

Observing submissions for reclassification at Medicine Classification Committee meetings

Survey Response Summary

The 49th meeting of the Medicines Classification Committee (MCC) is the fourth and last meeting that will pilot having observers during reclassification submissions. The pilot has also taken place at the 46th, 47th and 48th meetings.

At the 48th meeting it was agreed that the MCC will review the pilot at the 49th meeting using feedback from a survey of the companies involved.

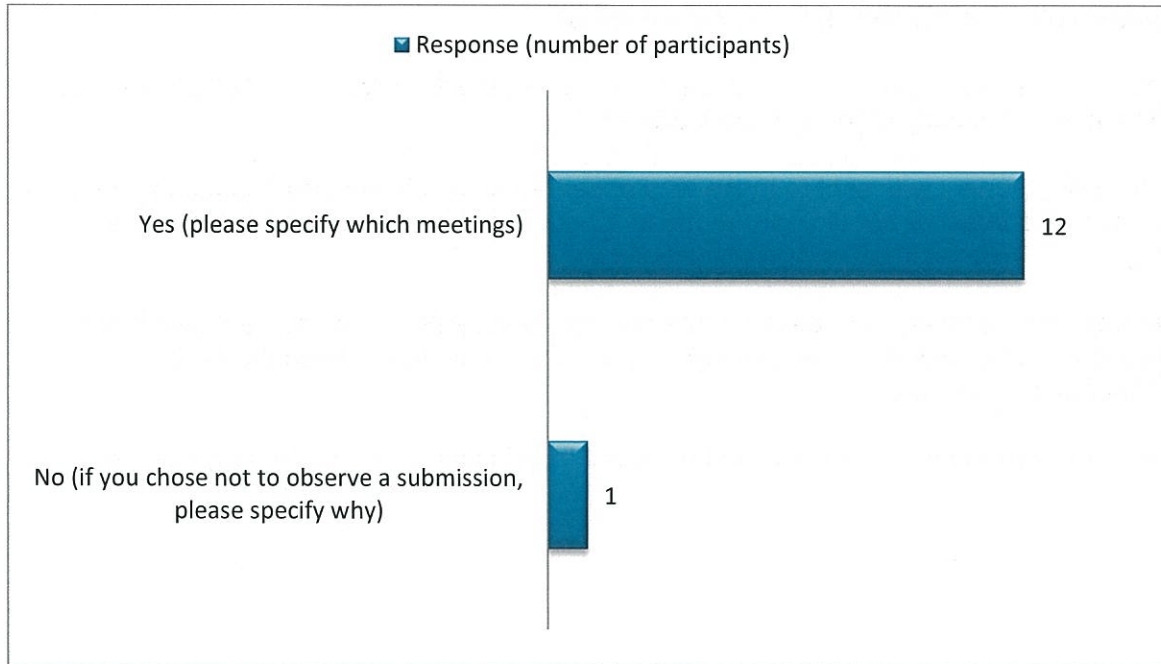
The following survey was sent to those who observed an MCC meeting and also those who were invited to observe but did not. A total of 13 out of 16 recipients responded to the survey.

Apart from the summary in question 1, the comments provided in the survey have been repeated verbatim. Some of the comments have been redacted to keep the survey participants anonymous.

These survey responses are published pursuant to Principle 10 of the Privacy Act 1993.

Question 1: Did you observe a submission(s) for reclassification at a Medicines Classification Committee meeting?

13 out of 13 survey participants answered the question (survey participants could respond to only one answer)



Yes (please specify which meetings):

In summary (of those who responded to this question) five survey participants attended one meeting, two survey participants attended two meetings and two survey participants attended three meetings.

