15 December 2011
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Patient Health Protection

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

Background

Patients and consumers have been involved with the Agency for many years and are already well integrated into numerous areas of its work. Overall interactions with patients groups have proved useful; they bring a crucial patient perspective to the discussions on medicinal products and can help to provide valuable insights such as acceptable levels of associated risks, etc.

On this basis, the Agency has been looking into ways to further develop and improve the existing involvement of patients/consumers in its benefit/risk assessments throughout the evaluation process.

This has been highlighted within:

- The "reflection paper on the further involvement of patients and consumers in the Agency's activities" which proposes the development of criteria on when patients should be involved in benefit/risk considerations (EMA/MB/753771/2009),
- The imminent revision of the "framework of interaction with patients and consumers' organisations" which aims to further integrate patients' values into benefit/risk assessments (EMEA/354515/2005),
- The agency roadmap to 2015 which emphasises the need to improve the benefit/risk assessment process through enhanced dialogue with patients/consumers,
- The CHMP work program for 2011-2013 (EMA/CHMP/65166/2011).

Involvement in SAG meetings

The legal basis for involvement of patients/consumers in SAG meetings lies within Article 78(2) of Parliament and Council Regulation (EC) No 726/2004: "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".

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Following the occasional participation of patients in some SAG meetings early in 2010, (as agreed by the CHMP - EMA/312354/2009), the CHMP requested to explore and further reflect on the participation of patient representatives in these meetings. For that purpose the CHMP included in its work program for 2011-2013 a specific action to run a pilot phase in which patients would participate in SAGs meetings for 1 year. It was also proposed that the analyses of this experience would be used to further decide on the way forward.

Pilot phase

During the pilot phase patients were invited to attend SAG meetings during a period of one year as of October 2010. The objectives of the pilot phase were:

- To evaluate the contribution from the patient to the SAG meeting,
- To evaluate the impact on the overall process,
- To serve as a basis to define the way forward.

Methodology

Patients were selected making use of the European network of patients' organisations which are eligible as per EMA selection criteria. Eligible organisations were contacted and were asked to identify suitable experts in the therapeutic area of interest for each SAG meeting and 1 to 2 (maximum) patients were selected to participate.

Each patient completed a Declaration of Interests (DoI) and signed a confidentiality undertaking. They received in advance relevant information as well as the questions to be addressed at the SAG. A member of EMA staff contacted the patient to brief him/her and to ensure they had understood the process and what was expected from them at the meeting, and remained available for any additional information or clarification the patient could need in advance of the meeting.

During the pilot phase, no case specific questions for patients were formulated in advance of the SAG meetings.

Patient participation and contribution was evaluated by way of questionnaires to be completed by both the patients and the SAG Chair and Rapporteur attending the different SAGs meetings.

The questionnaires are presented in Annexes 1 and 2 of this report.

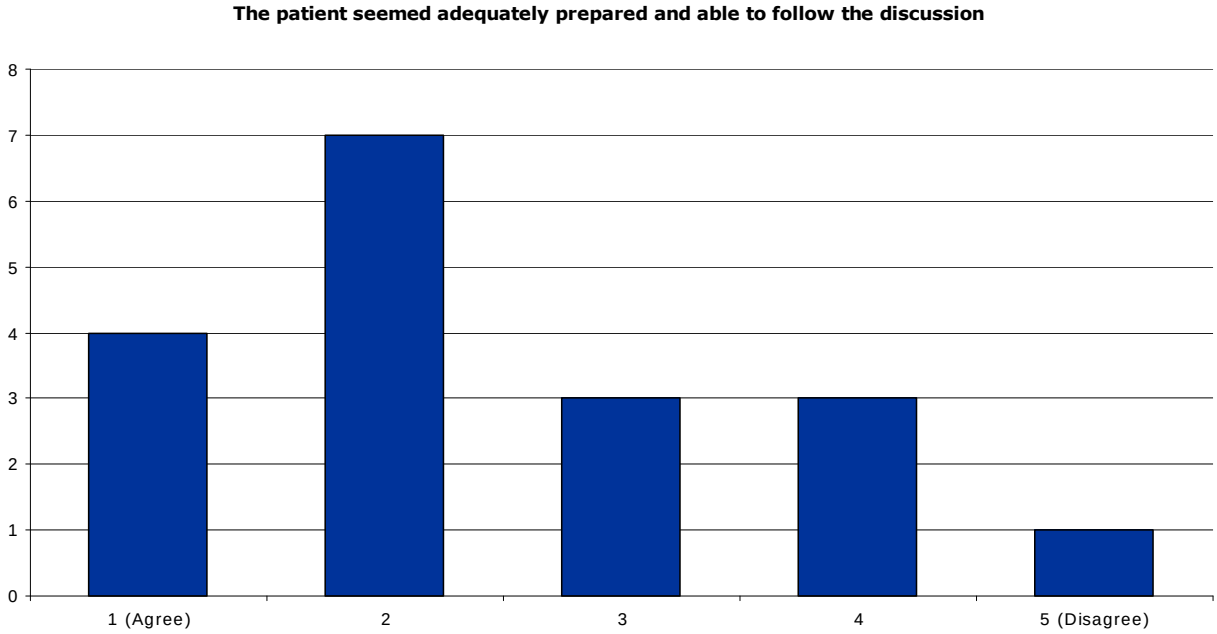
The feedback obtained and its analyses are the basis for the present report and recommendations.

