



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific Advisory Groups (SAGs)

PCWP and HCP WG Joint Meeting 28 February 2012

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- SAG mandate and rules of procedure
- Policy on Conflicts of Interests for SAG members
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The SAGs and the CHMP

- Legal basis: Art. 56 (2) of Regulation 726/2004
- SAGs are created by the CHMP to deliver answers, on a consultative basis, to specific questions
- The CHMP remains responsible for its final opinion

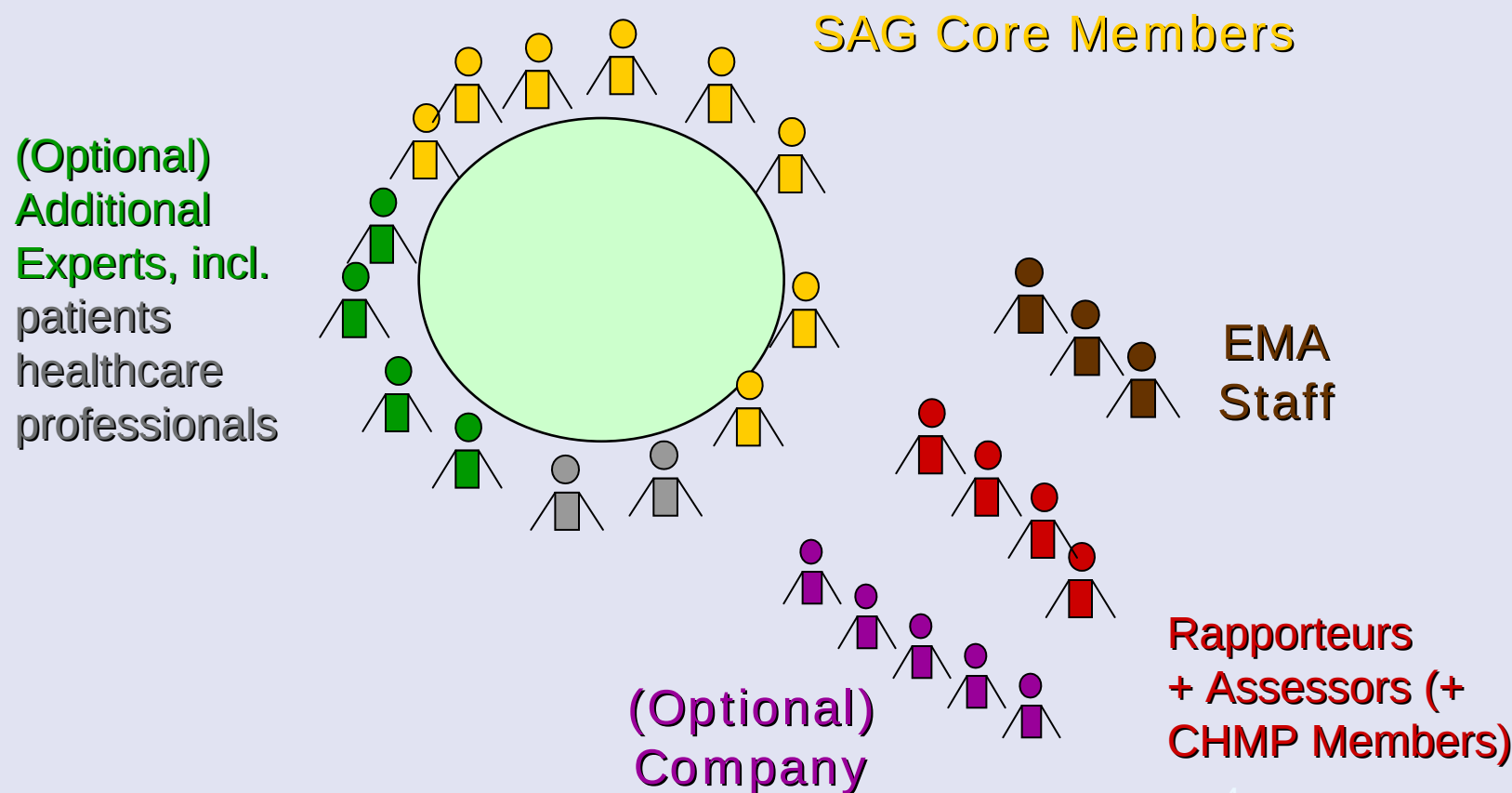


CHMP Request for SAG Meeting

- Rapporteurs indicate need for SAG
- CHMP adopts
 - Questions to SAG
 - List of additional experts
 - Date for the meeting
 - Company to attend or not
- SAG meeting
 - Written answers to CHMP questions
 - SAG chair briefs CHMP during plenary



Who participates in a SAG meeting?





EMA Policy On Handling Of Conflicts Of Interests

SAG core members

- No payments (honoraria, etc.) from companies during (3 year) mandate
 - Payments to institution, reimbursement for travelling expenses are acceptable
- Consultancy work (current): Excluded from meetings on relevant product
- Consultancy work (past), Principal Investigator (current): Excluded from Conclusions/Voting on relevant product

SAG additional experts

- Same rules but mandate only for duration of activity (from appointment to the meeting)



How does a SAG meeting work?

Conflict of Interests Disclosure

“Open” session with the company (≈120’)

- Rapporteurs present the questions to the SAG
 - Questions to Rapporteurs
- Presentation by the company
 - Questions to the company

Closed session, conclusions (≈ 60’)

