



PMCPA Guidance on Advisory Boards

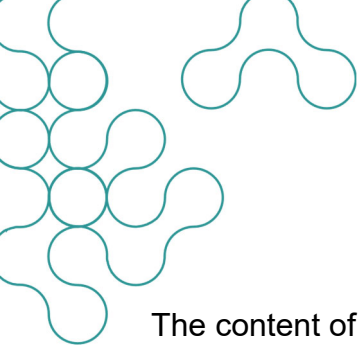
The PMCPA cannot approve any materials or activities, it can only give informal advice based on its interpretation of the ABPI Code. In the event of a complaint being received about a matter upon which advice was sought, it would be considered in the usual way; the ABPI Code of Practice Appeal Board would make the final decision if a case went to appeal. It is important to note that each case is considered upon its own merits and based upon the allegations raised by the complainant.

The arrangements for advisory board meetings are often the subject of enquiries to the PMCPA for informal advice and there have been complaints about them. It is acceptable for companies to arrange advisory board meetings and to contract health professionals and others for advice on subjects relevant to their products and therapy areas of interest. Advisory boards should only be held to enable companies to answer legitimate business questions to which they do not know or have the expertise in-house to answer. The arrangements for such meetings must comply with the ABPI Code.

Health professionals, other relevant decision makers or their employers on their behalf, healthcare organisations, patient organisations, individuals representing patient organisations, and members of the public, including patients and journalists, may be used as consultants and advisors, whether in groups or individually, as set out in **Clause 24.1**.

Advisory board meetings need to meet the requirements for meetings as set out in **Clause 10** of the ABPI Code including the requirements that the meeting is held in an appropriate venue conducive to the business purpose of the meeting and that hospitality is secondary to that purpose and not out of proportion to that occasion.

To be considered a legitimate advisory board the choice and number of advisors should stand up to independent scrutiny; each should be chosen according to their expertise such that they will be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of advisors should be limited to allow active participation by all and should not be driven by the invitees' willingness to attend nor by the number of desired company attendees. The agenda should allow adequate time for discussion; any presentation(s) should be limited to what is necessary to provide a basis for discussion. The number of meetings and the number of participants at each should be dictated by need i.e., both should be strictly limited to no more than the number required to achieve the stated objective. Multiple advisory boards on the same topic should be avoided unless a clear need can be demonstrated. Companies should determine if and when advisory board meetings are required; advisory boards should never be held in response to participants' willingness to discuss issues or to meet internal targets. Invitations to participate in an advisory board meeting should state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken.



The content of advisory board meetings should relate solely to the matter in hand. Discussion of clinical data about a particular medicine should only take place at an advisory board if such discussion is essential to meet the stated objective. To do otherwise might risk the meeting being viewed as disguised promotion for that medicine or promotion of an unlicensed medicine or indication.

If an honorarium is offered it should be made clear that it is a payment for such work and advice. Honoraria must be commensurate with the time and effort involved and the expertise of the advisors. The payment of advisory board members must be declared in accordance with **Clauses 28 to 31**.

The number of company attendees (including agency staff) should normally be well below the number of advisors; much would depend on the number of advisors required. Each company attendee (including agency staff) at an advisory board meeting should have a clear and documented need to be there.

PRACTICAL GUIDANCE – POINTS TO CONSIDER

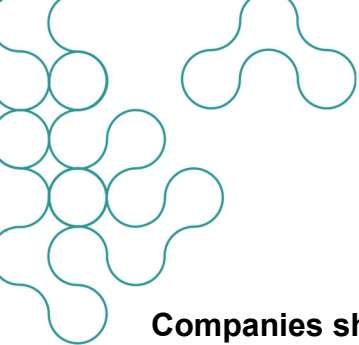
The PMCPA has developed the following points to consider which are to help companies and others ensure that advisory boards meet the requirements of the ABPI Code and that the relevant information is available when assessing proposals. The points to consider reflect what information might be required in the event that a company has to respond to a complaint under the ABPI Code.

The answers to the following questions should be ‘yes’:

- Does the company have a legitimate unanswered business question?
- Is an advisory board the most appropriate way of obtaining the information?
- Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?
- Is the number of participants limited to allow active participation by all?
- Does the agenda allow adequate time for discussion?
- Is a significant majority of the time spent on feedback from the participants?
- Has the company wholly and solely determined its need for the advisory board, with no input from expected attendees?
- Is the number of delegates/meetings strictly limited to that required to answer the question?
- Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?
- Are the participants being paid no more than ‘fair market value’?
- Are intended presentations to participants relevant to their role in answering the business question?

If the answers to any of the following questions is ‘no’ then there may be a compliance issue to be addressed:

- Is this the only advisory board to address the business question at issue?
- Are the participants expected to do any preparatory work?
- Are all those involved with the meeting (staff, third parties, participants) clear on the need for and expected output from the meeting?



Companies should ensure that the following questions are considered:

- Are the arrangements (e.g., venue, subsistence, travel, contract/written agreement) appropriate?
- How were the participants selected?
- Who from, or on behalf of, the company is attending and why?
- Do all company attendees (including those attending on behalf of the company) have a defined role and is the ratio of company employees/others to participants reasonable?
- Will there be a conclusions/recommendations report?
- What use will be made of conclusions/recommendations report?
- Have any advisory boards for the same medicine/therapy area already taken place/been planned within e.g., a 12 month period? If so, what is the justification for another one?
- What follow-up, if any, is to be undertaken with participants? If so, is this appropriate given the non-promotional nature of advisory boards?
- Is this advisory board held in conjunction with any other meeting such as a learned society congress?

Last updated June 2023