Standard operating procedure

Title: Management Board consultation on new nominations to the CHMP and CVMP		
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1. Purpose

In accordance with Article 61(1) of Regulation (EC) No 726/2004 as amended and under Article 4 (3) of the Management Board rules of procedure, the European Medicines Agency Management Board adopted, on 18 March 2010, a revised procedure for consultation of the Management Board on CHMP and CVMP appointments EMA/MB/281553/2007/Rev.2. This SOP describes how this procedure is carried out.

2. Scope

This SOP applies to the CHMP and CVMP secretariats and to the Management Board secretariat.

This SOP applies to new nominations of members and alternate members in the CHMP and CVMP.

This SOP does NOT apply to renewed nominations in the CHMP and CVMP or to nominations where an existing alternate member is nominated to act as a member and vice versa.

3. Responsibilities

It is the responsibility of each HoU and HoS to ensure that this procedure is adhered to within their own unit and sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**".

4. Changes since last revision

This SOP is updated in view of the Agency's new policy on handling conflicts of interest of scientific committee members and experts, specifically the *"obligatory screening by the Agency of the declared conflicts of interests of Scientific Committee members prior to any formal nomination by the Competent Authority"* (EMA/513078/2010 p.7).

5. Documents needed for this SOP

All word templates can be found in: Word\File\New\On my computer\More\MB Management Board

All outlook templates can be found in: Outlook\File\New\Choose form\Personal forms library

- Template: Written procedure - MB consultation on CHMP and CVMP nominations

- Template email: LAUNCH: MB consultation procedure

- Template email END: MB consultation procedure

- Template email: EXTENDED MB consultation procedure

- Nominee's Curriculum Vitae

- Nominee's Nomination form

- Nominee's Declaration of interest

- Evaluation of the DoI

- Nominating Authority's written confirmation of the nomination following screening of CoI

- SOP/EMA/0066 Nominations and re-nominations of representatives to the MB and scientific committees (available on web)

- SOP/EMA/0040 Evaluation of conflicts of interests of experts for involvement in EMA activities (available on web)

- WIN/EMA/0072 Administration of nomination procedure (available on web)

6. Related documents

- Regulation (EC) No 726/2004, as amended

- Procedure for consultation of Management Board on CHMP and CVMP appointments EMA/MB/281553/2007/Rev.2

- SOP/EMA/0020 Management Board meeting documents

- WIN/EMA/0064 Management Board organisation

- Management Board; CHMP and CVMP rules of procedure

- Template Curriculum Vitae

- Template Nominations form

- Electronic Declaration of Interest

- Evaluation of declared conflicts of interests

7. Definitions

CHMP: Committee for Medicinal Products for Human Use

CVMP: Committee for Medicinal Products for Veterinary Use

CV: Curricullum Vitae

DoI: Public Declaration of Interests & Confidentiality of Undertaking

ECD: Eudra Common Directory

EDMS: Electronic Document Management System (presently known also as DREAM)

