

Centralized Procedure CHMP/EMA

- Overview of CHMP Operations

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11 Plenary Meetings / year

- Monday: 09.30 – 19.30
- Tuesday – Wednesday: 08.30 - 20.30
- Thursday: 08.30 - 16.00

Satellite meetings:

DG's/Briefings/NCA
Consultation



11 Meetings / year

Dates set and published up to 5 years in advance

<http://www.ema.europa.eu/htms/human/presub/q25-2.htm>

Submission dates / Response Timetables etc... set, based on CHMP Meeting dates

No meeting in August – replaced by written procedure (timetables / letters for information etc... – no opinions adopted)

Extraordinary meeting whenever is needed

Paperless meeting!

- Agenda and Minutes circulated in paper
- Oral Explanation slides provided by company
- All other documents via MMD (Managing Meeting Documents)



Centralized procedure Primary Driver dictating timing
Plenary meetings

= Adoption LOQ 120

* Start of procedure

= Adoption LOQ 180

* Submission of responses

= Adoption Opinion 210

* Timing of oral explanation

= Post Authorisation Variations

Icelandic Volcano





Customised Meeting Room

= VDU / 2 seats

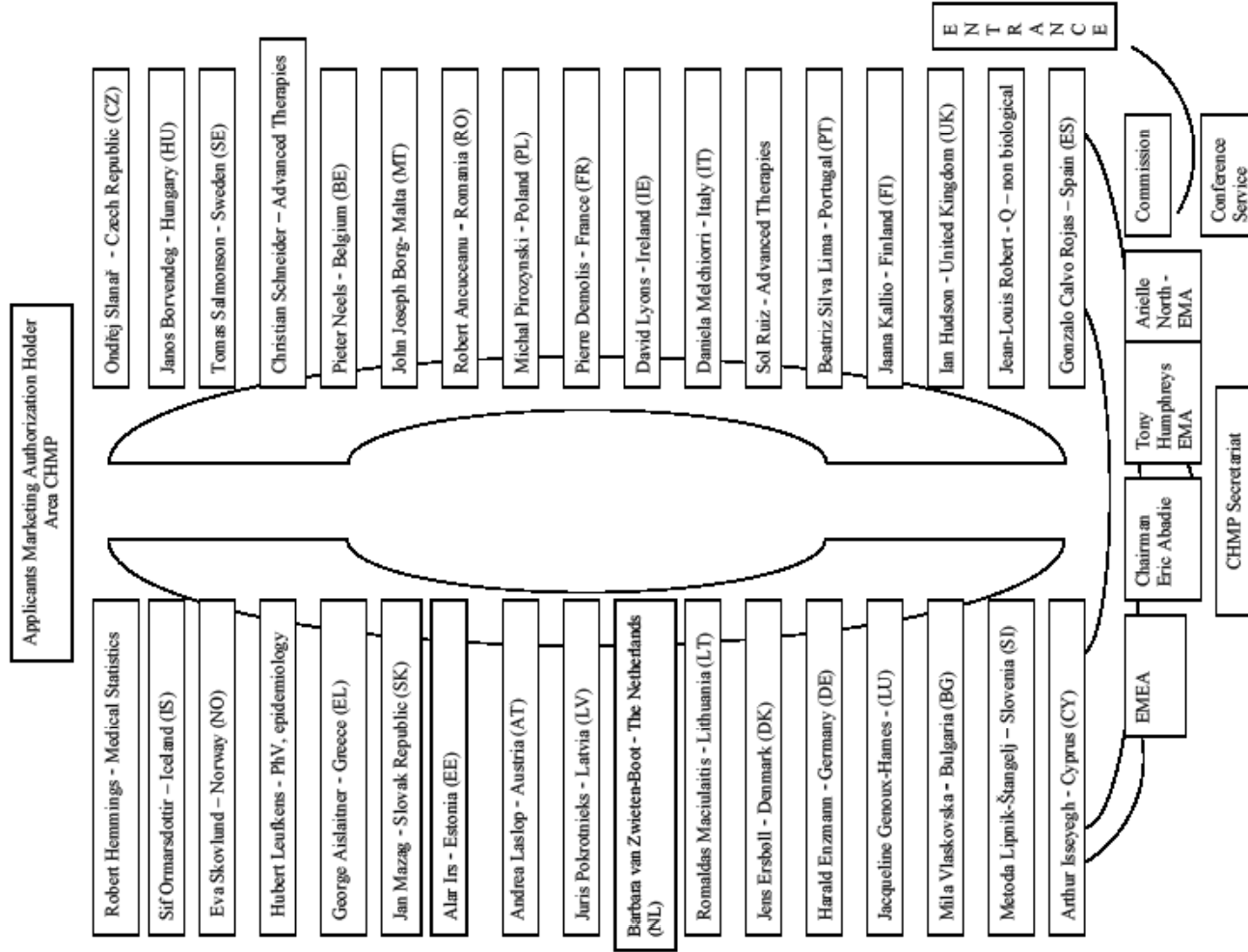
= MMD System = meeting documents

= Voting software trends/final votes

= WIFI



CHMP Seating Plan Under Spain Presidency

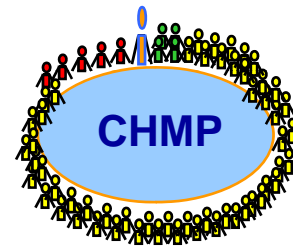


Who is Invited to the CHMP