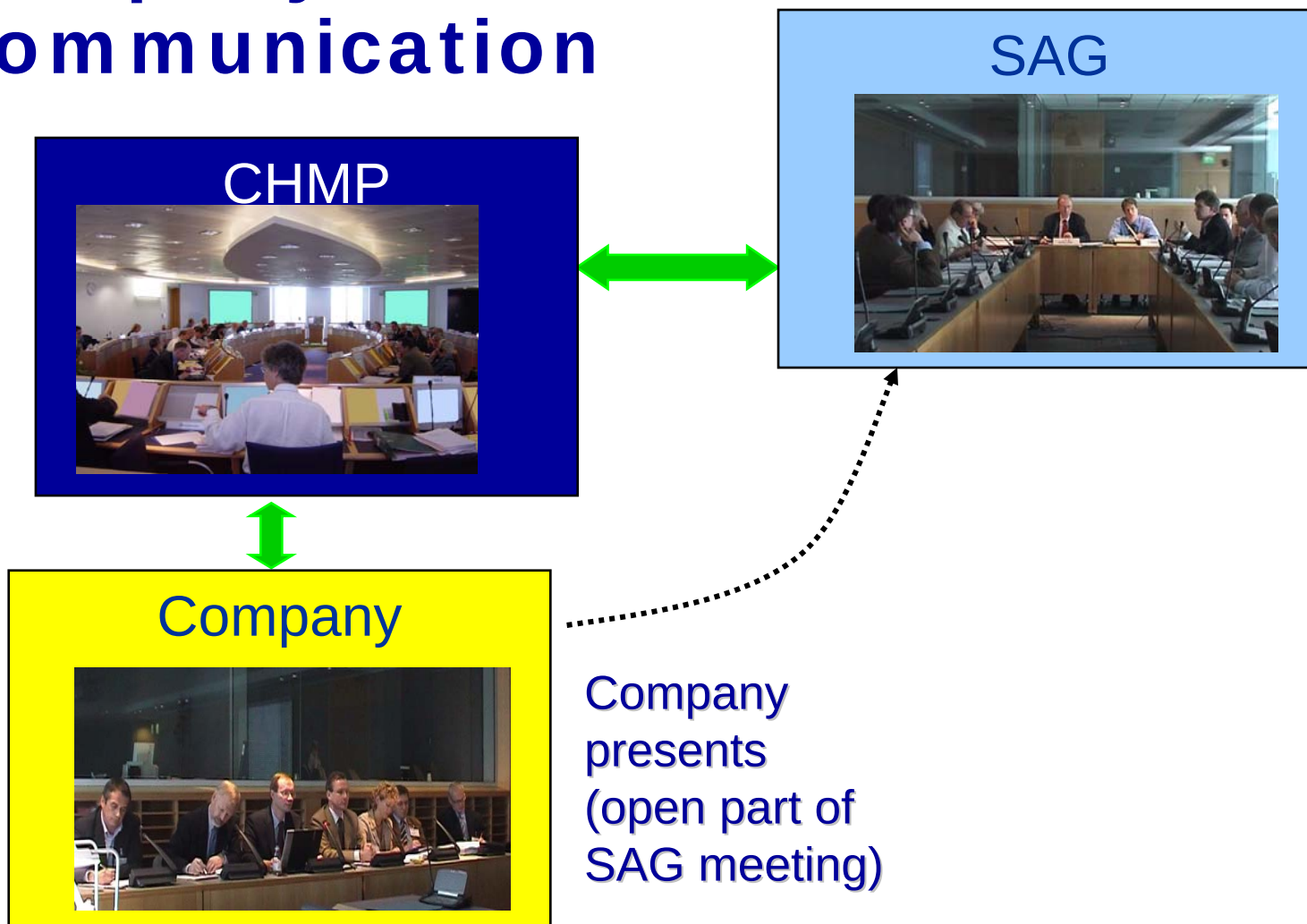
- Discussion
- Conclusions

Company debriefing (≈10’)

Conflict of interests may result in experts being excluded from conclusions



Company – CHMP – SAG Communication





Working Parties vs. SAGs

WPs	SAGs
Members normally regulators from national agencies	Members normally academic clinical experts, patients
CHMP delegates drafting guidelines (rarely product related issues with exceptions)	CHMP asks questions mainly in the context of evaluation of products
Meet regularly , publish work programme	Meet when needed

In both cases, the CHMP remains responsible for its final opinion



Scientific Advisory Groups (EMA/CHMP) vs. Advisory Committees (US FDA)

- Many similarities
 - overall concept, structure, experts
- Key differences

FDA: public (recorded, transcript, media)	EMA: not public (but reflected in EPAR)
FDA: generally longer timelines (sponsors' backgrounder submitted 48 days prior meeting)	EMA: more flexible (min. 2 weeks notice) May be challenging to find available experts at short notice



When to convene a SAG?

- Expected major public health interest where public controversy might be expected (e.g.: first-in-class)
- Substantial disagreement between rapporteurs on clinical aspects
- Controversial issues (e.g., high impact on health care professionals, the public and other stakeholders)
- Complex technical aspects, rare diseases