D-EXO: Executive Office in Directorate
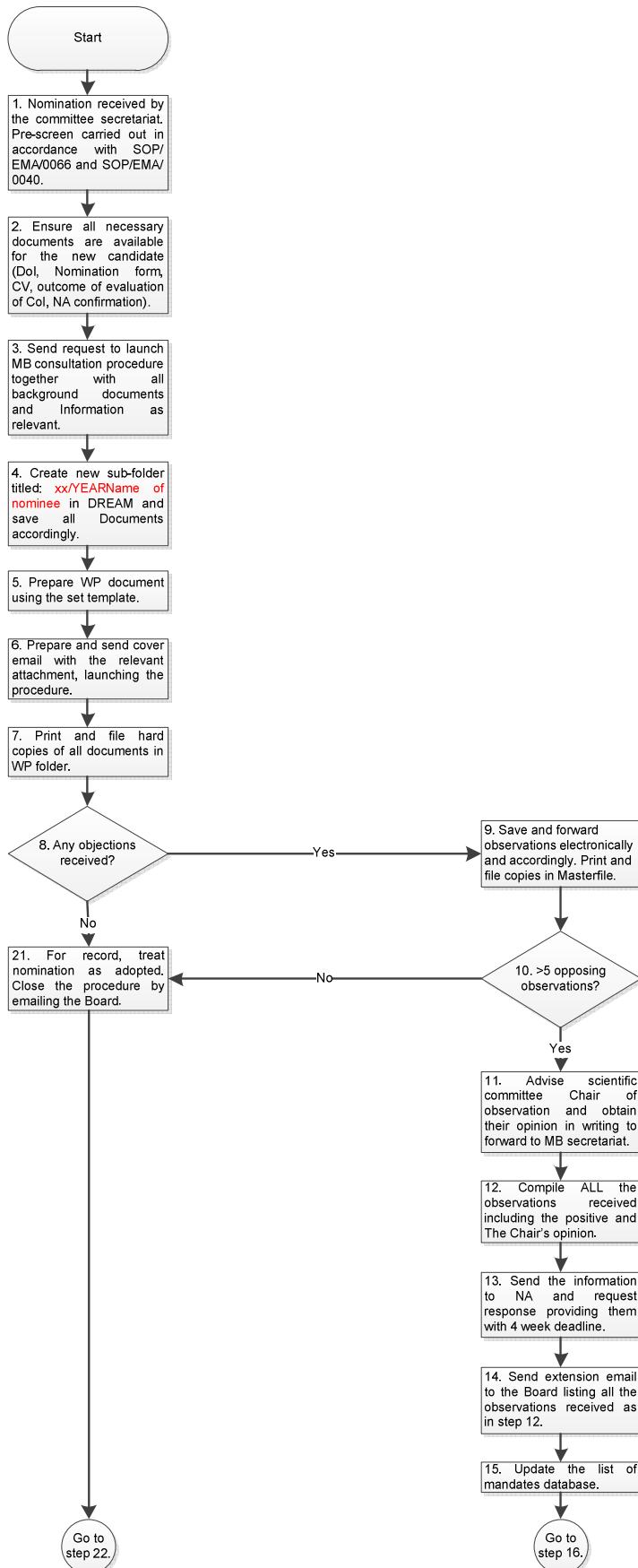
HoS: Head of Sector
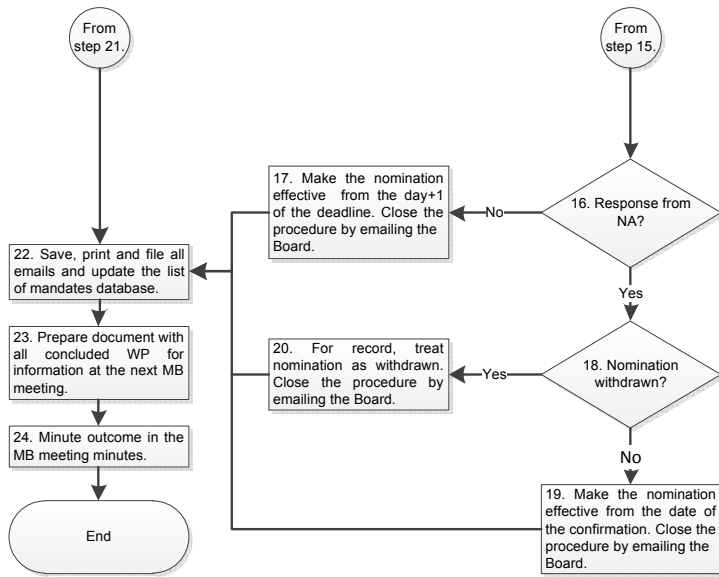
HoU: Head of Unit