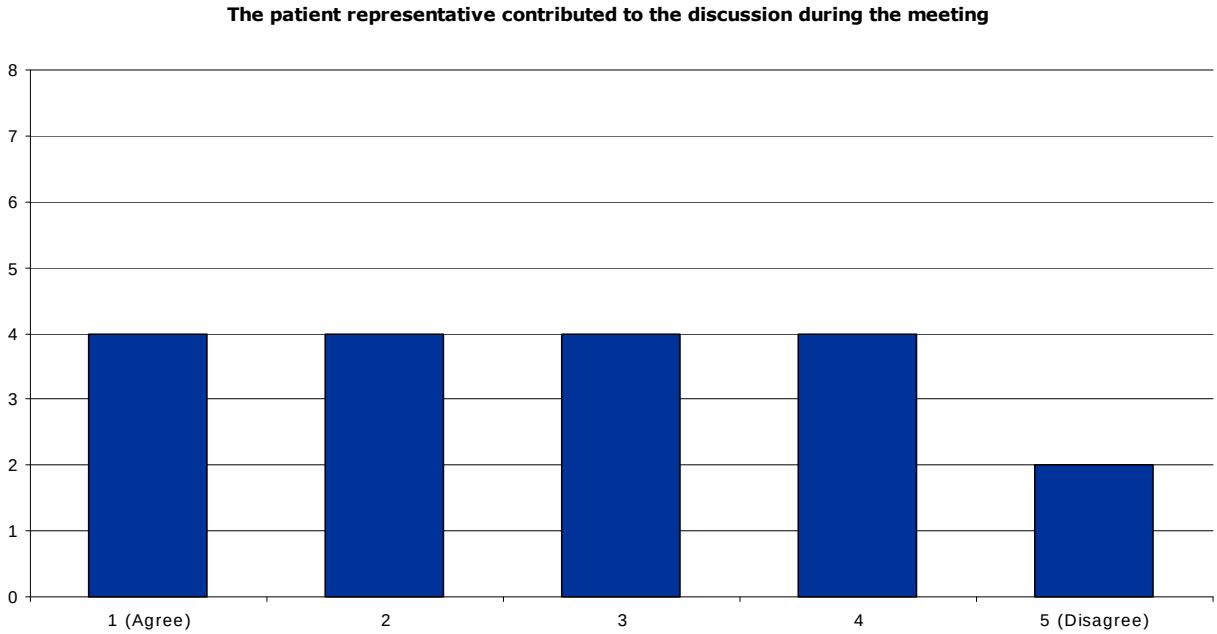
- During the period of the study 21 SAG meetings were held.
- A total of 22 patients participated in 18 of these meetings (for 3 SAGs no patients were available).
- Completed questionnaires were received from 18 patients and 19 Chairs / Rapporteurs.

Outcome results

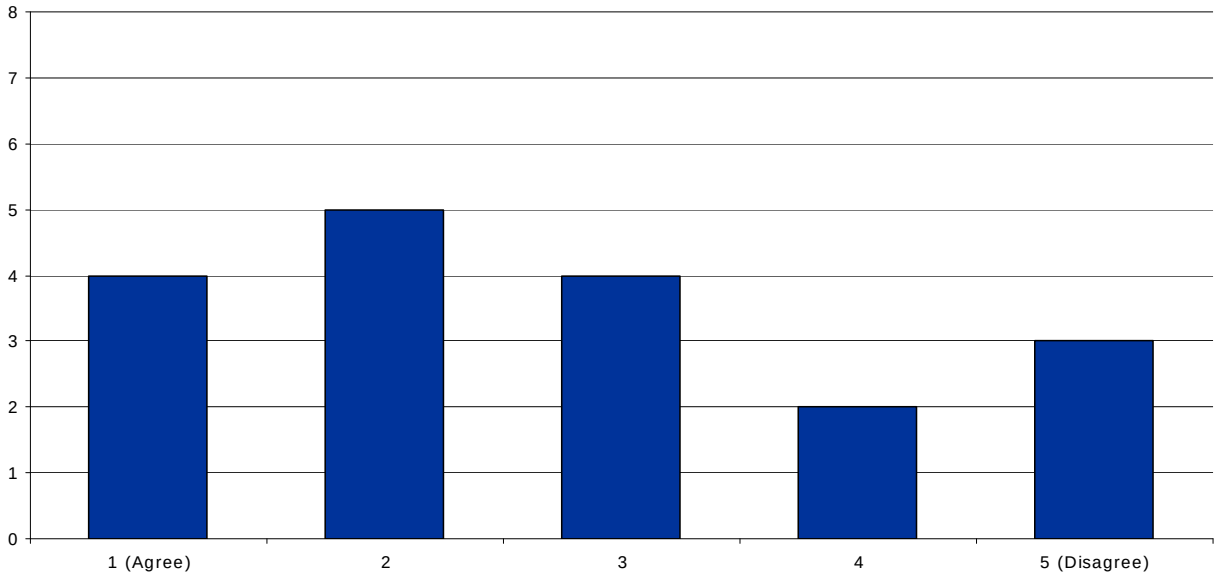
The overall results for each question are shown in the graphs below:

Responses to the questionnaire from Chairs/Rapporteurs:

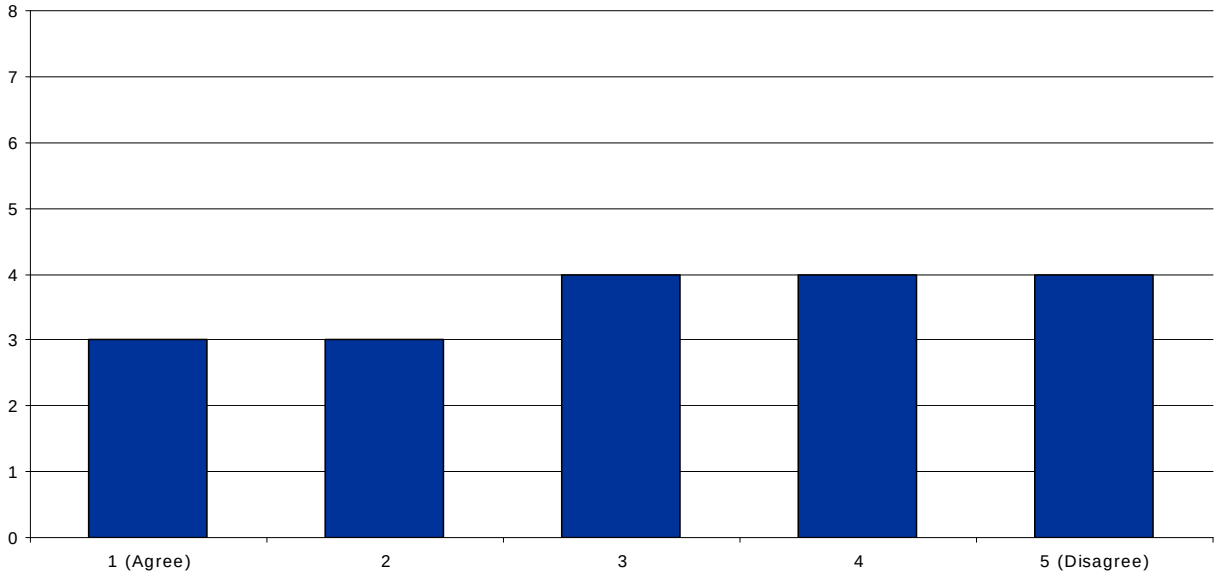


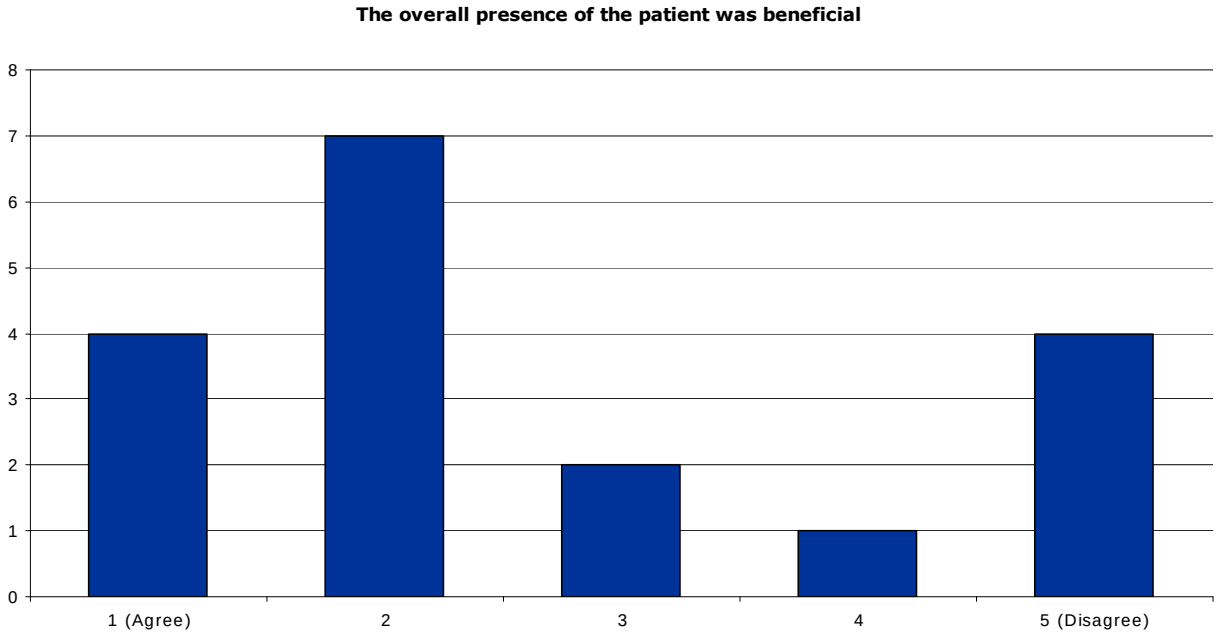


The patient representative contribution was valuable



The patient representative contribution had an impact on the outcome



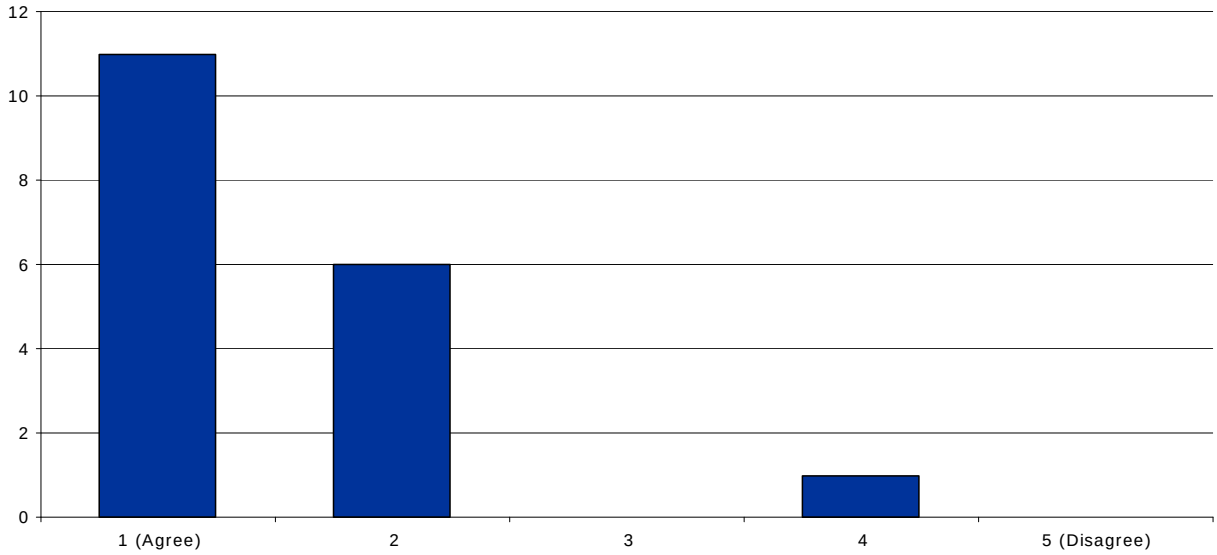


Open comments received from Chairs/Rapporteurs:

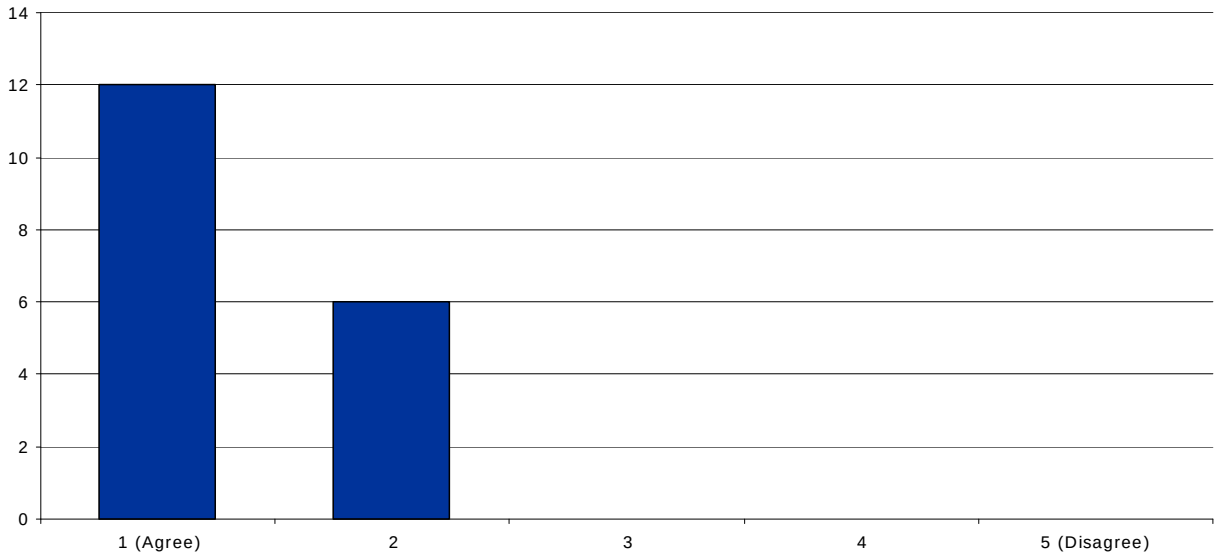
- The patients were very active in the discussions and gave a really interesting perspective that was very useful in forming an opinion on the product.
- As Chairman of the CNS-SAG for approx 5 years a number of patient representatives have helped during this time. My general feeling is that they contribute 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.
- 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.
- 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.