- All CHMP members/alternates invited
- All CHMP members plus alternates with responsibility for items on the agenda or replacing member for that meeting are reimbursed
- SAG Chairpersons reporting on outcome of SAG meeting
- Working Party Chairpersons (for ORGAM section) are reimbursed

- We don't reimburse invitations for:
- Experts accompanying Rapporteurs for specific product
 - Alternates who do not have any key items on agenda (invited to attend at own expense)



N = 70-90

EMA Secretariat – live intranet
broadcast

No permanent record

NCA Assessors / Experts - telecon





- May 2010 Meeting

Agenda

107 pages (revision 4)



35 main 72 annex

- Time schedule

- » Established Pattern
- » Flexibility required



I.1 Agenda I.2 Minutes

I.3 Opinions

New MA/II indications/II safety (controversial)
Annual re-assessments/renewals ++

I.4 List of Questions

List of Outstanding Issues
Request for Supplementary Information

I.5 Re-examination Procedures Suspensions / Withdrawals

I.6 Referrals



II. Pharmacovigilance

II.1 Report for the PhVig Working Party

II.2 Pharmacovigilance Issues

- » Early Notification System
- » Product Specific Follow Up



III. Oral Explanations (mixed procedures)



IV. Other Product Related Issues/Inspections

- IV.1 Pre + Post Submission Issues
Eligibility / Rapporteur /
Post-Authorization Issues
- IV.2 Inspections gxp / Pharmacovigilance Inspections