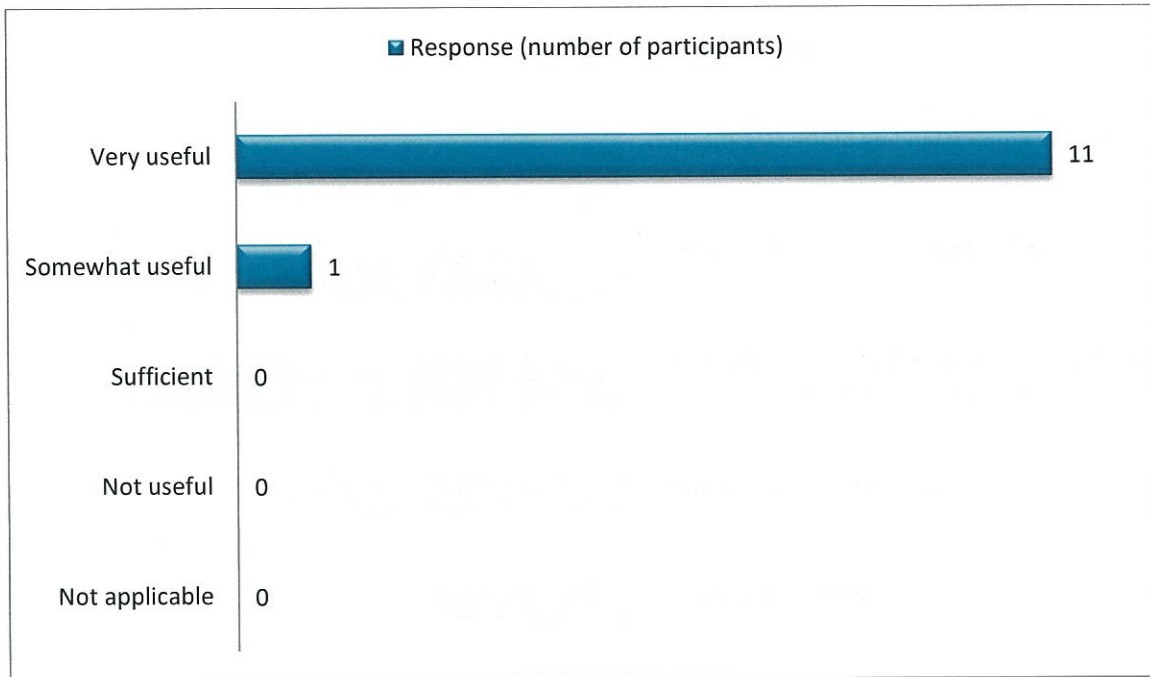
- This was very valuable as it enabled us to answer questions that the MCC had immediately.

No (if you chose not to observe a submission, please specify why):

- The company MD did not see the need.

