



Standard operating procedure

Title: Organisation of NRG meetings		
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1. Purpose

The purpose of this SOP is to ensure that the tasks associated with the general organisation, conduct and follow-up of the NRG Meetings (Plenary), including the preparation, circulation and filing of meeting documents, and all other associated tasks, are consistently carried out.

2. Scope

This SOP applies to the NRG Secretariat, Medical Information Sector, Patient Health Protection Unit.

3. Responsibilities

It is the responsibility of the Section Head to ensure that this procedure is adhered to within their own section. 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

New SOP.

5. Documents needed for this SOP

Template 1: Template Agenda (EMA/201943/2010 <Rev. 0> CONFIDENTIAL) - This template can be found in: Cabinets/Old EDMS Structure/Meetings/Scientific Meetings/C H M P/NRG/Invented Name General/Agenda Template

Template 2: NRG Outcome faxes



- IN accepted (EMA/634321/2010)
- IN comb accepted + non accepted (EMA/634322/2010)
- IN non accepted (EMA/634317/2010)
- INN + CY accepted (EMA/634318/2010)
- INN + CY non accepted (EMA/634319/2010)
- Justification (EMA/634320/2010)

These templates can be found in Cabinets/Old EDMS Structure/Meetings/Scientific Meetings/C H M P/NRG/Invented Name General/Template Faxes outcome

Template CHMP Annex 5 (to be provided by CHMP Secretariat)

Human pre-submission Q&A:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000157.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002251f&jsenabled=true

6. Human pre-submission Q&A: Related documents

Guideline on the acceptability of Names for Human Medicinal Products processed through the Centralised Procedure – CPMP/328/98, Revision 5

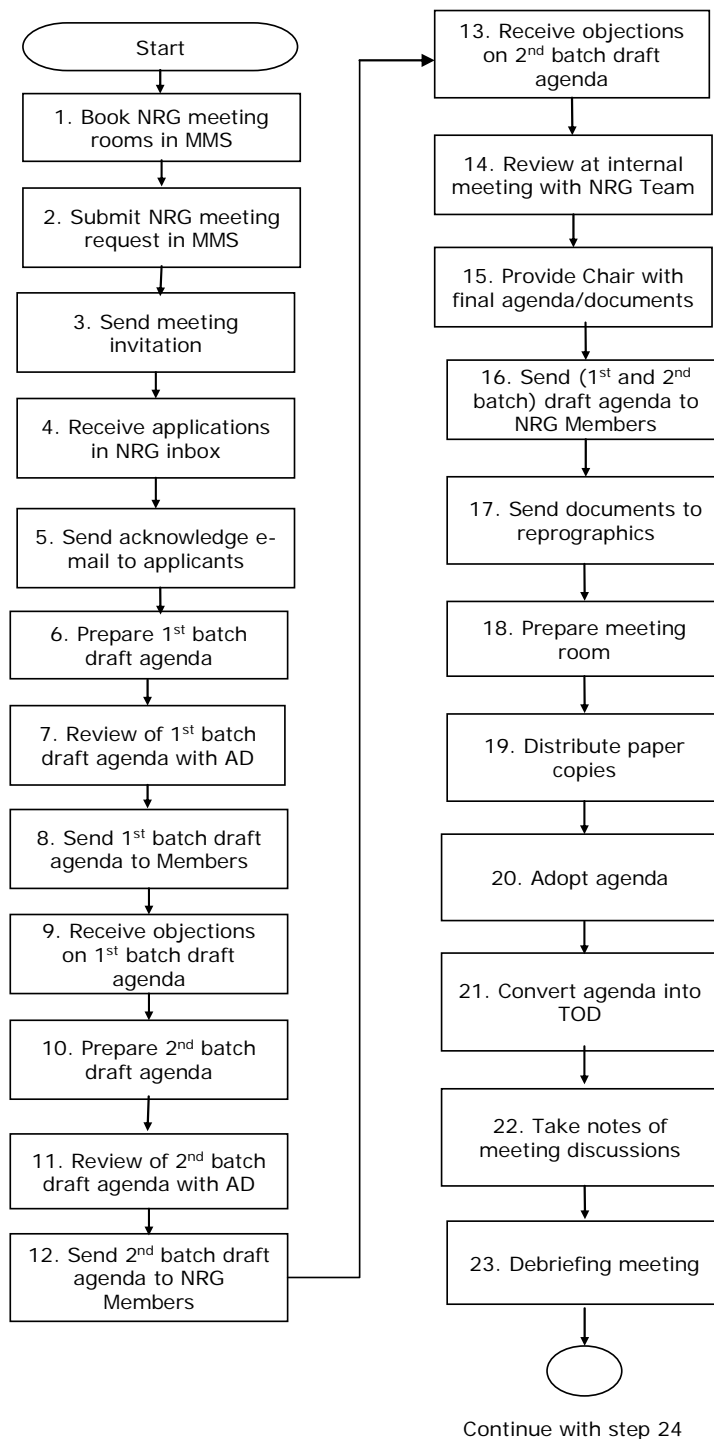
(<http://www.ema.europa.eu/pdfs/human/regaffair/032898en.pdf>)