Responses to the questionnaire from patients:

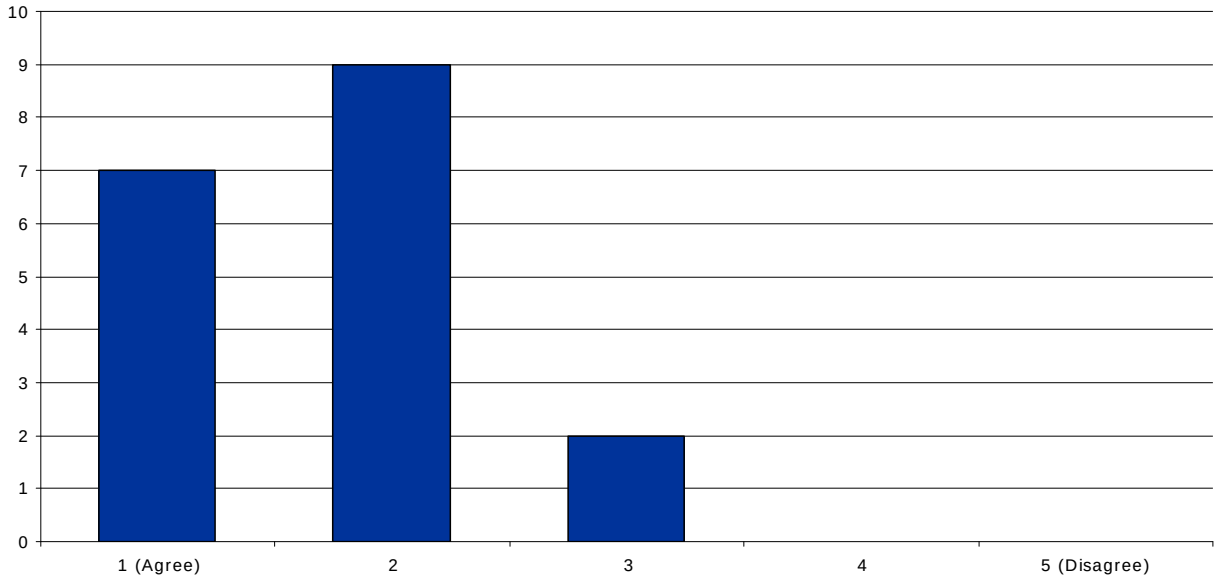
I received sufficient and understandable backgroun information on what a SAG is and how it fits in the Agency's work



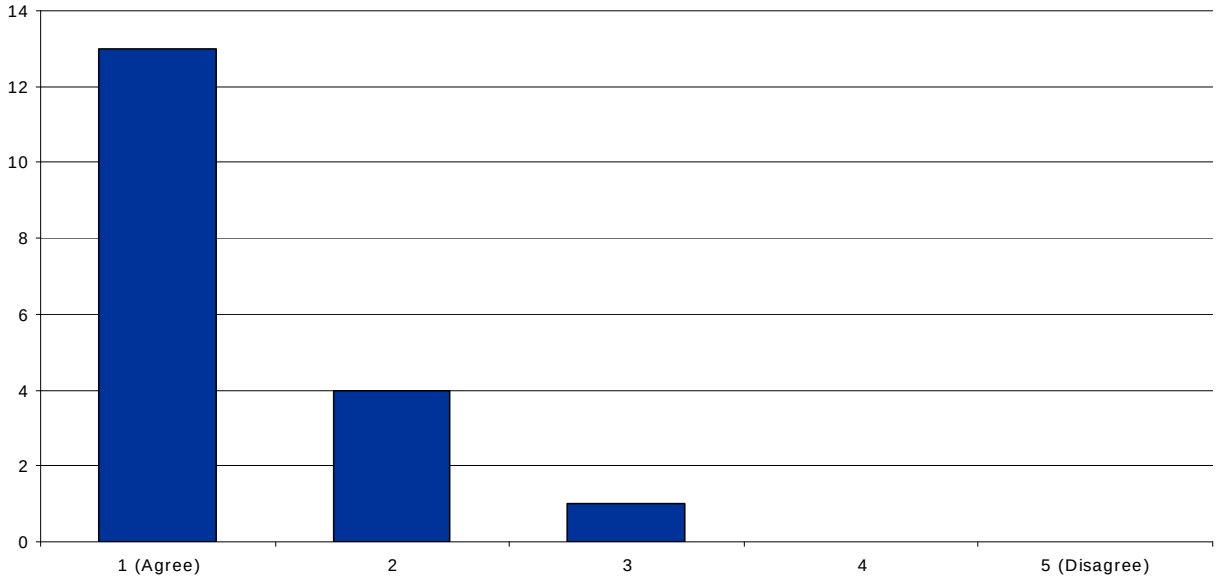
I received sufficient and understandable information on the issues(s) for discussion at the meeting