V. Scientific Advice / Working Parties / ICH

V.1 Scientific Advice

V.2 Working Parties

V.3 SAGs

V.4ITF

ORGAM

VI. Sattelite Groups / Other Committees

CMDh / CXMP's /NRG

Meeting Organization

Centralized Procedure

Audits / Improvement
Actions

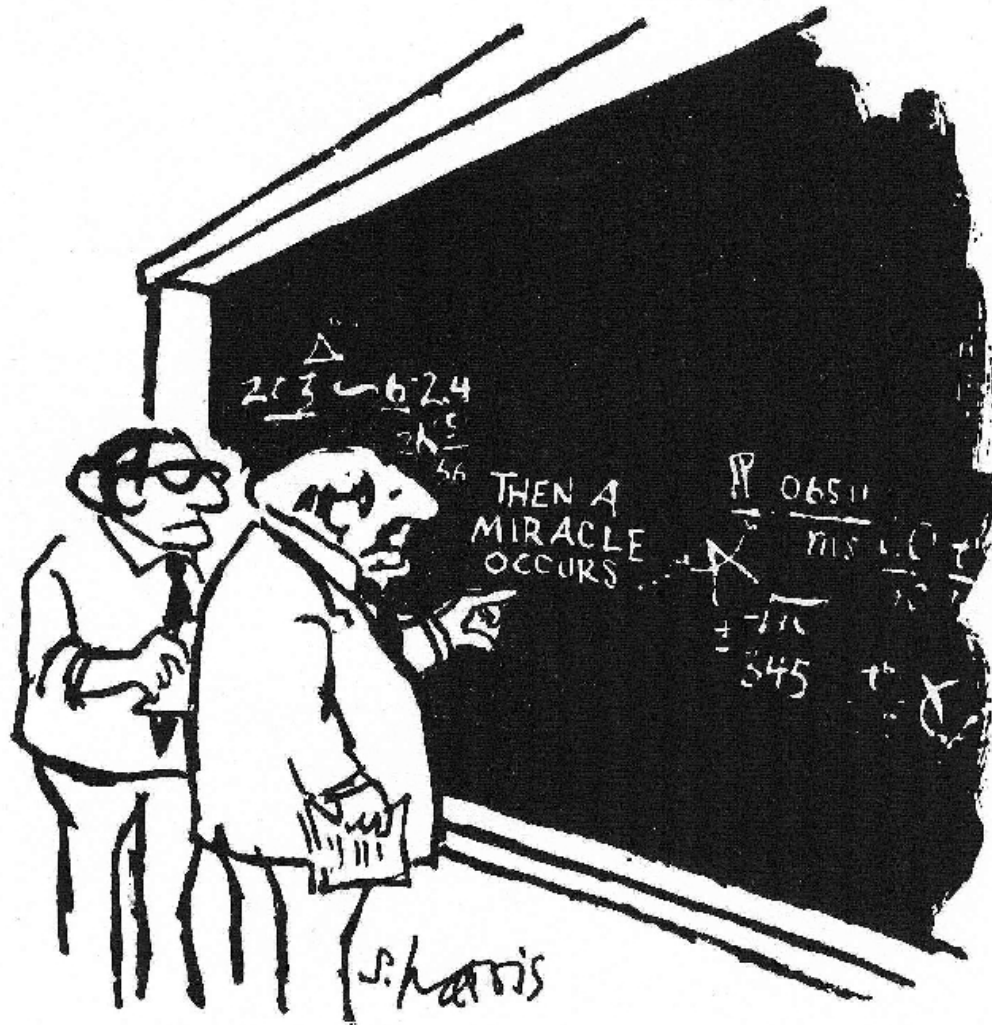
ORGAM

Transparency

Legislation Implementation /
Preparation

Pharmacovigilance

Miracle of Time schedule



"I think you should be more explicit here in step two."

The Miracle of the Time schedule



Monday

III. Preparation for oral explanations

V. WP Reports

I. New applications Opinions

Lunch time 

III. Oral Explanation

I.5 Article 20

I.6 Referrals

I.3 II Opinions

I.4 RSI II

IV. Eligibility

V. SAWP Report

Tuesday

IV. Post-authorization Issues

I.4 Log RSI LoOI'S

Lunch time 

I.4 Log RSI LoOI'S

I.6 Referrals

ORGAM

Wednesday

II. ENS

III. Oral Explanation

I.6 Referrals

I.5 Article 20

III. Oral Explanation

I.4 LoQ

Lunch time



III. Oral Explanation

II. Pharmacovigilance

Thursday

“Wrap-up” Adoption Slot

IV. Presubmission / Post-
Authorisation

V. ORGAM

Lunch time



I.4. Preparation for June 2010
(key identification potential for oral
explanation)

