. Any late submission will not be accepted.

d) The AHWP Chair has the full authority to review the voting rights and validity of the nominee and the supporter as stated in this form, and to reject any application that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this nomination form.

e) Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".

Nomination Form B

- AHWP TC Chair
- AHWP TC Co-Chair (Regulatory Authority)
- AHWP TC Co-Chair (Industry)



To : AHWP Secretariat (secretariat@ahwp.info)

Nomination Form B

(For AHWPTC Chair and Co-Chairs)

As according to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website for more information about the TOR and House Rules of AHWP at www.ahwp.info), the support from a minimum of **FIVE primary representatives of other AHWP member economies** (i.e. five supporters) were required for each of the nomination of the AHWPTC office bearers, i.e. one AHWPTC Chair, one AHWPTC Co-Chair (Regulatory Authority) and one AHWPTC Co-Chair (Industry).

PART 1 – Type of Nomination

The below filled nomination is for the election of the following post of AHWPTC in the 16th AHWP Bali Meeting -. (Please select by ticking either ONE of the following boxes)

☐ AHWPTC Chair
☐ AHWPTC Co-Chair (Regulatory Authority)
☐ AHWPTC Co-Chair (Industry)

PART 2 – Nominee's Information and Signatory

Name of Nominee : _____
 Job Title of Nominee : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

This is to confirm that I am eligible^a to be nominated and agreed to be nominated for the above position as stated in Part 1 of this nomination form. I will submit my CV to the Secretariat at secretariat@ahwp.info together with this completely filled form before the deadline of 28 Oct 2011. I understand that the AHWP Secretariat would review the completeness of this application, and might request supplement information to support my application, otherwise any application would be rejected.

^a Eligible as according to the TOR and House Rules of AHWP, with highlights also provided in Part 4 of this nomination form

(Signature of the Nominee)

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PART 3 – Supporters' Information

Supporter ONE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter TWO

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter THREE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter FOUR

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter FIVE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

PART 4 – Instructions of Submission and Remarks

a) According to the House Rules, AHWPTC representatives from regulatory authorities can be nominees in the AHWPTC Chair and AHWPTC Co-Chair (Regulatory Authority) elections. AHWPTC representatives from the Industry can be nominees in the AHWPTC Co-Chair (Industry) election.

b) Each supporter in Part 3 of this nomination form can only support one nominee for each of the position as stated in Part 1 of this nomination form. According to the House Rules, supporter from the same member economy of the nominee is NOT accepted.

c) Only the submission of nomination with i) completely filled form, ii) email proof of support from each of the supporter in Part 3 of this form and iii) a brief CV (maximum 2 pages in A4 size paper) of the nominees will be processed. The submission should reach the AHWP Secretariat at "secretariat@ahwp.info" on or before 23:59pm (GMT+8), 28 October 2011. Any late submission will not be accepted.

d) The AHWP Chair has the full authority to review the voting rights and validity of the nominee and the supporters as stated in this form, and to reject any application that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this nomination form.

e) Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".

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Nomination Form C

- WG/STG Chair
- WG/STG Co-Chair



To : AHWP Secretariat (secretariat@ahwp.info)

Nomination Form C (For WG/STG Chair and Co-Chair)

As according to the Terms of Reference (TOR) and House Rules of AHWP, each Work Group (WG) or STG (Special Task Group) shall have one Chair from the Regulatory Authority and one Co-Chair from the industry. Since there was no mentioning of detail mechanism for the nomination of WG/STG Chair and Co-Chair in the TOR and House Rules, this form is designed based on the decision by the AHWPTC on 20 Oct 2011 regarding nomination requirements for WG/STG Chair and Co-Chair.

PART 1 – Type of Nomination

The below filled nomination is for the election of Chair / Co-Chair* (please delete as appropriate) of the following selected WG/STG of AHWPTC in the 16th AHWP Bali Meeting :- (Please select by ticking either ONE of the following boxes)

- ☐ Work Group 1 (WG1) - Pre-Market Submission and CSDT
- ☐ Work Group 1a (WG1a) - IVDD
- ☐ Work Group 2 (WG2) - Post-Market Surveillance and Vigilance
- ☐ Work Group 3 (WG3) - Quality Management System
- ☐ Work Group 4 (WG4) - Quality System Audit
- ☐ Work Group 5 (WG5) - Clinical Safety/Performance
- ☐ Work Group 6 (WG6) - Capacity Building and Regulatory Training
- ☐ Special Task Group (STG) - Nomenclature - Medical Device Nomenclature
- ☐ Special Task Group (STG) - Legal Entity - AHWP Legal Entity

PART 2 – Nominee's Information and Signatory

Name of Nominee : _____
 Job Title of Nominee : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

This is to confirm that I am eligible* to be nominated and agreed to be nominated for the above position as stated in Part 1 of this nomination form. (*Eligible as according to the Remarks in Section 4 of this Nomination Form C, as well as the guidance note regarding WG and STG terms of reference available on AHWP website.)