Target dates for sending objections and agenda in advance of NRG meetings <year> (EMA/627502/2010) (<https://docs.eudra.org/webtop/drl/objectId/0b0142b281085b2c>)

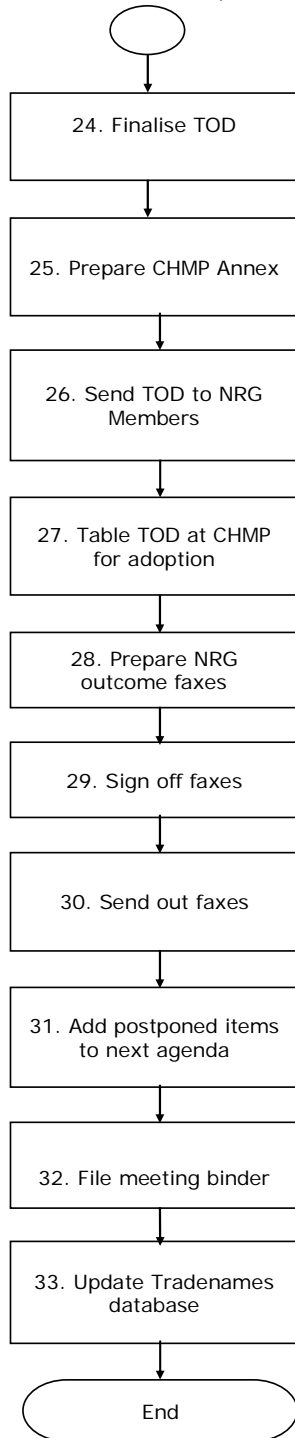
7. Definitions

AD:	Administrators responsible for NRG
AST:	Secretary(ies) responsible for NRG
CHMP	Committee for Medicinal Products for Human Use
DREAM:	Document Records Electronic Archive Management
MMD:	Meeting Management Document system
MMS:	Meeting Management System
NRG Inbox:	Outlook application
NRG Members:	Representatives from Member States
NRG Team:	Chairperson, Administrators and Assistants responsible for NRG
NRG:	Name Review Group
ToD:	Table of Decisions
Tradenames:	NRG Database

8. Process map(s)/ flow chart(s)



Continue from step 23



9. Proceduree

Step	Action	Responsibility
1.	Agree meeting dates with NRG Members and book meeting rooms in MMS at least 1 year in advance.	NRG AST
2.	Submit NRG meeting request in MMS.	NRG AST
3.	Send meeting invitation using MMS system – no later than 4 weeks in advance of NRG meeting. If new information is received on members/alternates attending the meeting, send out meeting invitation to these participants.	NRG AST
4.	Receive Invented Name application requests in NRG Inbox (NRG@ema.europa.eu) via e-mail or Eudralink, following deadlines set in our public website for applicants, Pre-Authorisation, Q&A, question 4a, see document: NRG plenary dates.	NRG AST
5.	Send acknowledgement e-mail to applicants (copy Chrono H-NRG).	NRG AST
6.	Prepare 1st batch draft agenda from template with new application requests received in NRG Inbox (outlook/all Public folders/Chrono in/Workflow): <ul style="list-style-type: none"> • open application request message • file Electronic copies in DREAM under CHMP/NRG/<year>/<meeting>/<II.1 New requests> as follows: create one new folder per application and name: <ul style="list-style-type: none"> – <agenda number> <INN/scientific name> • file paper copies of application requests in meeting master binder • add proposed invented names/ names to 1st batch draft agenda • cross-out message in NRG Inbox 	NRG AST
7.	Review 1 st batch draft agenda in internal meeting with AD and amend accordingly.	NRG AD
8.	Send 1st batch draft agenda to NRG members for objections (follow deadlines set in the document Target dates for sending objections and agenda in advance of NRG meetings) by Eudralink including: <ul style="list-style-type: none"> • 1st batch draft agenda • Zipped justification documents • Zipped documents for comments 	NRG AST
9.	Receive objections from NRG members on 1 st batch agenda and save CHMP/NRG/<year>/<meeting>/<Objections/1 st batch> (follow deadlines set in document Target dates for sending objections and agenda in advance of NRG meetings) and compile Objections/Comments from NRG members into 1st batch draft agenda.	NRG AST
10.	Prepare 2 nd batch draft agenda from template with justification requests received in NRG Inbox: <ul style="list-style-type: none"> • open justification request message • file Electronic copies in DREAM under 	NRG AST

Step	Action	Responsibility
	<p>CHMP/NRG/<year>/<meeting>/<II.2 Justifications> as follows: create one new folder per application and name:</p> <ul style="list-style-type: none"> – <agenda number> <INN/scientific name> • file paper copies of application requests in meeting master binder • add proposed justifications to 2nd batch draft agenda • cross-out message in NRG Inbox 	
11.	Review 2 nd batch draft agenda in internal meeting with AD and amend accordingly.	NRG AD
12.	Send 2nd batch draft agenda to NRG Members (follow deadlines set in document Target dates for sending objections and agenda in advance of NRG meetings) by Eudralink including: <ul style="list-style-type: none"> • 2nd batch draft agenda • Zipped justification documents • Zipped documents for comments 	NRG AST
13.	Receive objections from NRG members and save in CHMP/NRG/<year>/<meeting>/<Objections/2 nd batch> (follow deadlines set in document Target dates for sending objections and agenda in advance of NRG meetings) and compile Objections/Comments from NRG members into 2nd batch Draft Agenda.	NRG AST
14.	Review agendas (batch 1 and 2) and justification documents at internal meeting with NRG Team and finalise agenda. Make changes if necessary.	NRG Team
15.	Provide the Chairperson with the final copy of agenda/documents.	NRG AST
16.	Send draft agendas (batch 1 and 2) to NRG members prior to meeting (no later than 1 week in advance of NRG meeting).	NRG AST
17.	Send documents for printing to Reprographics (no later than one day before the plenary meeting).	NRG AST
18.	Prepare Meeting Room. Check all audiovisual equipment in the meeting room and liaise with ISERV or IT.	NRG AST
Meeting Phase		
19.	Distribute paper copies of the final draft agenda (batch 1 and 2) and other meeting documents to all participants.	NRG AST
20.	Adopt agenda.	NRG Chairperson
21.	Convert final agenda into Table of Decisions (ToD). Save the draft ToD in DREAM under: CHMP/NRG/<year>/<meeting>/TOD + Annex 5. Send link to AD.	NRG AST
22.	Take notes of meeting discussions to facilitate preparation of the minutes.	NRG AD
Post Meeting Activities		
23.	Organise debriefing meeting with NRG team to follow-up actions, if necessary.	NRG AST
24.	Finalise TOD 1 week in advance of CHMP meeting (CHMP meeting following NRG plenary).	NRG Chairperson
25.	Prepare NRG Annex 5 for CHMP Monthly Report (Annex provided by	AD

Step	Action	Responsibility
	CHMP Secretariat) by Tuesday following CHMP.	
26.	Send TOD for comments to NRG members (deadline day before CHMP meeting) and review if necessary.	NRG AST
27.	Table the final version of the TOD in MMD for adoption at the CHMP.	NRG AST
28.	Prepare NRG outcome faxes for sign off and provide paper copies to AD for review and amend, if necessary.	NRG AST
29.	Sign off of NRG outcome faxes.	NRG Chairperson
30.	Send NRG outcome faxes to applicants.	NRG AST
31.	Include postponed items into template draft agenda 1 st batch of next meeting (go to step 4).	NRG AST
32.	File meeting binder in the NRG core master file cabinet.	NRG AST
33.	Update Tradenames database according to adopted TOD.	NRG AST

10. Records

Meeting related documents are saved electronically in the appropriated folder in DREAM using the following folder structure (Cabinets/Old EDMS Structure/Meetings/Scientific Meetings/C H M P/NRG):

- Agenda
- II.1 New requests
- II.2 Justifications
- II.3 MP Names
- II.4 New Information
- Objection forms
- Other documents
- Outcome faxes
- TOD + Annex 5

Signed hard copies of NRG outcome faxes are filed in the master file with the meeting documents.