EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific Advisory Groups (SAG)

Experience and impact of patient involvement

PCWP/HCPWP joint workshop, London, 26 September 2013
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Human Medicines Evaluation Division, EMA

“Our expectations”

EUROPEAN MEDICINES AGENCY

Greater involvement of the public, moving away from comitology

Better understanding of regulatory decisions

(public explanation of an already made decision)

Participation in decision making by providing different insight (e.g. regulating access via the indication)

‘Permanent’ patient representatives on some EMA committees but not CHMP

Modified from François Houÿez

PCWP and HCP WG Joint Meeting 28 February 2012 - Contents

- SAG mandate and rules of procedure
- Policy on Conflicts of Interests for SAG members
- Running of SAG meetings
- SAGs compared to other bodies
- Experience
- Summary

Company – CHMP – SAG Communication

CHMP

SAG

Company

Company presents (open part of SAG meeting)

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

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

FDA: public meetings (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)

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)

Typical Questions for SAG (Oncology)

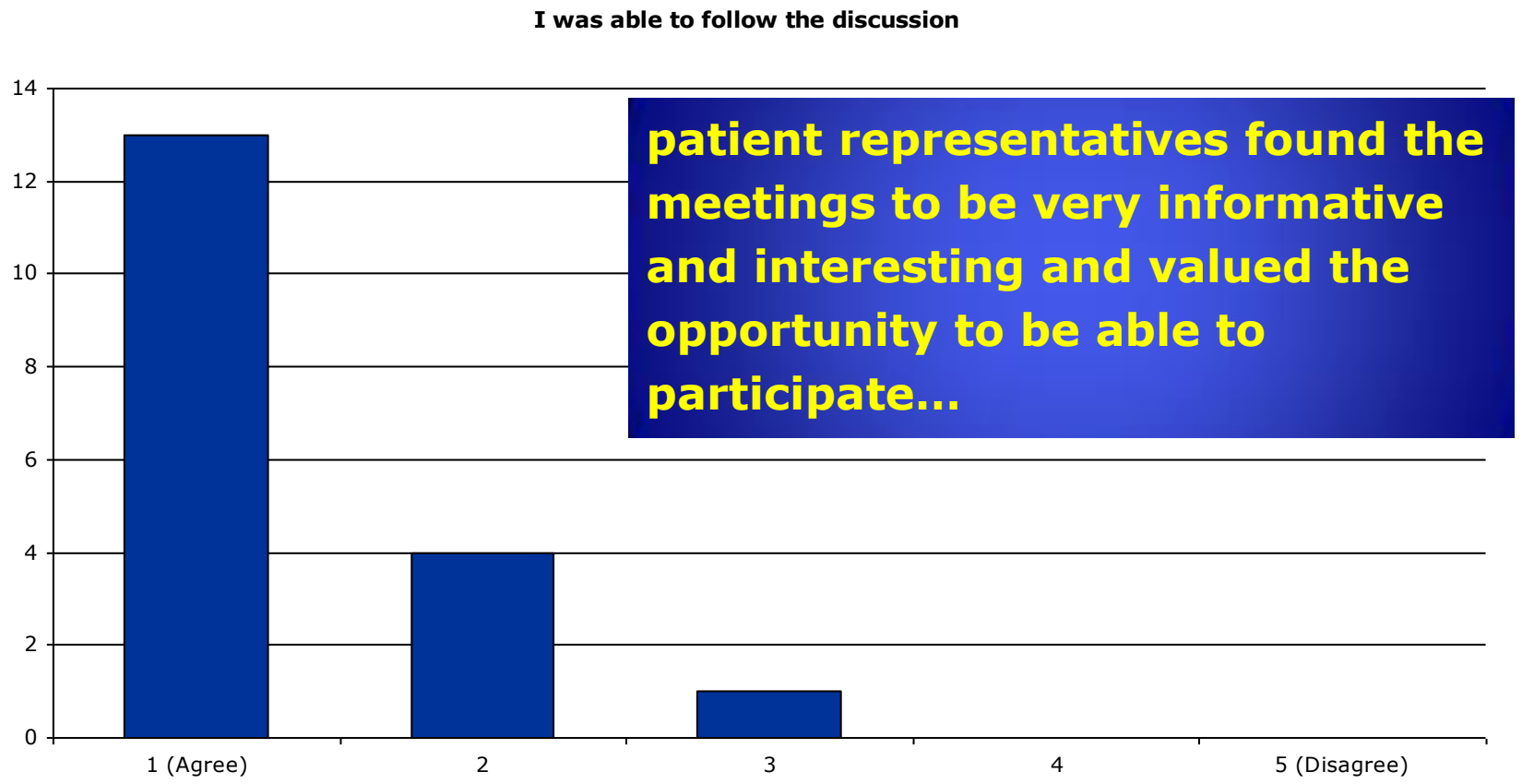
- Benefit-risk negative or marginally positive
- Clinical meaningfulness of benefits
- Clinical impact of risks
- Need for further studies
- Biologic rationale to support findings
- Guidelines

Should patient representatives be involved in SAGs?