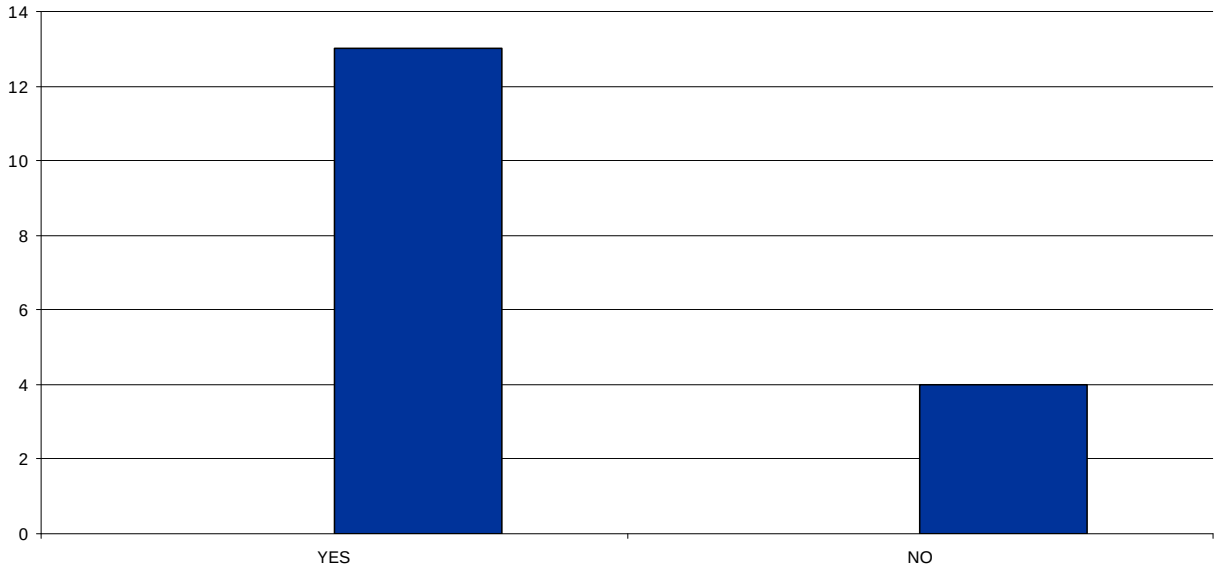
I knew what was exected of my participation at the meeting



