EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific Advisory Group (SAG) meetings "Pilot Phase" report

Background

The legal basis….

“SAGs shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular **patient organisations** and heath care professionals’ associations relevant to the indication of the medicinal product concerned”

(Article 78(2) of Regulation (EC) No 726/2004):

Background

- Occasional participation of patients in some SAG meetings 2010
- Explore and further reflect on the participation of patient representatives in SAGs
- Pilot phase for period of 1 year
- Objectives:
  - To evaluate the contribution of the patient to the SAG meeting,
  - To evaluate the impact on the overall process,
  - To serve as a basis to define the way forward.

Pilot phase - methodology

- 1 or 2 patient representatives selected via eligible organisations
- Each patient completed a Declaration of Interests (DoI) and a confidentiality undertaking
- EMA staff contacted each patient to brief him/her and give support
- Each patient, SAG Chair and Rapporteur was given a questionnaire after the meeting

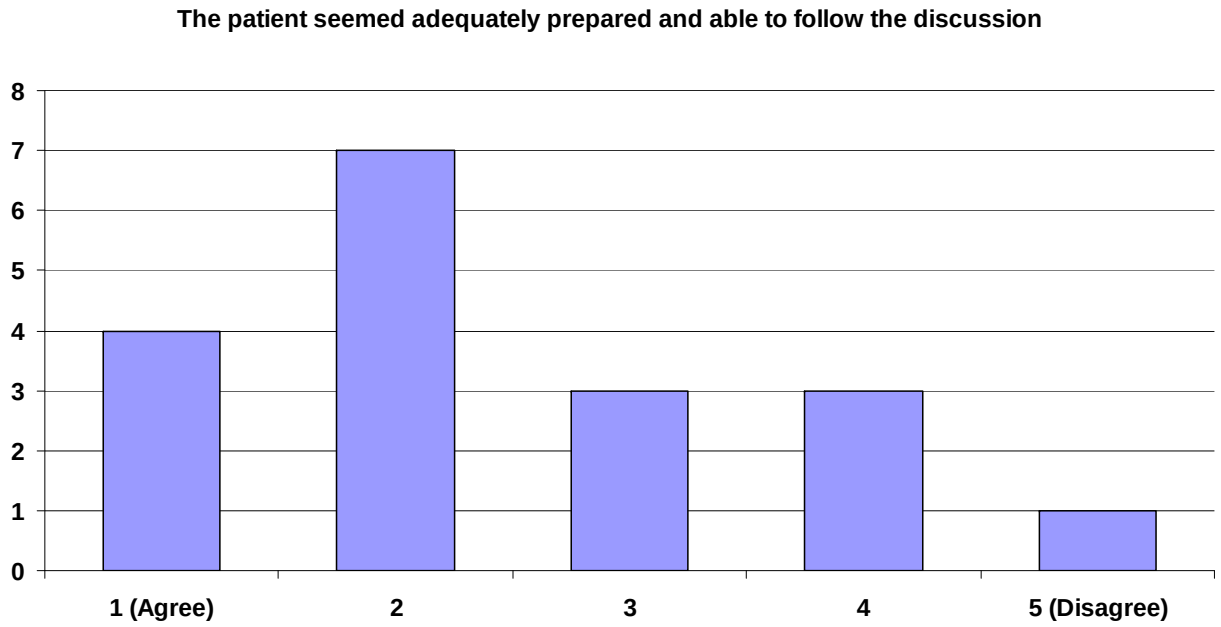
Pilot phase - outcome

- During study **21** SAG meetings held
- **22** patients participated in **18** meetings (for 3 SAGs no patients were available)
- Completed questionnaires were received from 18 patients and 19 Chairs & Rapporteurs
- Feedback and analyses are the basis for report and recommendations