- Risk minimisation measures affecting the clinical practice
- Design and feasibility of a clinical trial
- Major post-authorisation safety issues

Procedural Advice for CHMP on the need to convene a Scientific Advisory Group (SAG) or *Ad Hoc* Expert Meeting (EMA/CHMP/551508/2010)



Scientific Advisory Groups and No. of Meetings

Advisory Group	2010	2011
Cardiovascular Issues	2	2
Anti-infectives	1	2
Diabetes/Endocrinology	3	2
(Diagnostics)	2	0
HIV/Viral diseases	2	1
Neurology	3	3
Oncology	8	6
Psychiatry	3	0
+Ad-hoc expert groups	2	9



Typical Questions for SAG (Oncology)

- Benefit-risk negative or marginally positive
- Clinical meaningfulness of benefits
- Clinical impact of risks
- Need for further studies
- Biologic rationale to support findings
- Guidelines



Summary

- SAGs provide advice → CHMP remains responsible for final opinion
- SAG members normally academic clinical experts
- Can include views from patients and healthcare professionals advocates and representatives
- Follows EMA policy on conflicts of interests
 - No payments (honoraria, etc.) from companies during mandate
- Most frequent questions to SAG: clinical interpretation of benefits and risks
- SAG involvement very frequent particularly in oncology



Thank You!

Further Readings (ema.europa.eu)

- Mandate, rules of procedure for each SAG
- Core members
- Procedural Advice for CHMP on the need to convene a Scientific Advisory Group (SAG) or *Ad Hoc* Expert