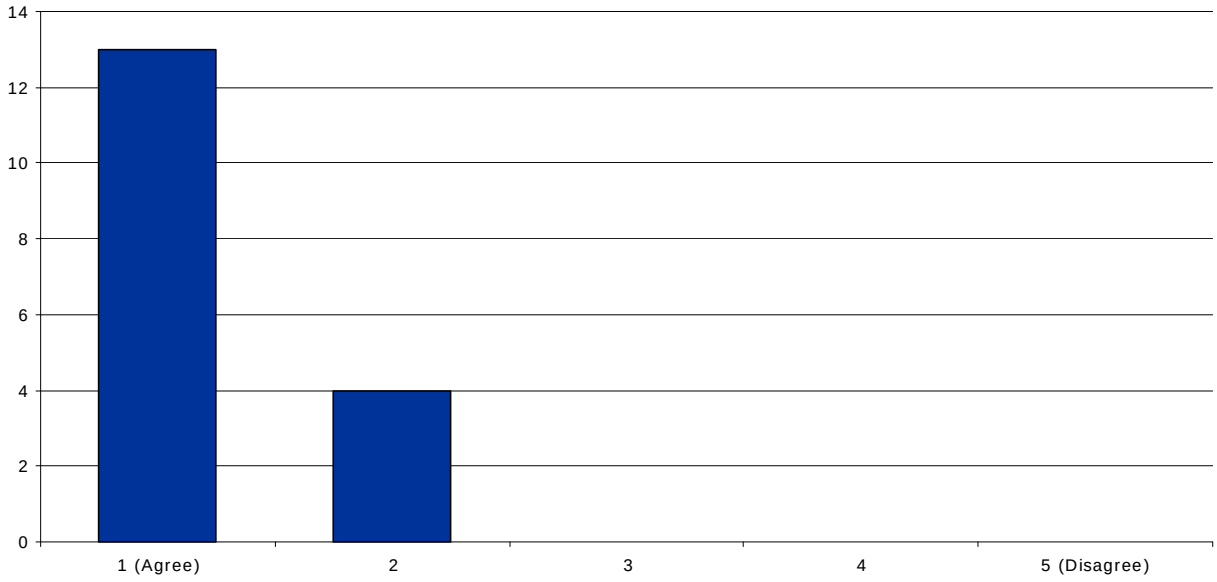
I was able to follow the discussion

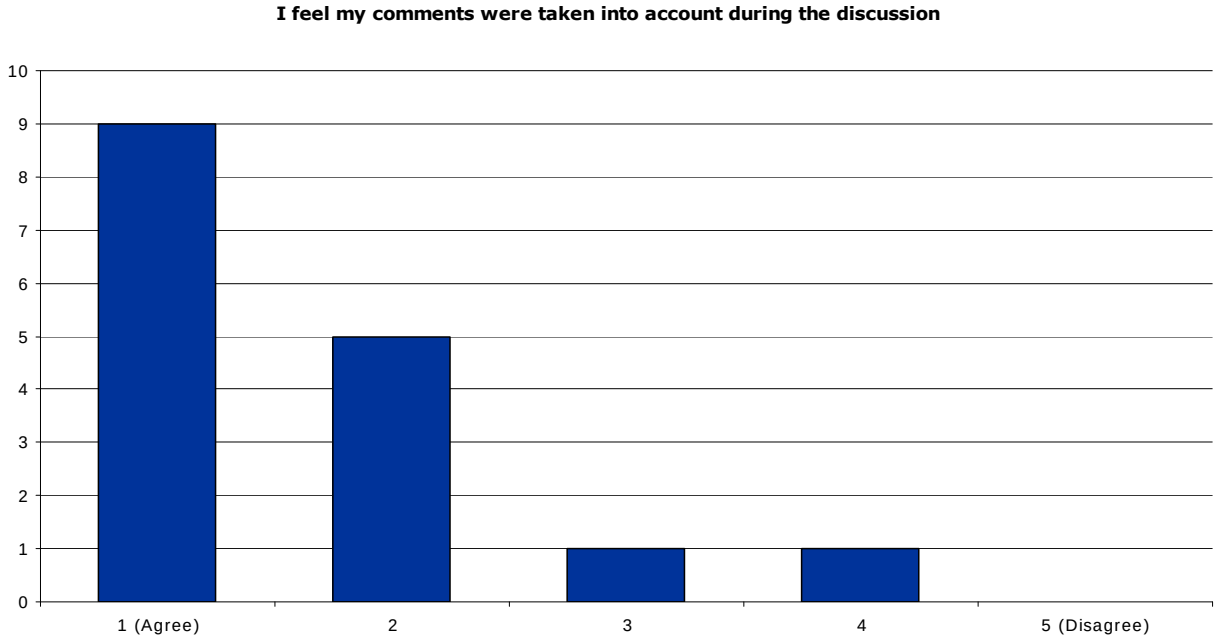


Was the patients' view specifically requested?



I was given adequate opportunities to provide input to the discussion





Open comments received from patients:

- 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.
- 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.

Summary of responses

Chairpersons and rapporteurs:

If we look at the responses received from the chairs/rapporteurs, it is evident that they are to some extent varied but it can be summarised as follows:

- The majority (61%) felt that the patient was able to follow the discussions, (4 disagreed),
- Feedback on whether the patient contributed to the discussion is varied, and it seems that on several occasions the patients did not actively participate in the discussions or voice any opinions,
- More responders felt that the patient representative contribution was valuable (9), however there were several responders who felt that it was not important (5),
- There were mixed perceptions as to whether the patient contribution had an impact on the outcome, with 8 responders 'disagreeing', 6 agreeing that there had been an impact and 4 were neutral,
- The final question "was the overall presence of the patent beneficial" was generally positive; 11 agreed (61%), 5 disagreed and 2 were more neutral.

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.

Patients:

Looking at the responses received from the patient participants it would seem that overall:

- The majority felt that their view had been specifically sought and that there had been adequate opportunities to participate in the discussions,
- There were a reasonably high number of patient representatives who felt that their comments had been taken into account during the meeting,
- Patients received adequate background information prior to the meetings, both in terms of the purpose of a SAG, as well as details of the particular issues under discussion,
- It was however felt that this information could be provided earlier, to allow for better preparation.

The overall impression is that the patient representatives found the meetings to be very informative and interesting and valued the opportunity to be able to participate and to be listened to.