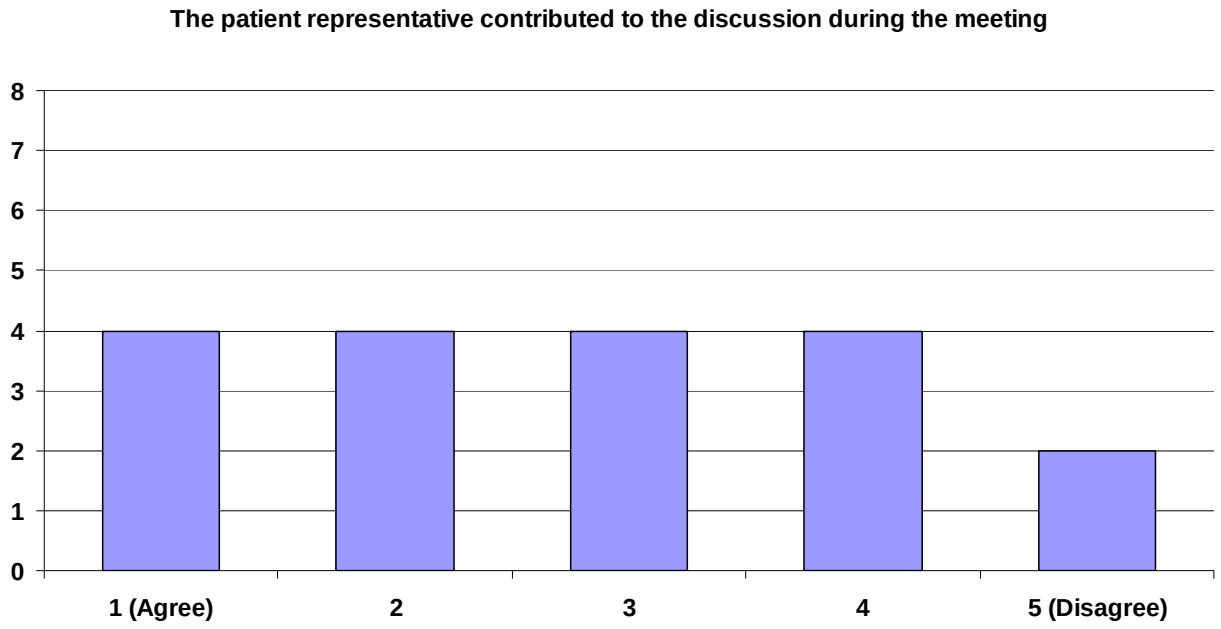
Pilot phase - results

The overall results for each question are shown in the following graphs:

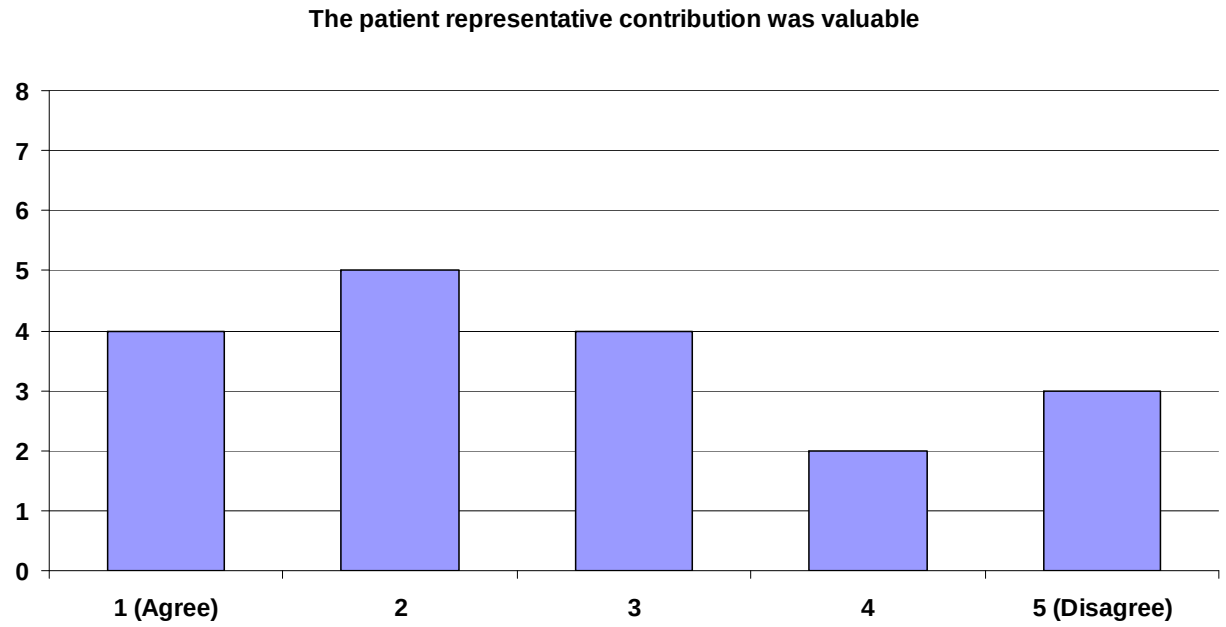
Regulators:



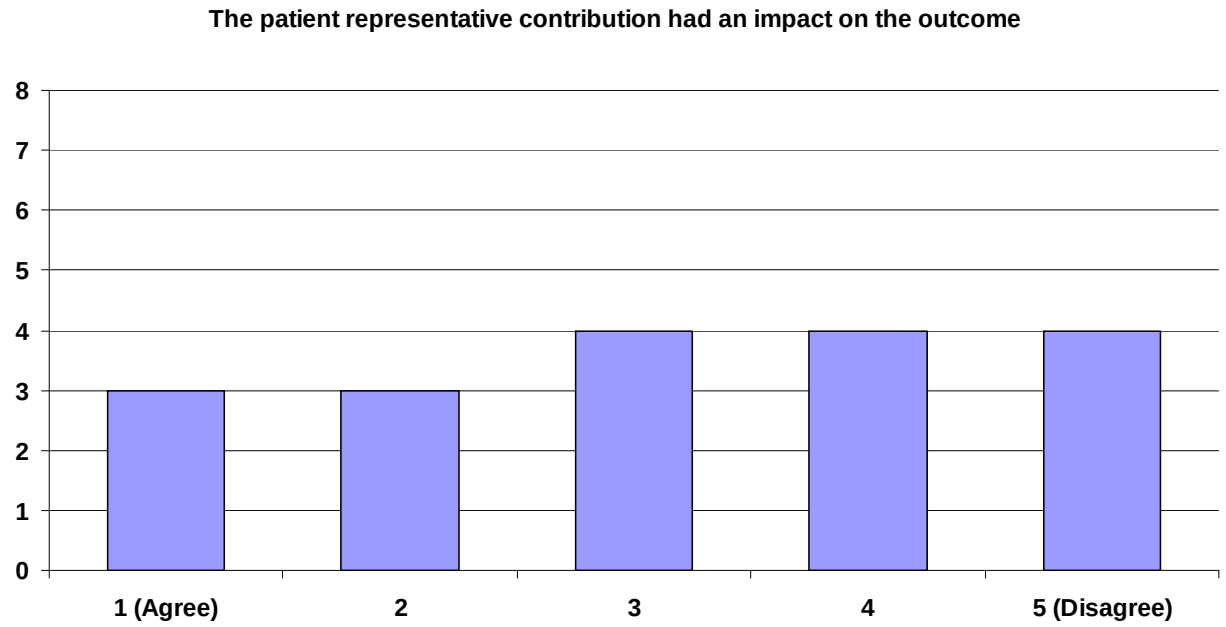
Pilot phase - results



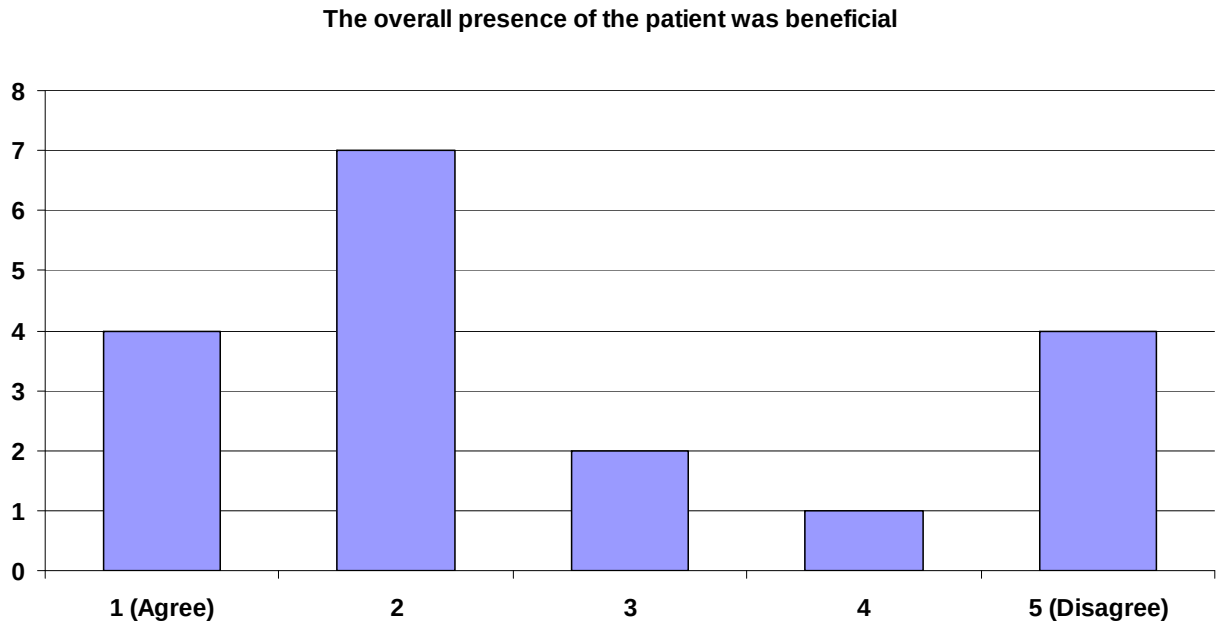
Pilot phase - results



Pilot phase - results



Pilot phase - results



Pilot phase - results

Open comments from regulators:

- The patients were very active in the discussions and gave a really interesting perspective that was very useful in forming an opinion on the product.
- As Chairman of the CNS-SAG for approx 5 years a number of patient representatives have helped during this time. My general feeling is that they contribute valuably to decisions about the benefit-to–risk decision, particularly by seeming less cautious about risks than the medical experts. Unsurprisingly they are not in a position to contribute to the scientific discussion about efficacy, but in the main they themselves recognise the limits of their expertise. My overall feeling is of a positive contribution and I would continue with their participation.

Pilot phase - results

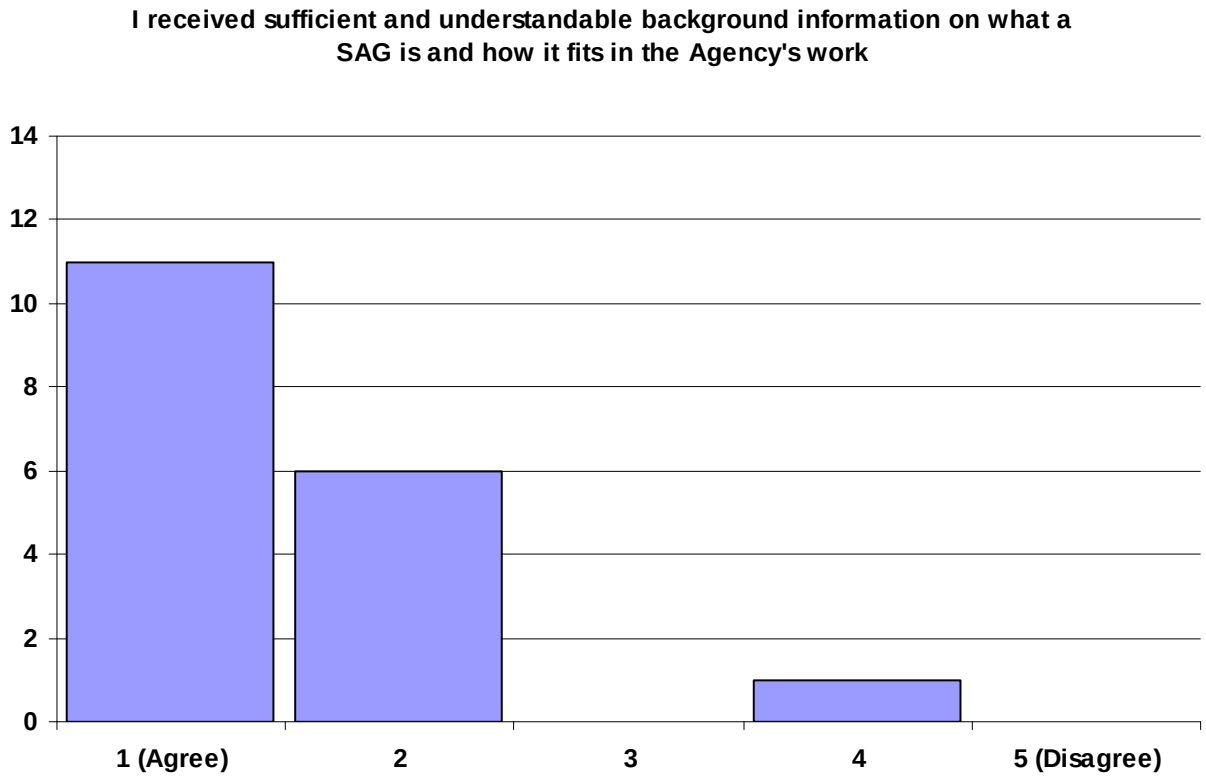
- The patient representative on the HIV SAG has always contributed well as they are nominated by the European AIDS Treatment Group a most impressive and well informed European patient and treatment advocacy group.
- Helpful and valuable!
- The discussion of the questions was quite technical so the opportunities for the patient representative to contribute as much as they normally would were somewhat limited. However, when he did contribute the comments were mostly useful.