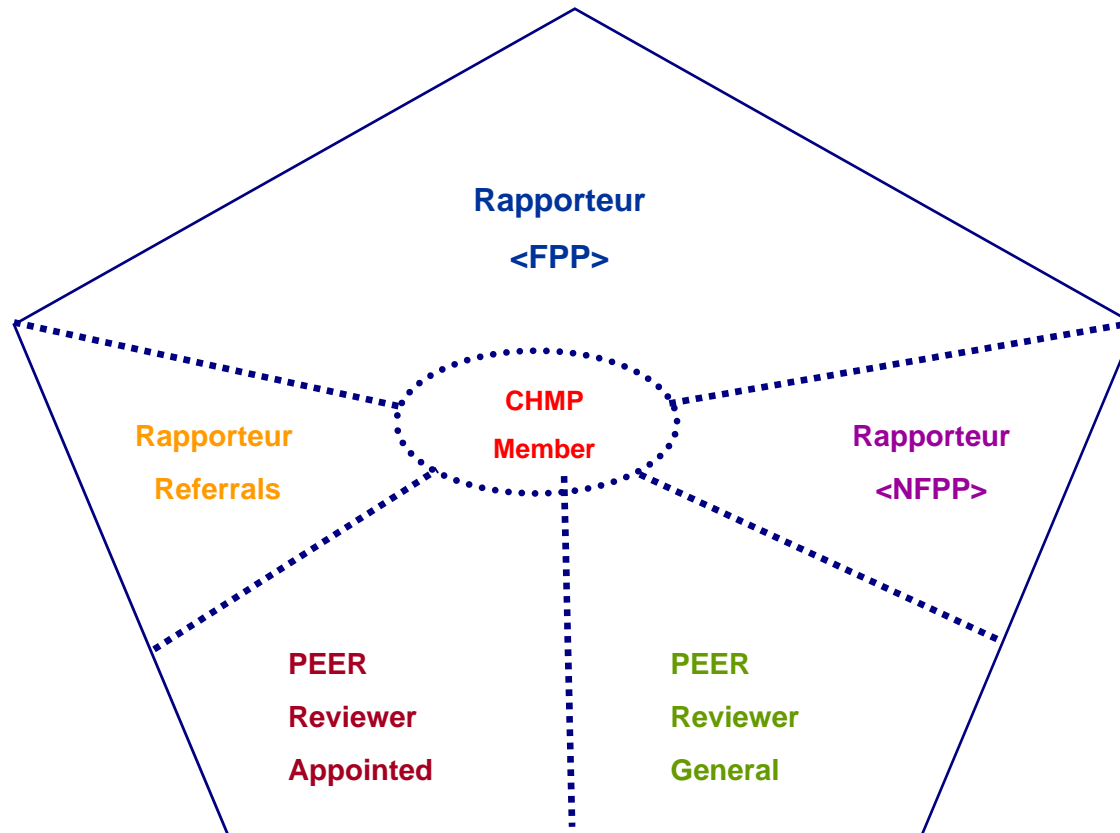
IV.2. GXP Inspections

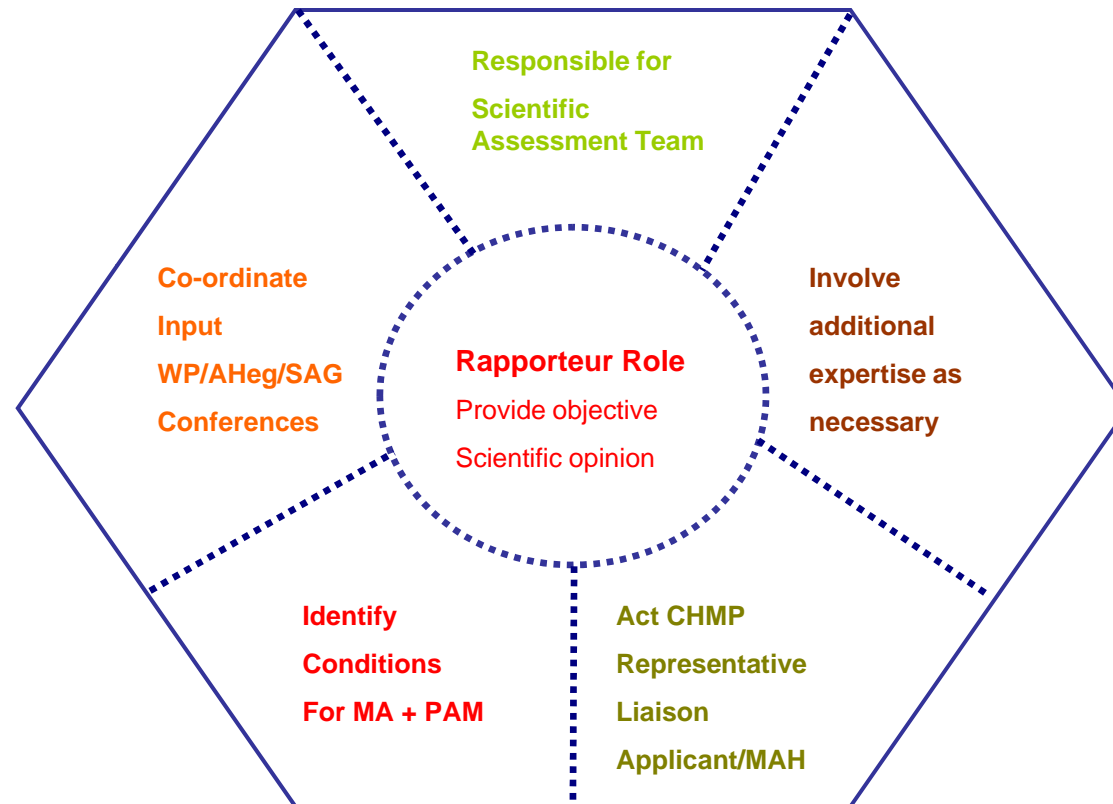
- CHMP Press Release: Created by Press Office and published on last day of Meeting
 - Product related issues only
- Product Press Releases, Questions and Answers documents, EPARs etc...
 - Responsibility of individual PTLs
- CHMP Monthly Report: Created by CHMP Secretariat and published a week after CHMP
 - Products and non products related issues