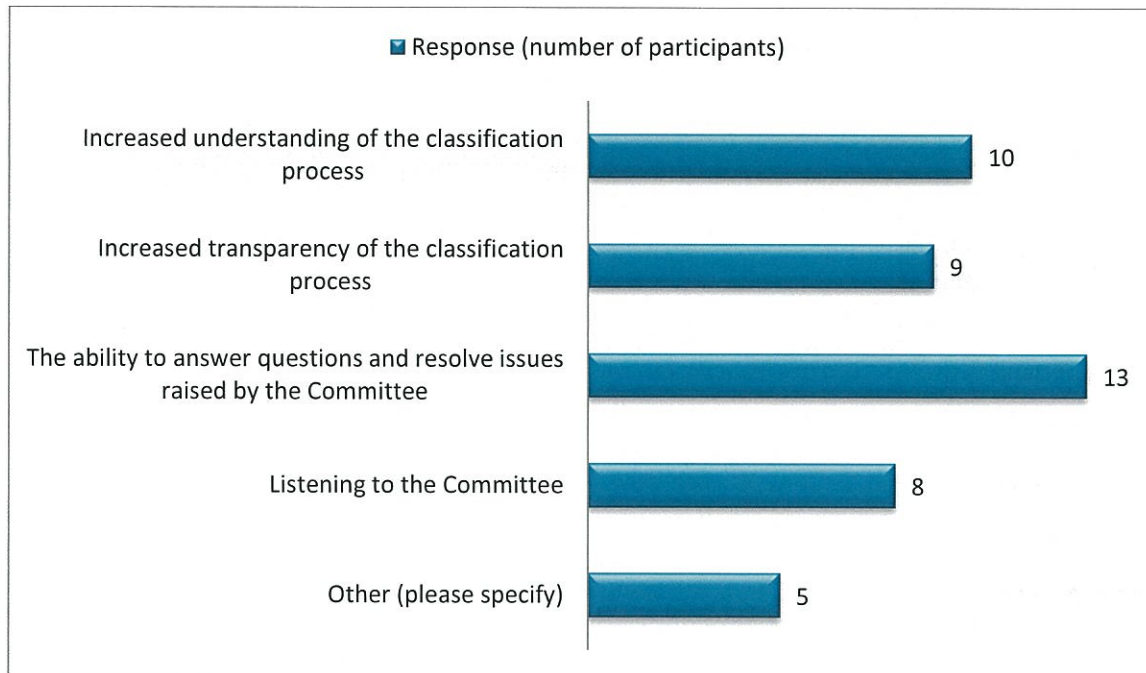
Question 2: If you participated as an observer, how useful did you find it?

12 out of 13 survey participants answered the question (survey participants could respond to only one answer)



Question 3: What do you think are the benefits of participating as an observer?

13 out of 13 survey participants answered the question (survey participants could respond to more than one answer)

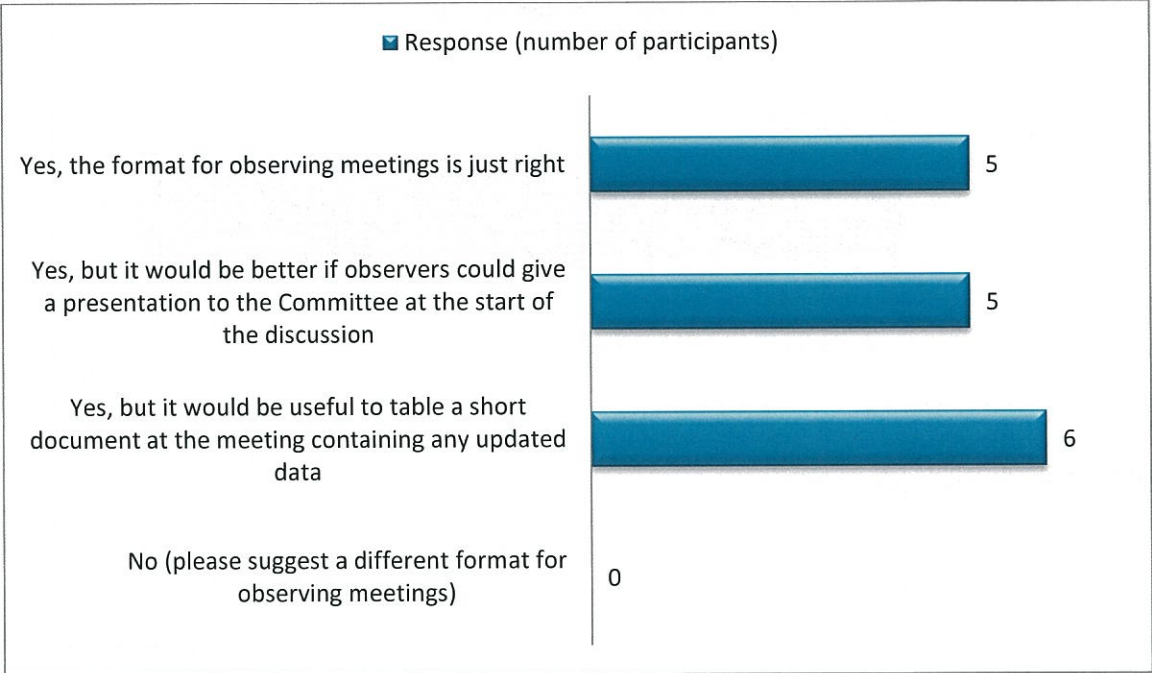


Other (please specify):