Pilot phase - results

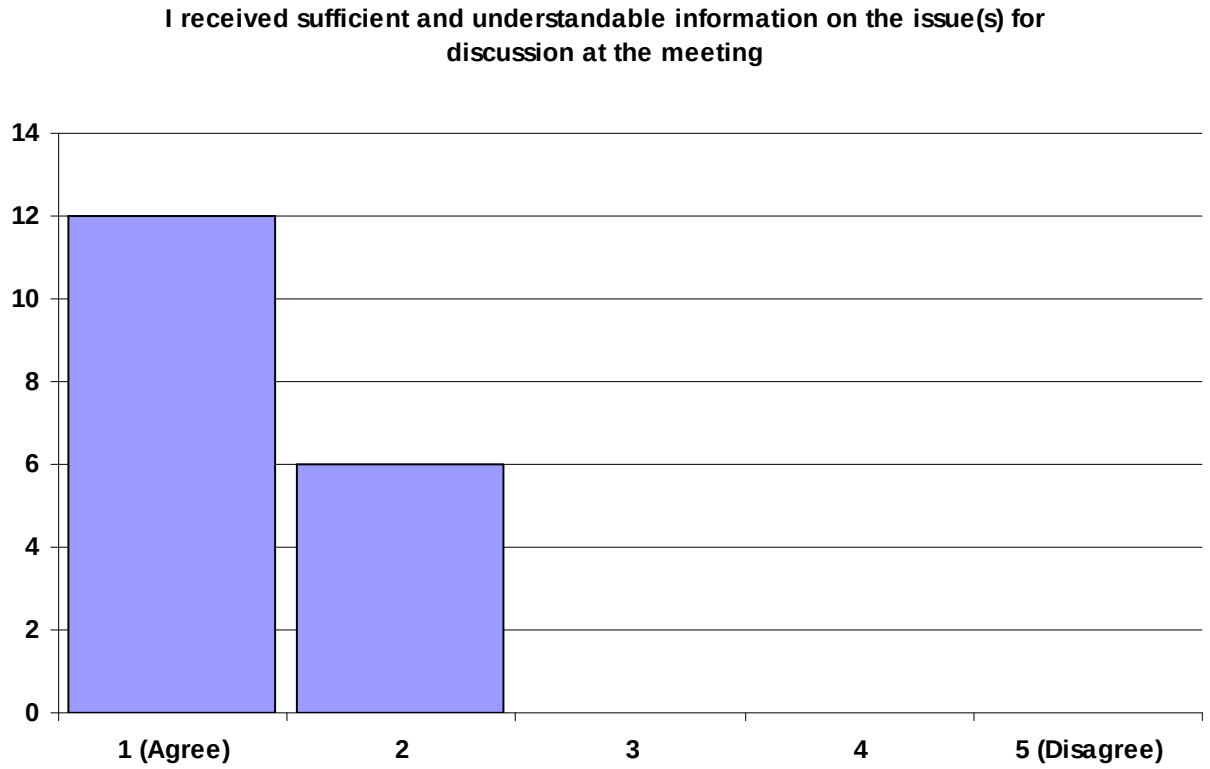
- The value of patient representatives is variable. On this occasion the patient representative appeared well informed and able to follow the discussion. Her comments on the value of this therapy for patients were well received, but did not materially affect the outcome.
- She was given the opportunity to speak but she did not use this opportunity.
- She did not really contribute in my opinion.
- Patient representatives most often play a remote role.

Pilot phase - results

Patient representatives:



Pilot phase - results



Pilot phase - results

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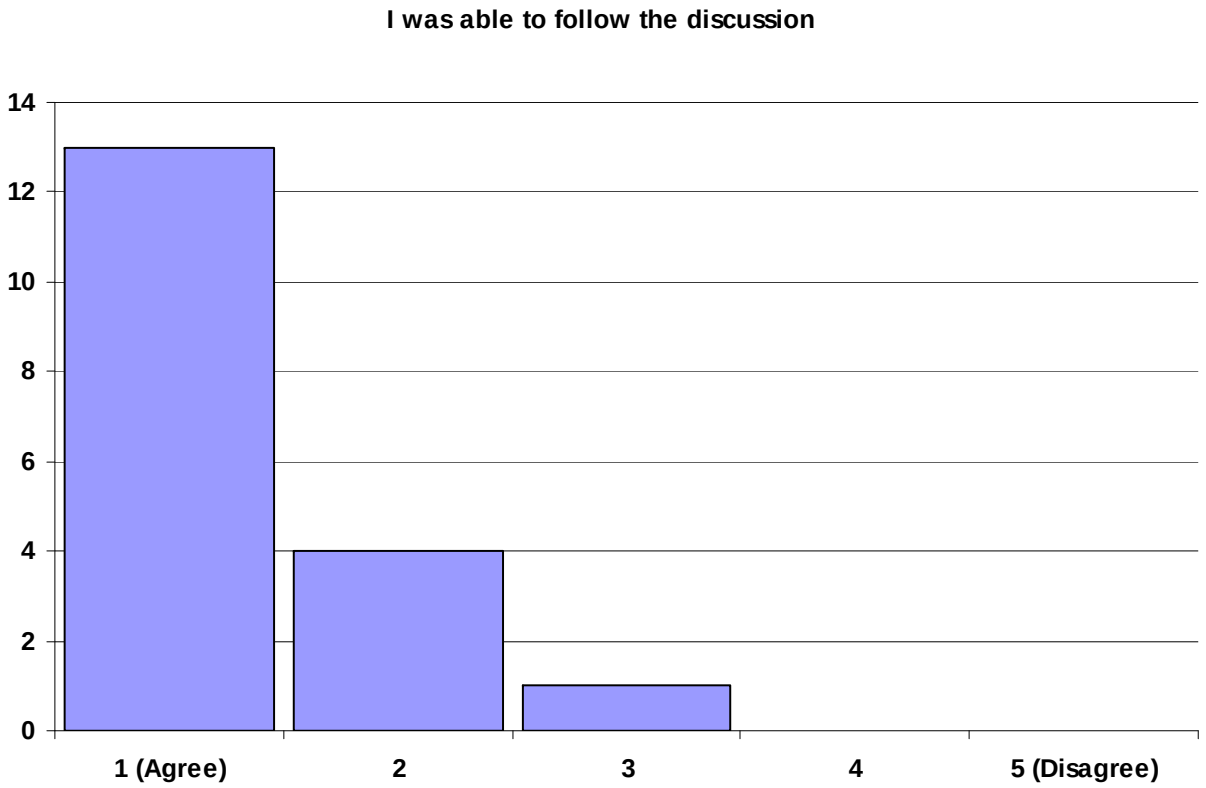
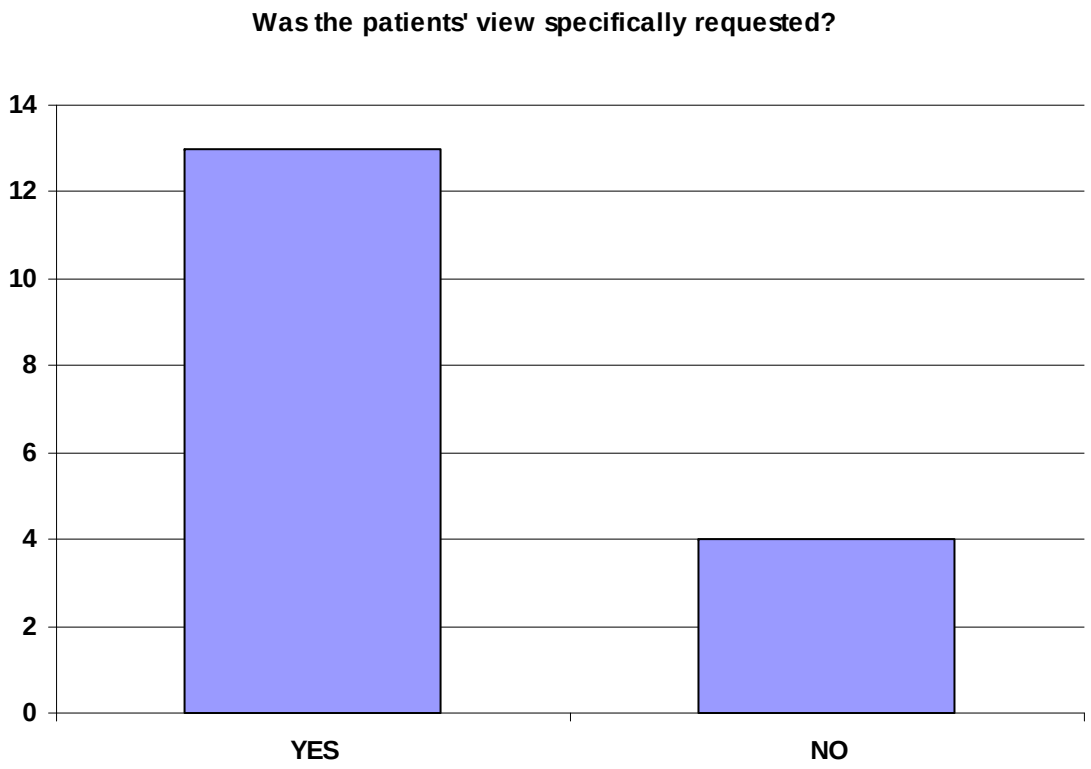
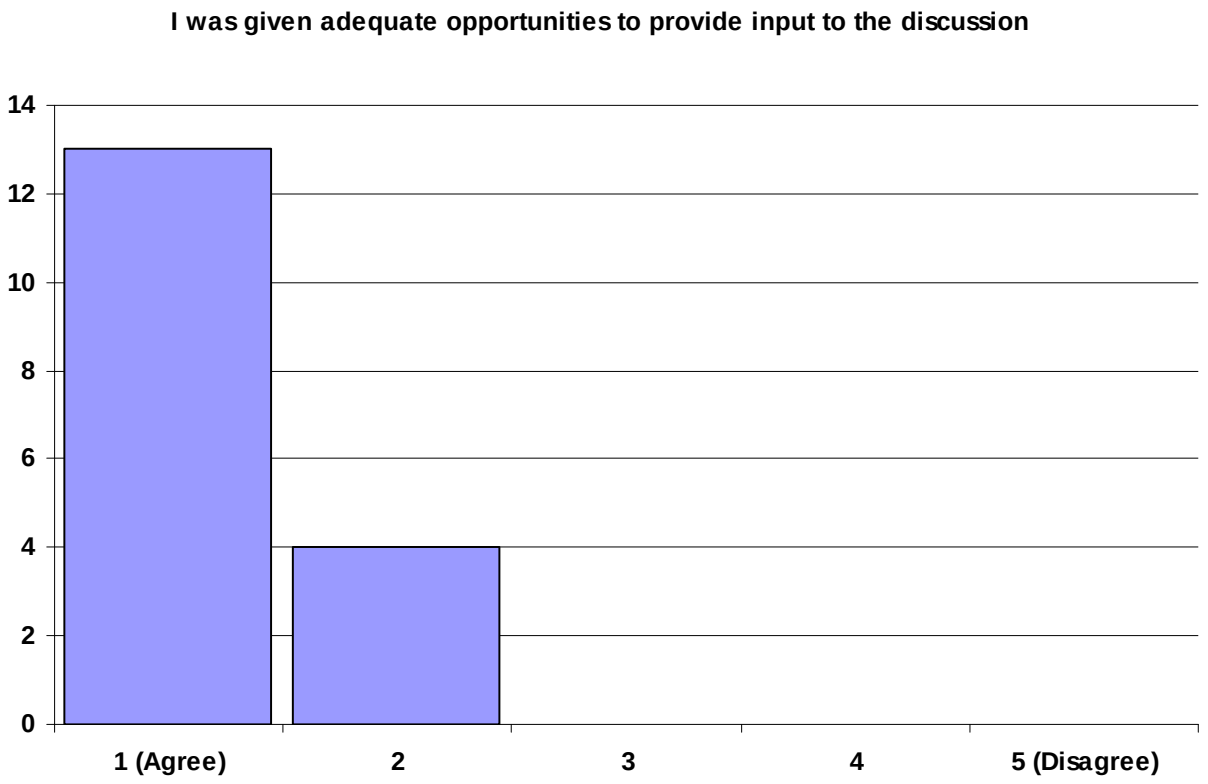