CHMP Member Endangered Species?







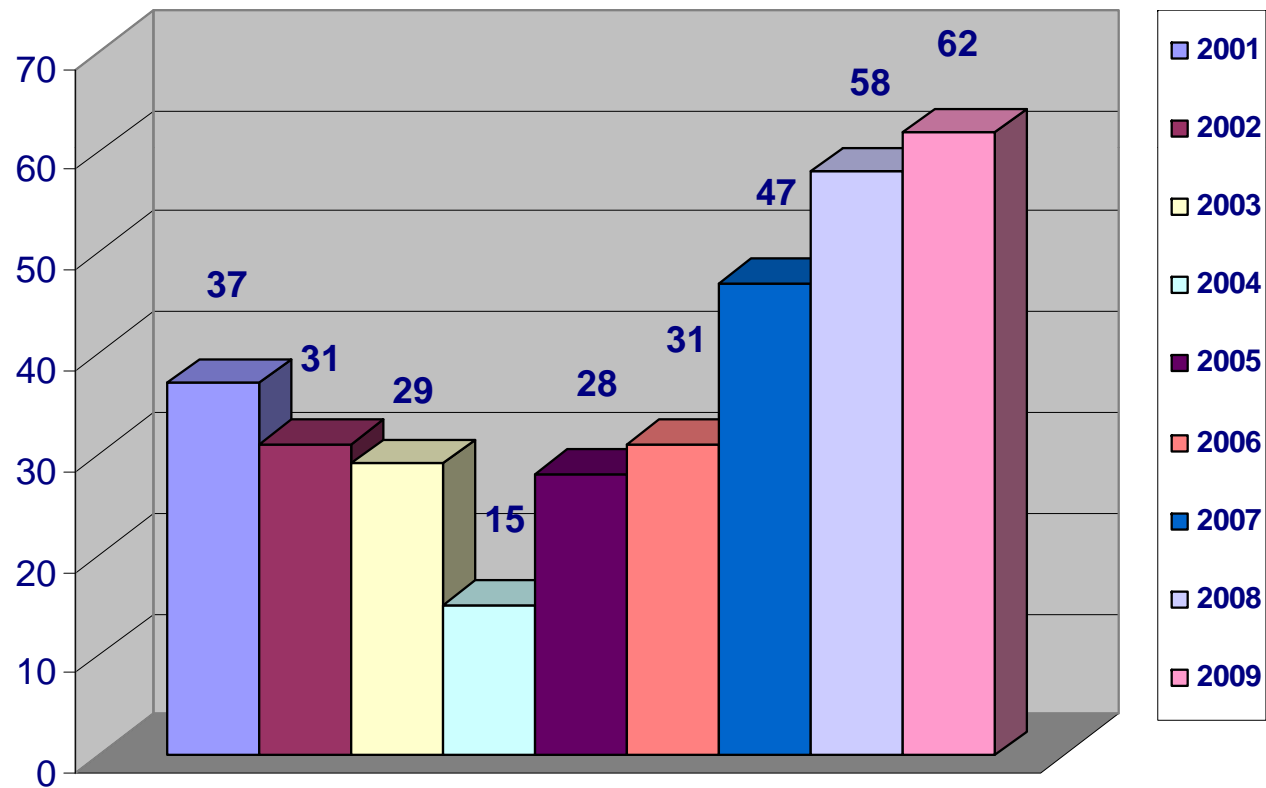
Voting at the CHMP



- Quorum required for adoption of opinions: two thirds of total members eligible to vote (22)
- Positive or negative votes – abstention not possible
- Where possible, opinions should be taken by consensus. Where consensus cannot be reached, opinion adopted by absolute majority of members (favourable votes by at least half the total members eligible to vote plus one - 17). Divergent position appended to opinion. Need to record names of those expressing divergent opinion
- Norway and Iceland can vote but their votes are recorded separately and not counted in reaching the Committee's opinion
- In case of no absolute majority, Committee's position is deemed to be negative