- Increased understanding of concerns raised and the rationale behind them.
- Understanding the level of expectation for submissions, which allows future submissions to be of a higher quality.
- Gain feedback on quality of submission and also further understanding of what the committee need to make a decision. That needs to be included within the submission.
- It was very interesting to gain an understanding of the different viewpoints of the committee and to have the ability to respond to misunderstandings or questions immediately to allow discussion to continue.
- Listening to the committee gives a deeper perspective than what minutes can. It is helpful to understand this and be there to try to correct some misperceptions.

Question 4: Do you think the current format for observing meetings has the right balance (ie, observing the discussion around a submission for reclassification with the opportunity to answer questions if asked by the Committee)?

12 out of 13 survey participants answered the question (survey participants could respond to more than one answer)

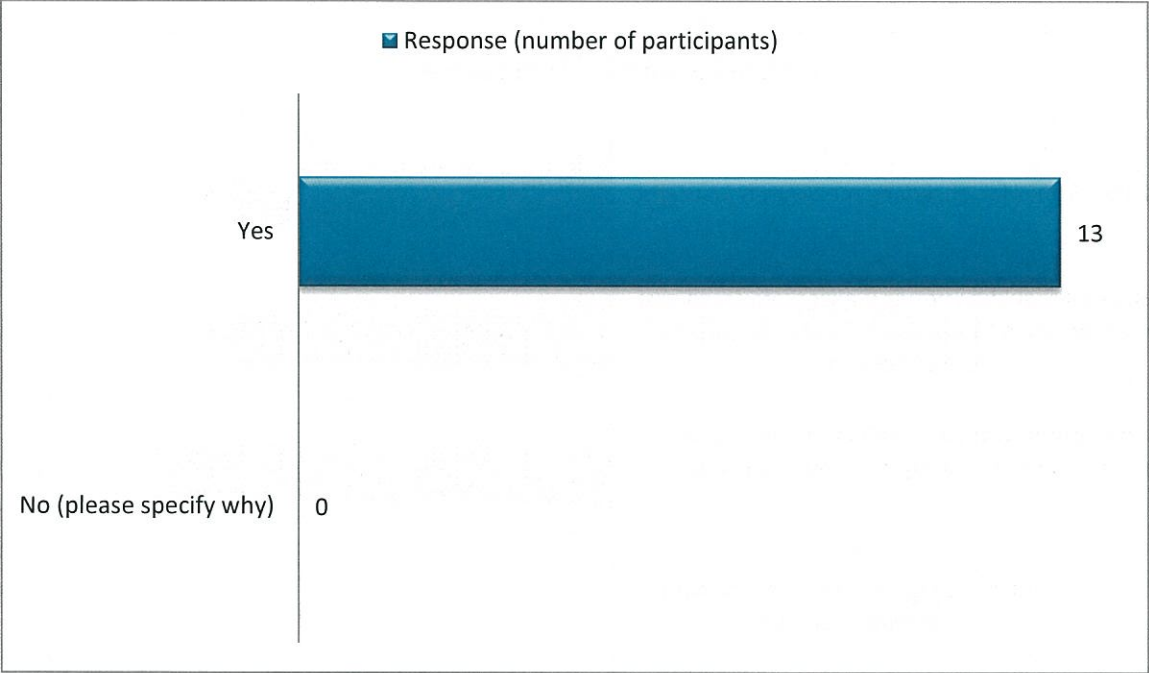


No (please suggest a different format for observing meetings):