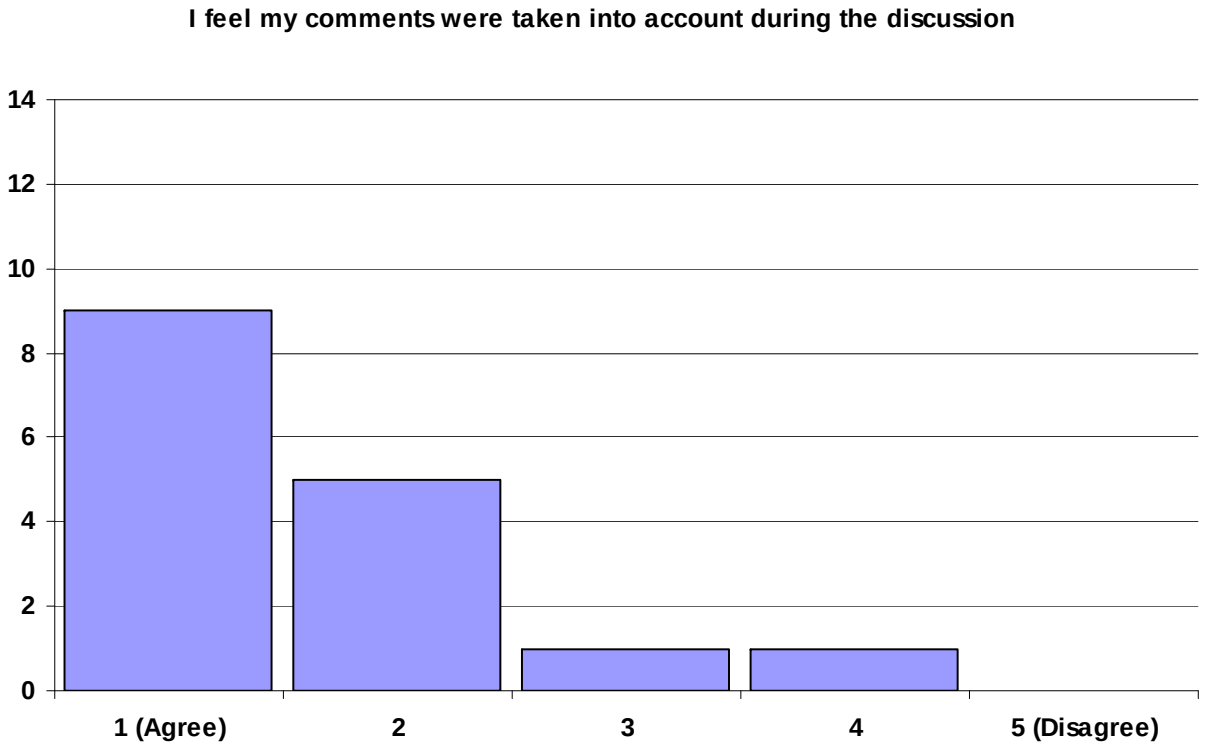
Pilot phase - results



Pilot phase - results



Pilot phase - results



Pilot phase - results

Open comments from Patient representatives:

- Absolutely fascinating, I learnt a lot that I didn't know about the drug. The other SAG members asked all the questions that were formulating in my head in much more succinct and elegant way, so I didn't actually say much in the meeting. The chair of the meeting was really excellent.
- A fascinating and valuable process. Thank you for this opportunity to learn about this therapy.
- A very good meeting.

Pilot phase - results

- The information which was generally good, was received very late and therefore difficult to prepare sufficiently for the meeting. More background information on EMA procedures and acronyms would be welcome.
- Would have appreciated the paperwork earlier to study it.
- Would have appreciated being met at the lift as difficult to find the room. Paper work was not available until one week before - inadequate time to prepare.
- Problem with disability arrangement.

Pilot phase – summary of results

Regulators:

- The majority (61%) felt that the patient was able to follow the discussions
- Patients did not always actively participate in discussions or voice opinions
- 9 felt that the patient representative contribution was valuable, however 5 reported the contrary
- Mixed perceptions on whether the patient contribution had “an impact on the outcome”
- The final question “was the overall presence of the patent beneficial” was generally positive; 11 agreed (61%), 5 disagreed and 2 were neutral.

Pilot phase – summary of results

Regulators:

The **overall impression** from the feedback is that

- the patient contribution is variable,
- it can depend on the type of questions addressed during the SAG, and
- on the individual patient who attended

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

Pilot phase – summary of results

Patient representatives:

- The majority felt that their view had been sought and adequate opportunities given to participate
- Many patient representatives felt their comments had been taken into account
- Patients received adequate background information, however information could be provided earlier to facilitate preparation

Pilot phase – summary of results

Patient representatives:

The **overall impression** from the feedback is that

- The patient representatives found the meetings to be very informative and valued the opportunity to be able to participate
- Participation could be enhanced with earlier background information

Pilot phase – conclusion

Feedback relates to performance of single experts; not all individual experts contribute equally or have an impact on the outcome

- A patient representative contribution to any SAG meeting is, as would be expected with any expert, variable
- The contribution depends on the type of questions to be addressed and on the patients who actually attend
- Although patients do not always verbally participate to the discussion; there is an intrinsic value to their presence; only by having them there can their views be requested if, and when, needed

Pilot phase – conclusion

- Adds robustness to the SAG output and enriches the overall evaluation of the benefit and risk of the medicine
- Specific questions for patients and further training could improve contribution
- Highly valued from the patients' and increases transparency into the assessment process
- No disruption or issues in relation to confidentially

Way forward

- Following the finalisation of the pilot phase, patients will continue to be included at SAG meetings
- However patients may not be invited if the discussion is of too technical nature or does not specifically relate to benefit or risk of the product.
- EMA to provide extra training and support to facilitate patients participation
- Continue to monitor patient participation and contribution to SAG meetings

Implementation (Organisational matters)

It is proposed to maintain the current organisational arrangements:

- Patient representatives principally contacted via the EMAs' existing network of eligible PCOs
- Patients should have direct knowledge of the disease
- Every patient representative will complete a DOI/confidentiality undertaking
- Participation of preferably 2 patients per meeting (maximum)
- Patient representatives should feel part of the meeting - Chairs continue to make efforts to involve and facilitate patient participation
- CHMP may identify specific questions where patient input would be valuable; however not as a routine