Conclusion

It should be noted that we are evaluating feedback obtained on the performance of single experts. These results and their subsequent analyses need to be put into the context of the dynamic of a meeting like the SAG where not all individual experts attending any one meeting will contribute equally and have an impact on the meeting's outcome.

The following is concluded:

- The patient representative contribution to SAG meetings is, as would be expected with any expert, variable,
- This contribution depends on the type of questions addressed during the SAG (more on acceptability of risk, less in terms of efficacy) and on the selected patients who attend the meeting,
- Patients do not always verbally participate in the discussion; however, there is an intrinsic value to their presence; only by having a patient present can his/her views be requested if, and when needed. This provides the potential for useful contributions (which the pilot phase demonstrated does occur, although not every time).
- Identifying in advance specific questions to be answered by patients would be expected to improve the capacity for patients to contribute.
- The SAG Chairpersons generally fulfilled their role in welcoming the patients, asking for their input and where applicable, identifying and addressing specific questions for them. This seems to be a factor which facilitates their participation.
- The inclusion of a patient viewpoint adds robustness to the SAGs output and enriches the overall evaluation of the benefit and risk of the medicine.
- Involvement in SAG meetings is highly valued from the patients' perspective and is an activity which provides increased transparency into the assessment process.
- The pilot phase demonstrated that patient participation does not disrupt the SAG process and that meetings ran smoothly. Additionally no issues in relation to confidentially were identified at any point of time during the pilot phase.
- It may not always be suitable and/or beneficial to include a patient representative in every SAG meeting.

Way forward - proposal for endorsement

- Following the finalisation of the pilot phase, patients will continue to be invited to SAG meetings.
- Select the SAG meetings which, as per the outcome of the pilot phase, would more likely benefit from patient participation (i.e. exclude those where their attendance would not be useful; either due to the technical nature of the proposed discussions and/or where they do not specifically concern the benefit/risk of the product).
- Whenever possible, identify specific questions in advance to be answered by the patients.
- Provide extra training and support to facilitate patients' participation and performance.
- Ensure that a system is in place at the EMA in order to be able to select appropriate patients for participation.

- Continue to monitor patient participation and contribution to SAG meetings.

Implementation (Organisational matters)

It is proposed to maintain the current organisational arrangements concerning patient participation, as during the pilot phase:

- Patient representatives are principally contacted via the EMAs' existing network of European patients' organisations (and their members) who have been evaluated by the Agency and who fulfil the eligibility criteria (if there are none at EU level, a national one may be proposed).
- Selected patients should have direct knowledge of the disease and of the issues faced by patients (as patients, carers or through their organisation).
- Participation will consist preferably of 2 patients per meeting (maximum).
- Patient representatives should feel part of the meeting and able to contribute to the discussion at any point. The patients appreciate being welcomed, acknowledged and specifically asked if they have any comments; this encourages their involvement and their perspectives to be heard. It is recommended that Chairs continue to devote efforts to involve and facilitate patient participation in the discussions.
- The CHMP can take full advantage of patient participation and is encouraged to identify in advance any specific questions where patient input would be particularly valuable; however it is not expected as a routine.
- It is proposed to increase the support provided by the EMA by ensuring that the patient receives at least 2 weeks in advance of the meeting:
  - 'Patient friendly' background information on the issues for discussion,
  - An "information pack" on the Agency's work in general, including SAG meetings.
- Apart from written material, a conversation with an EMA member of staff will also continue to take place via telephone, to answer any queries prior to the meeting.
- Every patient representative will complete a DOI and confidentiality undertaking; these aspects will be carefully explained to them.
- The annual report on the interaction with patients and consumers, which is presented to the EMA Management Board and is published on the EMA website, will provide continued information on patient involvement in SAGs.

ANNEX 1

SAG Questionnaire (Patient participation) for SAG Chair / Rapporteur

1.

Product:_____ **Date:**_____

2.

1. The patient representative seemed adequately prepared and able to follow the discussion

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

2. The patient representative contributed to the discussion during the meeting

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

3. The patient representative contribution was valuable

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

4. The patient representative contribution had an impact on the outcome

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

5. The overall presence of the patient representative was beneficial

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

3.

Additional comments:

ANNEX 2

SAG Questionnaire for patient representative

1.

Product:_____ Date:_____

2. Pre-meeting

1. The meeting arrangements were well taken care of (e.g. travel, meeting room)

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

2. I received sufficient and understandable background information on what a SAG is and how it fits in the Agency's work

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

3. I received sufficient and understandable information on the issue(s) for discussion at the meeting

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

4. I knew what was expected of my participation at the meeting

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

3. During the meeting

1. I was able to follow the discussion

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

2. Was the patients' view specifically requested?

○ YES ○ NO

3. I was given adequate opportunities to provide input to the discussion

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

4. I feel my comments were taken into account during the discussion

	1 (Agree)	2	3	4	5 (Disagree)
Rating	○	○	○	○	○

4.

1. Additional comments: