Election Arrangement for Office Bearers of AHWP and AHWPTC

8-12 Nov 2011, 16th AHWP Bali Meeting

Mr Bryan SO AHWP Secretariat



Content

- Nomination Requirement in TOR & House Rules
- Nomination Administrative Procedures
- Election Requirement in TOR & House Rules
- Voting Slip A1 and A2



Requirement on <u>AHWP Main Nominees</u> 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



Requirement on <u>AHWP TC Nominees</u> 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



Requirement on <u>WG/STG Nominees</u> 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



Supporters to Nominees of <u>AHWP Main</u> 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



Supporters to Nominees of <u>AHWP TC</u> Office Bearers

- As according to the Terms of Reference (TOR) and House Rules of AHWP, the support from a minimum of FIVE primary representatives (<u>NOT</u> 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

- 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

- 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 <u>based on</u> <u>the decision made by the AHWPTC on 20 Oct 2011 regarding</u> <u>nomination requirements for WG/STG Chair and Co-Chair</u>
- 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 <u>not</u> 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

- 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 Secretarial (backers and back from the second of	AND	PART 3 – Supporters' Information <u>Supporter ONE</u> Name :
Supporter TVO Ar according to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the difference (TOR) and House Rules of AHWP (revealer upport to the support from a minimum of TCL primary regressitations of the AHWP Chear and View Chair (Industry). Ar according to the Terms of Reference (TOR) and House Rules of AHWP (Please reference in the 16 th AHWP Chear and View Chair (Industry). ArXIV - Type of Nomination in the the nomination of the the nomination of the AHWP Chear and View Chair (Industry). ARXIV - Chair (Regulatory Authority) and one AHWP View Chair (Industry). ARXIV - Chair (Regulatory Authority) AHWP View Chair (Regulatory Authority) And or Chair (Segulatory Authority) Ather of Nominato and Signatory Supporter TIOL And or Chair (Segulatory Authority) Ather of Nomination (Segulatory Authority) Ather of Nomination (Segulatory Authority) Athit Chair (Segulatory Authority) <td>To: AHWP Secretariat (secretariat@ahwp.info)</td> <td>Member Economy :</td>	To: AHWP Secretariat (secretariat@ahwp.info)	Member Economy :
An accoding to the Terms of Reference (TOR) and House Roles of AHTVP (Flexer optor to the AHTVP free Networking if no, in the import from a minimum of EUE painary representatives. of codes AHTVP Three Networking if no, in the support from a minimum of EUE painary representatives. of codes AHTVP Three Networking if no, in the support of AHTVP free Networking if no, in the support of AHTVP free Networking if no, in the support of AHTVP free Networking if no, in the support of AHTVP free Networking if no, in the support of AHTVP free Networking if no, in the SMTVP free Networking if no, in t		Supporter TWO Name :
Gare 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 [®] AHWP Bali Meeting :: (Planez stelet by filled nomination is for the election of the following boxe)	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	Organization : Member Economy :
Organization :: for the election of the following post of AHWP in the 16 ⁶ AHWP Bait Meeting :: //Ruse slacet by incling aibw OXE of the following boxe;) AHWP Chair AHWP Chair AHWP Chair AHWP Vice-Chair (Regulatory Authority) AHWP Vice-Chair (Industry) PART 2 - Nominee's Information and Signatory Name of Nominee Image: Information and Signatory Name of Nominee	one AHWP Vice-Chair (Regulatory Authority) and one AHWP Vice-Chair (Industry).	Name :
AHWP Chair Supporter FOUS AHWP Vice-Chair (Regulatory Authority) Common Section (Industry) AHWP Vice-Chair (Industry) Common Section (Industry) FART 2 - Nominee's Information and Signatory Supporter FOUS Name of Nominee : Common Section (Industry) Do Title of Nominee : Common Section (Industry) Organization : Supporter FUE Name of Nominee : Common Section (Industry) This is to confirm that 1 am eligible" to be nominated and agreed to be nominated for the above position as astated in Part 1 of this nomination from 1 will submit my CV to the Secretariat at secretaring above in the AdVP Secretariat at secretaring tablewing the disconder with the completeness of this application, and might request uppleteness of this application, and mogent request uppleteness of this application, and might request uppleteness of this application, and the request request uppleteness of this application, and the request the AdVP or Chair Chair the file form Advance of the some number eccored of the some number eccored for the some number eccored for the some number eccored for the some and of the some number eccored for the some number eccored for the some number eccored for the some and the some had of the some number eccored for the some and the some advance of this and the advance of the some advance of the some ad	The below filled nomination is for the election of the following post of AHWP in the 16 th AHWP Bali	Organization : Member Economy :
Name of Nominee	AHWP Vice-Chair (Regulatory Authority) AHWP Vice-Chair (Industry)	Name : Tule : Organization : Member Economy :
Email Centratet ::::::::::::::::::::::::::::::::::::	Name of Nominee :	Supporter FIVE Name : Tute : Organization : Member Economy :
	This is to confirm that I am eligible [*] to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat all advectuating allowing info together with this completely filled form before the deadline of 28 Oct 2011. I understand that the AHWOP Secretariat would review the completeness of this application, and might request supplement information to support my application, otherwise my application would be rejected. #Englishe as according to the TOR and House Rules of AHTP, with highlight also provided in Part 4 of this nomination form	 PART 4 - Instructions of Submitrision and Remarks a) According to the Hone Rules, AHW prepresentative from regulatory autorities can be nomines: in the AHW P (Net Nucl. 2014) decimal, AHW prepresentatives from the Inflative can be nomines AHW P (net Chair Chair) decimal. AHW prepresentatives (nom the Inflative) decimal. AHW prepresentatives (nom the Inflative) and the nomines AHW P (net Chair) and a contrast of the Hone Rules, report one nomines for such of the pointer and the inflative prepresentatives (nom the Inflative can be nomines accepted. Chair and Antonia (Inflative) decimal. AHW prepresentatives (Nom the Inflative) can be nomines accepted. Chair and an According to the Hone Rules, reported from the sum annual model of none of the nomine of nomines in the transmitter from the sum annual model of none for the sum of the Inflation of the AHW P (Sectement at "accentance idea) and of the sum of the Inflation of the AHW P (Sectement at "Accentance idea) and of the Inflation of the AHW P (Sectement at "Accentance idea) and of the Inflation of Inflation



Nomination Form B

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

To: AHWP Secretariat (secretariat@ahwp.info)	PART 3 - Supporters' Information Supporter ONE Name : Title :
	Organization : Member Economy :
Neurise diese Deeme D	Email Contact :
Nomination Form B	Linit Constr
(For AHWPTC Chair and Co-Chairs)	Supporter TWO
	Name :
As assarching to the Tanne of Deference (TOP) and House Pulse of AHIVD (Places unfor to the start)	Title :
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	Organization :
from a minimum of FIVE primary representatives of other AHWP member economies (i.e. five	Member Economy :
supporters) were required for each of the nomination of the AHWPTC office bearers, i.e. one AHWPTC	Email Contact :
Chair, one AHWPTC Co-Chair (Regulatory Authority) and one AHWPTC Co-Chair (Industry).	
	Supporter THREE
PART 1 - Type of Nomination	Name :
	Title :
The below filled nomination is for the election of the following post of AHWPTC in the 16th AHWP Bali	Organization :
Meeting :- (Please select by ticking either ONE of the following boxes)	Member Economy :
AHWPTC Chair	Email Contact :
AHWPTC Co-Chair (Regulatory Authority)	Supporter FOUR
	Name :
AHWPTC Co-Chair (Industry)	Title :
	Organization :
PART 2 - Nominee's Information and Signatory	Member Economy :
	Email Contact :
Name of Nominee :	
	Supporter FIVE Name :
Job Title of Nominee :	
Job Title of Nominee : Organization :	Title :
Job Title of Nominee :	Title : Organization :
Job Title of Nominee : Organization :	Title : Organization : Member Economy :
Job Title of Nominee : Organization : Member Ecocomy : Email Contact :	Title : Organization :
Job Title of Nominee : Organization : Member Economy : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position	Tute : Organization :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariant at	Title :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat adams info to cgetter with this completely filled form before the deadline of 32 Oct 2011. I	Title :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat@abavp.info together with this completely filled form before the deadline of 28 Oct 2011. I understand that the AHWP Secretariat would review the completences of this application, and might	Title
Job Title of Nominee : Organization : Member Economy : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariated anymin for together with this completely filled form before the deadline of 28 Oct 2011. I	Title :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat agreement this completely Elled 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 wrapplication, otherwise my application would be rejected.	Title:
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat agreement this completely Elled 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 wrapplication, otherwise my application would be rejected.	Tute :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat agreement this completely Elled 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 wrapplication, otherwise my application would be rejected.	Title::::::::::::::::::::::::::::::::::::
Job Title of Nominee :	Title :
Job Title of Nominee : Organization : Email Contact : This is to confirm that I am eligible ⁴ to be nominated and agreed to be nominated for the above position as stated in Part I of this nomination form. I will submit my CV to the Secretariat at secretariat agreement this completely Elled 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 wrapplication, otherwise my application would be rejected.	Title:
Job Title of Nominee :	Title:
Job Title of Nominee :	Tutle:
ob Tute of Nominee :	Title:



Nomination Form C

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

ALAYP	PART 3 - Supporters' Information
To: AHWP Secretariat (secretariat@ahwp.info)	Supporter ONE
	Name : Title :
	Title : Organization :
Nomination Form C	
(For WG/STG Chair and Co-Chair)	Member Economy : Email Contact :
	Email Contact :
As according to the Terms of Reference (TOR) and House Rules of AHWP, each Work Group (WG) or	Second TWO
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	Supporter TWO
and Co-Chair in the TOR and House Rules, this form is designed based on the decision by the AHWPTC	Name :
on 20 Oct 2011 regarding nomination requirements for WG/STG Chair and Co-Chair.	Title :
the second	Organization :
PART 1 - Type of Nomination	Member Economy :
The below filled nomination is for the election of <u>Chair / Co-Chair ' (please delete as appropriate</u>) of the following selected WG:STG of AHWPTC in the 16^{th} AHWP Bali Meeting :- (<i>Please select by ticking</i> <i>ether ONE</i> of the following boxes)	Email Contact :
Work Group 1 (WG1) - Pre-Market Submission and CSDT	PART 4 - Remarks
work oroup 1 (wor) - Fre-Market Submission and CSD1	 A nominee of WG/STG Chair or Co-Chair must be a member of AHWP, and from one of the AHWP mene economies
Work Group 1a (WG1a) - IVDD	 b) The nominee may not need to attend the WG/STG Chair or Co-Chair Election.
Work Group 2 (WG2) - Post-Market Surveillance and Vigilance	 c) The nominee may not need to anend the wors to chair of co-chair election. c) The two supporters in Part 3 of this Nomination Form C must either be a AHWP Primary Representation.
work Group = (wG=) - Fost-Market Surveinance and vignance	(Regulatory Authority) or AHWP Primary Representative (Industry) or AHWP Secondary Represent
Work Group 3 (WG3) - Quality Management System	(Regulatory Authority) or AHWP Secondary Representative (Industry).
Work Group 4 (WG4) - Quality System Audit	d) Each supporter in Part 3 of this Nomination Form C can only support one nominee for each of the position
Work Group 4 (WG4) - Quanty System Audit	stated in Part 1 of this nomination form.
Work Group 5 (WG5) - Clinical Safety/Performance	e) Only the submission of nomination with i) completely filled Nomination Form C ii) a brief CV (maximu pages in A4 size paper) of the nominee will be processed. The submission should reach the AHWP Secret
Work Group 6 (WG6) - Capacity Building and Regulatory Training	at "secretariat@ahwp.info" or by hand with attention to Bryan SO of the AHWP Secretariat on or before 1
Work Group 6 (WG6) - Capacity Building and Regulatory 1 raining	noon (GMT+5), 8 Nov 2011. Any late submission will not be accepted.
Special Task Group (STG - Nomenclature) - Medical Device Nomenclature	f) The AHWPTC Chair has the full authority to review the voting rights and validity of the nominee, and to r
	any application that cannot fulfill the requirements as stated in this Nomination Form C.
Special Task Group (STG - Legal Entity) - AHWP Legal Entity	g) Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".
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. (# Bitable as according to the Remarks in Scenar 4 of the Nomination Form C, as well as the	
as stated in Part 1 of this fioniniation form, (# Flighte as according to the Remarks in Section 4 of this Nomination Form C, as well as the andquee note regarding WG and STG terms of reference available on AHWP website)	
Sensitive sets actions and a character management of sets at a second 1	
(Signatory of the Nominee)	
(adman) di mananaki	
Page 1 of 2	