MB: Management Board

NA: Nominating Authority

SOP: Standard Operation Procedure

WP: Written Procedure

8. Process map / flow chart

```
        ( Start )
            │
            ▼
┌───────────────────────────┐
│ 1. Nomination received by │
│ the committee secretariat.│
│ Pre-screen carried out in │
│ accordance with SOP/      │
│ EMA/0066 and SOP/EMA/     │
│ 0040.                     │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 2. Ensure all necessary   │
│ documents are available   │
│ for the new candidate     │
│ (DoI, Nomination form,    │
│ CV, outcome of evaluation │
│ of CoI, NA confirmation). │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 3. Send request to launch │
│ MB consultation procedure │
│ together with all         │
│ background documents      │
│ and Information as        │
│ relevant.                 │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 4. Create new sub-folder  │
│ titled: xx/YEARName of    │
│ nominee in DREAM and      │
│ save all Documents        │
│ accordingly.              │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 5. Prepare WP document    │
│ using the set template.   │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 6. Prepare and send cover │
│ email with the relevant   │
│ attachment, launching the │
│ procedure.                │
└───────────────────────────┘
            │
            ▼
┌───────────────────────────┐
│ 7. Print and file hard    │
│ copies of all documents in│
│ WP folder.                │
└───────────────────────────┘
            │
            ▼
      ◇ 8. Any objections ◇ ──── Yes ────▶ ┌──────────────────────────┐
      ◇   received?       ◇                │ 9. Save and forward      │
            │                              │ observations electronically│
            No                             │ and accordingly. Print and│
            │                              │ file copies in Masterfile.│
            ▼                              └──────────────────────────┘
┌───────────────────────────┐                       │
│ 21. For record, treat     │                       ▼
│ nomination as adopted.    │ ◀── No ──── ◇ 10. >5 opposing ◇
│ Close the procedure by    │             ◇ observations?   ◇
│ emailing the Board.       │                       │
└───────────────────────────┘                       Yes
            │                                        │
            │                                        ▼
            │                              ┌──────────────────────────┐
            │                              │ 11. Advise scientific    │
            │                              │ committee Chair of       │
            │                              │ observation and obtain   │
            │                              │ their opinion in writing to│
            │                              │ forward to MB secretariat.│
            │                              └──────────────────────────┘
            │                                        │
            │                                        ▼
            │                              ┌──────────────────────────┐
            │                              │ 12. Compile ALL the      │
            │                              │ observations received    │
            │                              │ including the positive and│
            │                              │ The Chair's opinion.      │
            │                              └──────────────────────────┘
            │                                        │
            │                                        ▼
            │                              ┌──────────────────────────┐
            │                              │ 13. Send the information │
            │                              │ to NA and request        │
            │                              │ response providing them  │
            │                              │ with 4 week deadline.    │
            │                              └──────────────────────────┘
            │                                        │
            │                                        ▼
            │                              ┌──────────────────────────┐
            │                              │ 14. Send extension email │
            │                              │ to the Board listing all the│
            │                              │ observations received as │
            │                              │ in step 12.              │
            │                              └──────────────────────────┘
            │                                        │
            │                                        ▼
            │                              ┌──────────────────────────┐
            │                              │ 15. Update the list of   │
            │                              │ mandates database.       │
            │                              └──────────────────────────┘
            │                                        │
            ▼                                        ▼
       ( Go to )                               ( Go to )
       ( step 22. )                            ( step 16. )
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```
   ( From              ( From
    step 21. )          step 15. )
       |                    |
       |                    |
       |                    v
       |           ┌──────────────────┐      ┌─────────────────────┐
       |           │ 17. Make the     │      │                     │
       |           │ nomination       │◄─No──│  16. Response from  │
       |           │ effective from   │      │        NA?          │
       |           │ the day+1 of the │      └─────────────────────┘
       |           │ deadline. Close  │                │
       |           │ the procedure by │               Yes
       |           │ emailing the     │                │
       |           │ Board.           │                v
       v           └──────────────────┘
┌──────────────────┐                       ┌─────────────────────┐
│ 22. Save, print  │◄──────────┐           │                     │
│ and file all     │           │           │  18. Nomination     │
│ emails and update│  ┌──────────────────┐ │     withdrawn?      │
│ the list of      │  │ 20. For record,  │◄─Yes──                │
│ mandates database│  │ treat nomination │ └─────────────────────┘
└──────────────────┘  │ as withdrawn.    │           │
       │              │ Close the        │          No
       v              │ procedure by     │           │
┌──────────────────┐  │ emailing the     │           v
│ 23. Prepare      │  │ Board.           │  ┌──────────────────┐
│ document with all│  └──────────────────┘  │ 19. Make the     │
│ concluded WP for │                        │ nomination       │
│ information at   │                        │ effective from   │
│ the next MB      │                        │ the date of the  │
│ meeting.         │                        │ confirmation.    │
└──────────────────┘                        │ Close the        │
       │                                    │ procedure by     │
       v                                    │ emailing the     │
┌──────────────────┐                        │ Board.           │
│ 24. Minute       │                        └──────────────────┘
│ outcome in the   │
│ MB meeting       │
│ minutes.         │
└──────────────────┘
       │
       v
  (    End    )
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9. Procedure

Step	Action	Responsibility
1.	Receive new nomination for a CHMP / CVMP member / alternate in accordance with SOP/EMA/0066 (see **5. Documents needed for this SOP**). Ensure that the necessary obligatory screening of conflicts of interest had been carried out in accordance with SOP/EMA/0040 (see **5. Documents needed for this SOP**).	Committee secretariat
2.	Ensure that all necessary documents are available for the new candidate (nominees CV, Nomination form, DoI; and if relevant, outcome of evaluation of DoI (exact text used to inform the NA), and NA confirmation) in the correct format in order to conduct the MB consultation procedure (see **6. Related documents**).	Committee secretariat
3.	Send a request to launch a consultation procedure together with all background documents (see step 2) in electronic format to the MB secretariat. Advise whether the nominee has previously been a member or an alterante of any other committee (CAT/PDCO/COMP/HMPC) or working party, if such information is known. Provide the name of the member or alternate that the new nominee is replacing.	Committee secretariat
4.	Create a new sub-folder titled Year_ number[1]_Name of nominee (committee and type of memberhisp) Country in EDMS in the appropriate folder of the upcoming MB meeting in EDMS. (see **10. Records**). Save all relevant documents in this sub-folder, adhering to the established document naming convention. Create one sub-folder for each MB consultation procedure.	MB secretariat
5.	Prepare WP document using the relevant template (see **5. Documents needed for this SOP**). Provide details of one nominee per WP document.	MB secretariat
6.	Prepare and send cover email in Outlook using the set template (see **5. Documents needed for this SOP**). Documents are put into one zip filed attachment *(for large files use Eudralink instead of Outlook).* Update the list of mandates database with the date of the start of the WP and the deadline for comments in accordance with WIN/EMA/0072 (see **5. Documents needed for this SOP**).	MB secretariat

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[1] This refers to the written procedure number starting 01 at the beginning of each year.

Step	Action	Responsibility
7.	Print and file hard copies of all documents sent, including the cover email, in the WP folder (see **10. Records**).	MB secretariat
8.	Look out for observations. If there are observations received go to step 9; if there are no observations received go to step 21.	MB secretariat
9.	Save all observations electronically in EDMS in the respective sub-folder created in step 4. Forward all observations on to the relevant secretariat for information. Print all observations received and file them in the WP folder (see **10. Records**).	MB secretariat
10.	If more than 5 opposing observations are received, then contact the respective Committee secretariat and ask them to contact the Chair of their Committee, as per step 11. If less than 5 opposing observations are received, then go to step 21.	MB secretariat
11.	Contact the Chair of the respective scientific committee advising him of the concerns raised by the Board. Request the Chair's written confirmation of their opinion on the candidate's suitability for the committee bearing in mind the expertise already available in the committee. Forward Chair's response to MB secretariat.	Committee secretariat
12.	Compile all observations received by quantifying and qualifying them into relevant groups e.g. Favourable; Opposing; Did not comment; and Chair's opinion.	MB secretariat
13.	Send the information to the respective NA. Request their confirmation in regards to this nomination. Provide them with 4 week deadline for response.	MB secretariat
14.	Send extension email to the Board from Outlook using the set template (see **5. Documents needed for this SOP**) listing all the observation received as per step 12.	MB secretariat
15.	Update the list of mandates database in accordance with WIN/EMA/0072 (see **5. Documents needed for this SOP**).	MB secretariat
16.	Look out for response from NA: If no response is received: go to step 17; If response is received: go to step 18.	MB secretariat

Step	Action	Responsibility
	Keep the respective Committee secretariat informed.	

Step	Action	Responsibility
17.	Where there is no response submitted by the NA, the nomination is made effective from the day+1 of the deadline.	MB secretariat
	Close the procedure by sending an email to the Board from Outlook using the set template (see **5. Documents needed for this SOP**).	
	Go to step 22.	
18.	Check the response received:	MB secretariat
	If the nomination is confirmed go to step 19;	
	If the nomination is withdrawn go to step 20.	
	Keep the respective Committee secretariat informed.	
19.	If the nomination is confirmed to go ahead, the nomination is made effective from the date on the confirmation.	MB secretariat
	Close the procedure by sending an email to the Board from Outlook using the set template (see **5. Documents needed for this SOP**).	
	Go to step 22.	
20.	Where the NA response confirms the nomination is withdrawn, the nomination is treated as withdrawn.	MB secretariat
	Close the procedure by sending an email to the Board from Outlook using the set template (see **5. Documents needed for this SOP**).	
	Go to step 22.	
21.	Close the procedure by sending an email to the Board from Outlook using the set template (see **5. Documents needed for this SOP**).	MB secretariat
	Go to step 22.	
22.	Save, print and file all correspondence relating to the consultation procedure **(10. Records)**.	MB secretariat
	Update the list of mandates database with in accordance with WIN/EMA/0072 (see **5. Documents needed for this SOP**).	
23.	Prepare document with the results of all the MB consultations for information as part of the meeting documents for the next MB meeting in accordance with SOP/EMEA/0020 (see **5. Documents needed for this SOP**).	MB secretariat
	End of procedure.	
24.	Minute outcome in the MB meeting minutes.	MB secretariat

10. Records

Hard copies of all documents are filed in Master file: folder available from D-EXO.

Electronic copies are saved in the sub-folder of the upcoming Management Board meeting folder:

Docbases\EDMS\Meetings\Management Board\Management Board meetings YEAR\upcoming meeting date\Written procedures