- Only comment would be to provide observers with specific questions prior to the meeting if there are specific issues that need addressing.
- Presentations and data updates should be optional. It would be helpful if the questions and issues were addressed in a more structured way, possibly under subheadings e.g. proposed labelling, public health benefit. It would be good if all/more of the committee members provided comments or questions.
- No need for a presentation unless Committee would find useful.
- [REDACTED], while there would be benefit for applicants to be able to give a presentation, the committee should be completely familiar with the application already and it would slow the meeting down. When there are misperceptions by committee members but questions are not asked it is difficult to get the opportunity to address them in a timely fashion. It would be helpful to be able to fix them soon after they are stated so they are resolved (and not imprinted on everyone's minds as true). It would be helpful to know in advance that there is an opportunity to speak at the end to address outstanding issues. It also needs to be clear in the minutes (I think sometimes it is) whether the observers were present for the entire discussion or further discussion occurred after the observers left. It is reasonable to continue discussion after we have left.

Question 5: Do you think the opportunity to observe submissions for reclassification should continue at future meetings?

13 out of 13 survey participants answered the question (survey participants could respond to only one answer)

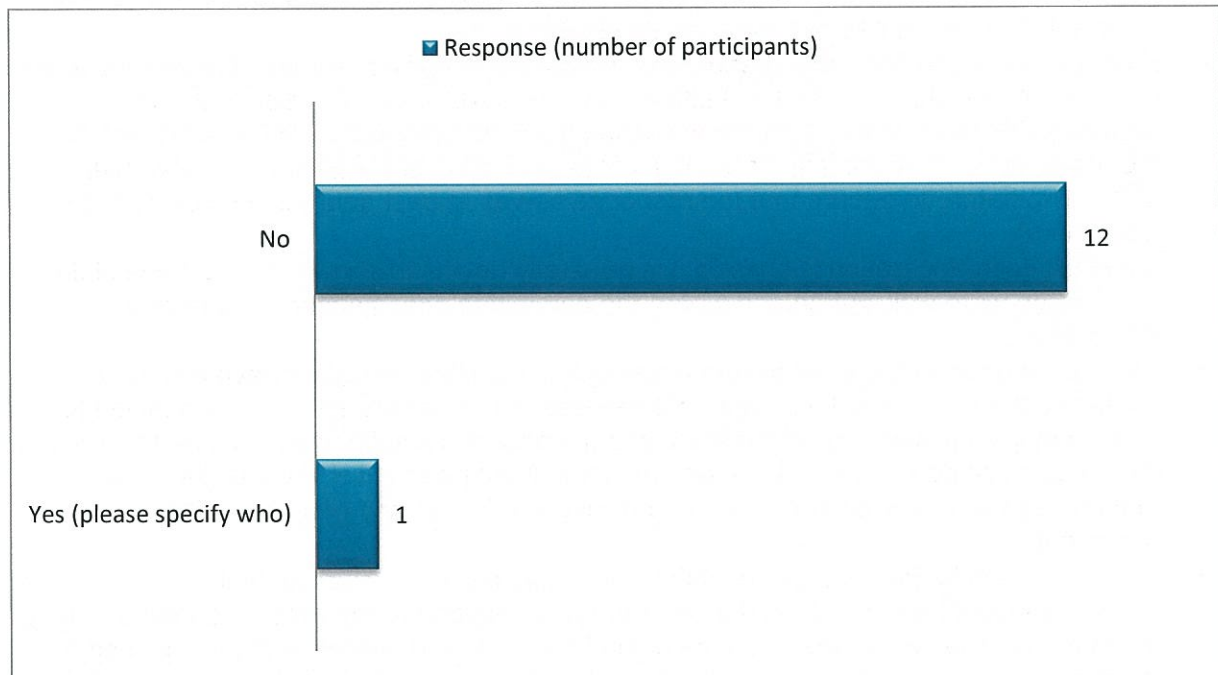


If no, please specify why:

- Definitely, huge value and benefit in attending the meetings.

