

# Election Arrangement for Office Bearers of AHWP

Mr Bryan SO  
AHWP Secretariat  
8-12 Nov 2011  
16<sup>th</sup> AHWP Bali Meeting



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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](http://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 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)
- 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](http://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 submission should reach the AHWP Secretariat at “[secretariat@ahwp.info](mailto:secretariat@ahwp.info)” **on or before 23:59pm (GMT+8), 28 October 2011**. Any late submission will not be accepted
- 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 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 a 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 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 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](http://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 16<sup>th</sup> 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<sup>a</sup> 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](mailto: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.

<sup>a</sup> 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](mailto: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](mailto: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](mailto: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](http://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 16<sup>th</sup> 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<sup>a</sup> 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](mailto: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.  
<sup>a</sup> 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**

- 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.
- 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.
- 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](mailto:secretariat@ahwp.info) on or before 23:59pm (GMT+8), 28 October 2011. Any late submission will not be accepted.
- 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.
- Should there be any queries, please contact the AHWP Secretariat at [secretariat@ahwp.info](mailto:secretariat@ahwp.info).

# Nomination Form C

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



To : AHWP Secretariat ([secretariat@ahwp.info](mailto: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 16<sup>th</sup> 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) A nominee of WG/STG Chair or Co-Chair must be a member of AHWP, and from one of the AHWP member economies.  
b) The nominee may not need to attend the WG/STG Chair or Co-Chair Election.  
c) 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).  
d) 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.  
e) 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.  
f) 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.  
g) Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".



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# Election Requirement in TOR & House Rules

- This is to highlight only the voting arrangement for AHWP Vice-Chair (Industry) for the 16th AHWP Bali Meeting
- As all AHWP Main and AHWP TC Office Bearer positions are having one candidate to elect for one vacant position, except AHWP Vice-Chair (Industry) with two candidates for one position

# Election Requirement in TOR & House Rules

As 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 AHWP Vice-Chair election, **every Primary AHWP Representative shall vote for one candidate**. The candidate with the **highest number of votes** will be elected the AHWP Vice-Chair.
- 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

As 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.



# Election Requirement in TOR & House Rules

- However, there was no mentioning of the cross-representation in TOR or House Rules
- It was supported by the AHWP Chair that NO cross-representation during voting
- Therefore, during voting industry representatives cannot represent regulatory representatives while regulatory representatives cannot represent industry representatives of their corresponding economy in case of absence of primary representatives

# Voting Slip A

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



## Voting Slip A

### Application of this Voting Slip

This Voting Slip A is designed for the election of **AHWP Vice-Chair (Industry)** at the 16<sup>th</sup> 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.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWP 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.

Candidates for AHWP Vice-Chair (Industry)		
Number	1	2
Name	Lindsay Tao	Tran Quan
Member Economy	People's Republic of China	Singapore
Please <b>put a tick "✓"</b> 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.

Ref : 2011041

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# Q&A