Election Requirement in TOR & House Rules

- This is to highlight <u>only</u> the voting arrangement for <u>AHWP Vice-Chair (Regulatory Authority) and AHWP</u> <u>Vice-Chair (Industry)</u> 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 <u>voting by all Primary AHWP Representatives</u> 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

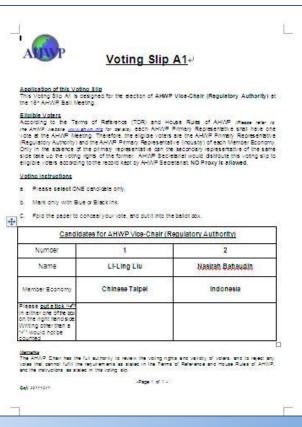
- Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence.
- Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent.
- The existing AHWP Chair has ruled that there should be <u>no</u> 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







Voting Slip A2

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



AHIVP	Voting Slip A2	ν.
Application of this Vo This Voting Silp A2 is Ball Meeting	ting Slip designed for the election of AHWP Vice-(Chair (Industry) at the 16" AHWP
the AHWP wecate way vote at the AHWP Me (Regulatory Authority) Only in the absence of side take up the votin	ims of Reference (TOR) and House I used and for detail each AHM/P Prima lating. Therefore, the eligible voters are to and the AHM/P Primary Representative (in d the primary representative can the sec- g rights of the former. AHM/P Secretariat ng to the record sect by AHM/P Secretariat	(y Representative shall have one he AHWP Primary Representative dustry) of each Member Economy, ordary representative of the same would distribute this voting slip to
Voting instructions		
18 900-12	NE candidate only.	
b. Mark only with B	ue or Blacklink	
C. Fold the paper to	conceal your vote, and put it into the ballo	of box
a) 1010-1004-1010-1		
	Candidates for AHWP Vice-Chair (and the second
Number	1	2
Name	Lindsay Tao	Tran Quan
Member Economy	People's Republic of China	Singapore
	6	
Please <u>put a flok "4"</u> In either one of the box on the right hand side. Writing other than a "4" would not be counted		4
In either one of the box on the right hand side. Writing other than a "" would not be counted Manacka The ArrivP. Chair has th	e full subhority to review the voting rights and the requirements as stated in the Terms of Re such in the voting sign	t validity of volers, and is reject any ference and House Rules of Arth(R)



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



- 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"



• Correct

<u>Candidates for AHWP Vice-Chair (Industry)</u> ↩			
Number.	1 ~	2	
Name⊷	Candidate ABC <i></i>	Candidate DEF⊷	
Member Economy	Economy ABC.	Economy DEFℯ	
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted ₽	√ _₽	ته ۲	



• INCORRECT (Void)

Candidates for AHWP Vice-Chair (Industry)		
Number.	1	2 *
Name⊷	Candidate ABC.	Candidate DEF.
Member Economy ⁴³	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 ₽	47	٦



• INCORRECT (Void)

Candidates for AHWP Vice-Chair (Industry)		
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	Ę.