CHMP Oral Explanations 2001/2009

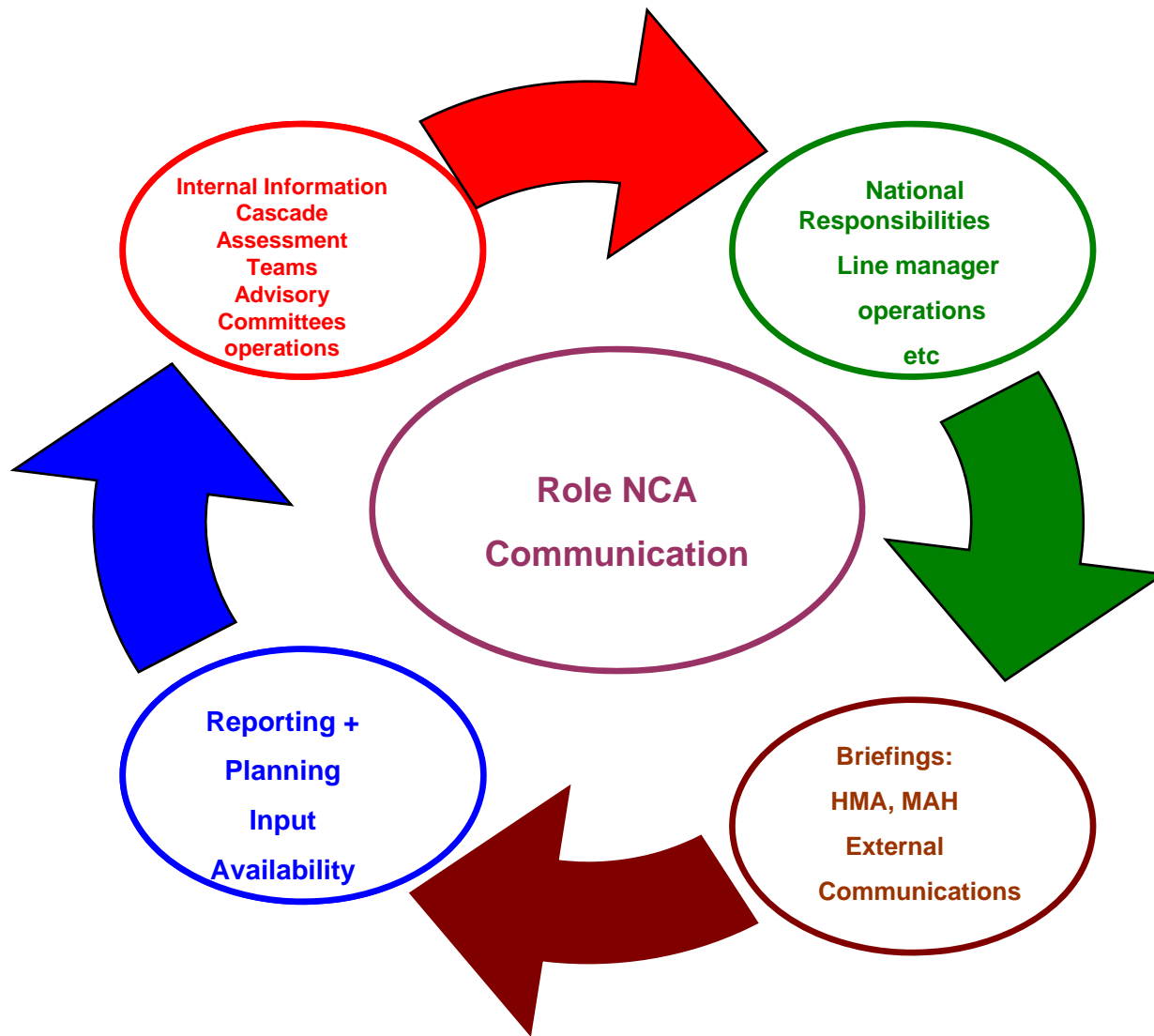


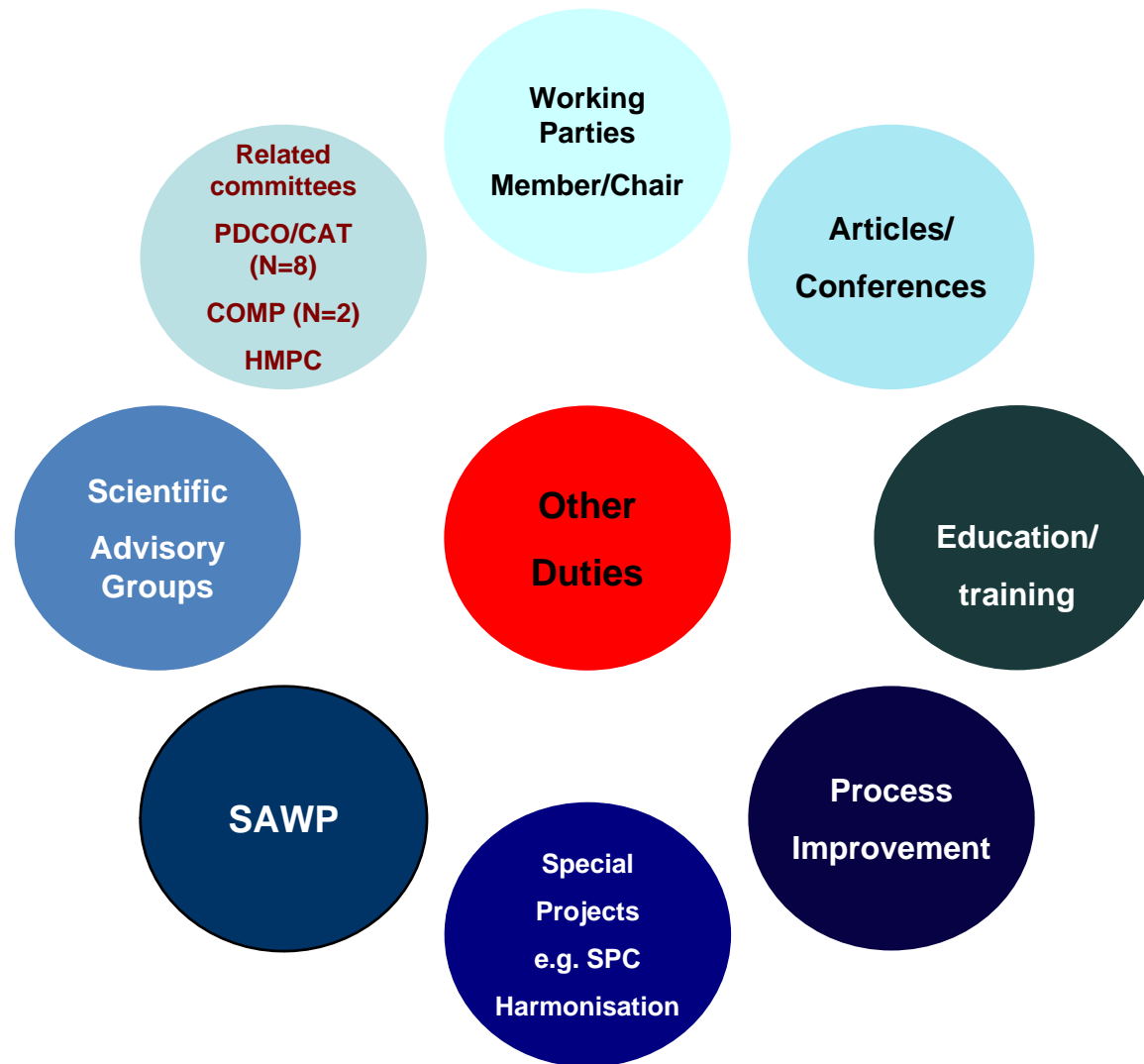
Timing of Oral Explanations



- Anything from 1 – 9 Oral Explanations per meeting
- Scheduled for Monday - Wednesday afternoon depending on number of oral explanations
- Procedures going for opinion at same meeting are given priority
- Slots may be requested in advance of meeting – CHMP Secretariat attempts to juggle time schedule
- Oral Explanation may be cancelled at last minute, if CHMP decides it is no longer necessary









Thank you