- Statistics for 2013
  - 18/22 (82%) SAG meetings had one or two patient representatives
- Some myths
  - Discussion too technical for patients to contribute
  - Patients contribution will have little impact

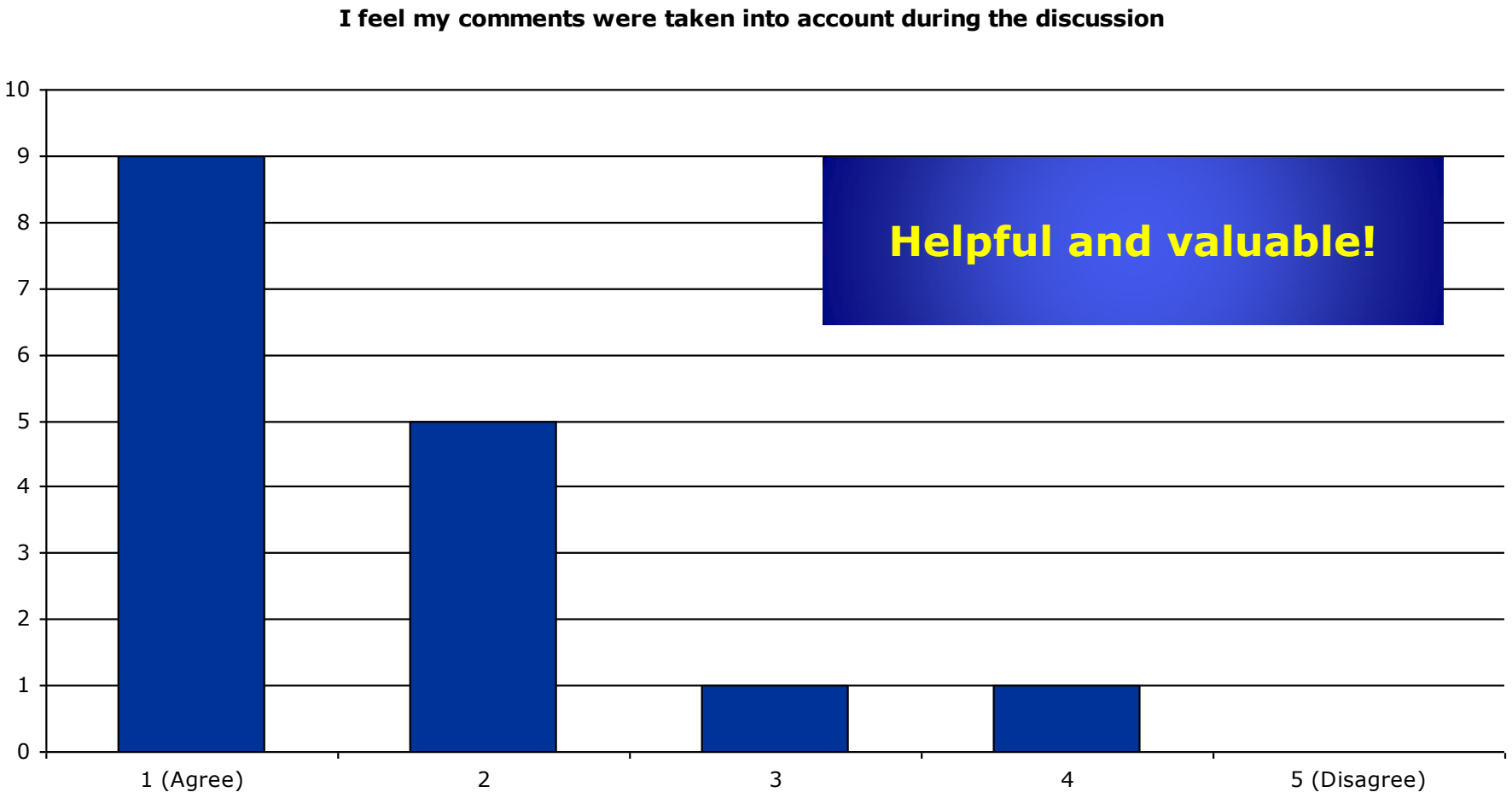
➢ 2011 Survey

Are patients able to follow the discussion?



8 EMA (2011) Outcome report on pilot phase for participation of patient representatives in Scientific Advisory Group (SAG) meetings.

Are patients' views taken into account?



9 EMA (2011) Outcome report on pilot phase for participation of patient representatives in Scientific Advisory Group (SAG) meetings.

Chairpersons and rapporteurs

The overall impression is that the **patient contribution is variable**, and can depend on the type of questions addressed during the SAG and on the individual patient who attended;

On the whole, the assessment of contribution ranged from being beneficial (able to obtain patient views with **an actual impact on the outcome**) to having no actual impact;

In all cases **patients were well integrated in the dynamic of the SAGs** and the meetings ran smoothly.

10 EMA (2011) Outcome report on pilot phase for participation of patient representatives in Scientific Advisory Group (SAG) meetings.

Conclusions

- Patients currently excluded from key decisions on licensing (CHMP)
- SAGs: important tool for bringing patients' values and preferences into the system
  - Overall interactions with patients groups have proved useful;
  - They bring a crucial patient perspective to the discussions on medicinal products
  - Can help to provide valuable insights such as acceptable levels of associated risks