(Signature of the Nominee)

PART 3 – Supporters' Information

Supporter ONE

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

Supporter TWO

Name : _____
 Title : _____
 Organization : _____
 Member Economy : _____
 Email Contact : _____

PART 4 – Remarks

- A nominee of WG/STG Chair or Co-Chair must be a member of AHWP, and from one of the AHWP member economies.
- The nominee may not need to attend the WG/STG Chair or Co-Chair Election.
- The two supporters in Part 3 of this Nomination Form C must either be a AHWP Primary Representative (Regulatory Authority) or AHWP Primary Representative (Industry) or AHWP Secondary Representative (Regulatory Authority) or AHWP Secondary Representative (Industry).
- Each supporter in Part 3 of this Nomination Form C can only support one nominee for each of the position as stated in Part 1 of this nomination form.
- Only the submission of nomination with i) **completely filled Nomination Form C** ii) a brief CV (**maximum 2 pages in A4 size paper**) of the nominee will be processed. The submission should reach the AHWP Secretariat at "secretariat@ahwp.info" or by hand with attention to Bryan SO of the AHWP Secretariat **on or before 12:00 noon (GMT+8), 8 Nov 2011**. Any late submission will not be accepted.
- The AHWPTC Chair has the full authority to review the voting rights and validity of the nominee, and to reject any application that cannot fulfill the requirements as stated in this Nomination Form C.
- Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".

Election Requirement in TOR & House Rules

- This is to highlight only the voting arrangement for AHWP Vice-Chair (Regulatory Authority) and AHWP Vice-Chair (Industry) for the 16th AHWP Bali Meeting
- Except for AHWP Vice-Chair (Regulatory Authority) and AHWP Vice-Chair (Industry), no voting is required for other AHWP or AHWPTC Office Bearers as each of these posts has only one candidate

Election Requirement in TOR & House Rules

According to the TOR and House Rules

- **One AHWP Chair and Two AHWP Vice-Chairs** shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all **Primary AHWP Representatives** for a term of office until the next election
- In the election of AHWP Chair and Vice-Chairs, **every Primary AHWP Representative shall vote for one candidate**, the **highest number** of votes will be elected the respective post.
- The chair of the meeting can cast an **extra vote** when there is more than one candidate having the highest number of votes


Election Requirement in TOR & House Rules

According to the TOR and House Rules

- Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence.
- Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent.
- The existing AHWP Chair has ruled that there should be no cross-side (i.e. regulator / industry) representation. In other words, the regulatory representatives cannot take up the voting rights of an industrial representatives, and vice versa.

Voting Slip A1

- The Voting Slip A1 is designed for the election of AHWP Vice-Chair (Regulatory Authority) at the 16th AHWP Bali Meeting

 **Voting Slip A1**

Application of this Voting Slip
This Voting Slip A1 is designed for the election of AHWP Vice-Chair (Regulatory Authority) at the 16th AHWP Bali Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP Website www.ahwp.org for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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.

Candidates for AHWP Vice-Chair (Regulatory Authority)


Number	1	2
Name	Li-Ling Liu	Maknan Rahardin
Member Economy	Chinese Taipei	Indonesia
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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Voting Slip A2

- The Voting Slip A2 is designed for the election of AHWP Vice-Chair (Industry) at the 16th AHWP Bali Meeting

 **Voting Slip A2**

Application of this Voting Slip
This Voting Slip A2 is designed for the election of AHWP Vice-Chair (Industry) at the 16th AHWP Bali Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (please refer to the AHWP website www.ahwp.org for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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.

Candidates for AHWP Vice-Chair (Industry)		
Number	1	2
Name	Lindsay Tao	Tran Quang
Member Economy	People's Republic of China	Singapore
Please put a tick mark in either one of the box on the right hand side. (Writing other than a "X" 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 do not fulfil the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

Ballot printed: Page 1 of 1

Eligible Voter

- Election of Vice-Chair (Regulatory Authority)

AHWP Primary Representative
(Regulatory Authority)

AHWP Primary Representative
(Industry)

Eligible Voter

- Election of Vice-Chair (Industry)

AHWP Primary Representative
(Regulatory Authority)

AHWP Primary Representative
(Industry)

Voting Procedure


- a) Verification of the eligibility of voters against the membership record of AHWP secretariat
- b) Distribution of Voting Slips
- c) Collection of Voting Slips
- d) Counting of Votes
- e) Announcement of the name of candidate with the highest number of votes

Voting Instruction (For Voters)

1. Signing on the “List of eligible voters” against the name printed on the list prepared by AHWP Secretariat
2. Receipt of 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”

Voting Instruction (For Voters)

- Correct

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

Q&A