Question 6: Apart from those who have made a submission for reclassification, do you think anyone else should be given the opportunity to observe submissions?

13 out of 13 survey participants answered the question (survey participants could respond to only one answer)



Yes (please specify who):

- Only caveat would be if the committee required clarification from a party that had made a submission through public comment (positive or negative).
- All stakeholders including patient groups etc.
- The number of observers who may want to be present may be large, and therefore act as a delay to discussions. I feel that the MCC panel is charged with canvassing interested parties as part of their research into the submission. The agenda is in the public domain and all interested parties have an opportunity to provide comment accordingly.
- Then it becomes a question of where do you draw the line with the number of observers.
- If this became a public meeting (as in the US) I think it would become more cumbersome, costly and difficult to manage, would take considerably longer, and potentially those with greater resource would end up having more influence because they could afford the time and expenditure of attending. I think there would be little benefit of this to committee due process given written submissions are welcomed and considered.

Question 7: Do you have any other feedback about observing submissions for reclassification (eg, specific improvements that could be made)?

8 out of 13 survey participants answered the question

- During the meeting, it would be very helpful if we were able to respond at the time that incorrect information had been presented or discussed.
- From personal (industry) experience the opportunity to discuss issues of relevance to the committee is invaluable. The Committee may well have discussion points which are weighted differently in the written submission from the perspective of the applicant. If there are issues that warrant further discussion could be useful to brief the observers a day or two before to ensure that the response serves to best address the committee's question(s).
- Although each application is specific it is generally helpful to know what sections of the submission were well written and where the committee expects more or different information.
- It would be good to know before the meeting if Committee members have any specific questions they wish to ask or clarify. Sometimes the observers are not in a position to make a quick decision e.g. would the company accept a smaller pack size restriction, but the question could be answered if we had some warning that it is likely to be asked.
- The process was very clear and an opportunity to address any concerns of the committee.
- That observers be present for the entire panel discussions, including final recommendation, and be given the opportunity to respond to the recommendation during the meeting. This would speed up the overall process, and decrease the likely need for resubmissions or objections. It would also allow the observers to understand what further information may need to be included in resubmissions.
- The one suggestion I have is around the ability for observers to attend the outcome of their submission and to comment on the result. With the ability to submit further data to respond to outstanding issues.
- Sometimes comments are not specific, for example, typically we are told that the training material is not up to standard - but without understanding what exactly is perceived to be wrong with it, it is very difficult to resolve the problem.

Question 8: Is there anything else we should know about observing submissions for reclassification at Medicines Classification Committee meetings?

6 out of 13 survey participants answered the question

- We appreciate that the Committee has put a lot of time into reviewing the submission. It would be greatly appreciated if we had the ability to ask for more guidance during the meeting when something is not clear.
- Discussion was succinct and the whole approach was pragmatic. It came across as a mechanism to ensure committee had all the available information to make a decision. Environment certainly did not come across as adversarial when asking questions of the observers.
- No.
- I strongly support that submitters be continued to allow observers at MCC meetings, as I believe the entire process benefits from this transparency. I believe that the clauses around confidentiality of discussions be upheld.
- I would strongly support the ongoing opportunity to attend these meetings as an observer as it has given tremendous insight to the process and the ability to provide the critical and relevant information needed for the committee to reach a final outcome. The Chatham house rules clause should still remain in place prior to the release of any communication into the public domain.
- Overall I think this is a great initiative and congratulate the MCC on thinking differently. I really appreciated the positive environment in the [REDACTED] discussion - we had a discussion about how it could happen where I felt we were all somewhat working together on how to get the best outcome for the consumer. Somehow none of the other discussions have felt as positive, but I'm not sure if that is always going to be possible. [REDACTED]
[REDACTED]. There may be benefit in having a speaker phone in the room and allowing clarification with an outside expert - for example, [REDACTED].

