PMCPA | Prescription Medicines Code of Practice Authority

ADVICE ON ADVISORY BOARDS

The arrangements for advisory board meetings are often the subject of enquiries to the PMCPA for informal advice. They are also discussed with companies when audits are carried out by the Authority. In the light of this the Authority thought it would be helpful to update its guidance on advisory boards.

It is acceptable for companies to arrange advisory board meetings and the like and to pay health professionals and others for advice on subjects relevant to their products. Advisory boards should only be held to enable companies to answer legitimate business questions to which they do not already know the answer. The arrangements for such meetings have to comply with the Code.

Advisory board meetings need to meet the requirements for meetings as set out in Clause 22 of the 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 of an appropriate standard.

To be considered a legitimate advisory board the choice and number of participants 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 participants should be limited so as to allow active participation by all and should not be driven by the invitees' willingness to attend. The agenda should allow adequate time for discussion. The number of meetings and the number of participants at each should be dictated by need ie 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. 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 professional status of the recipients. The payment of advisory board members must be declared in accordance with Clauses 23 and 24.

In November 2015 the President of the ABPI and the Director of the PMCPA highlighted the need to ensure that advisory board meetings comply with the requirements of the Code.

25 November 2015 Circular - Advice on Advisory Boards.pdf

PRACTICAL GUIDANCE – POINTS TO CONSIDER

The PMCPA has developed the following points to consider to add to the already available guidance about advisory boards. These points are to help companies and others ensure that advisory boards meet the requirements of the 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 Code.

The answers to the following questions should be 'yes':

1 Does the company have a legitimate unanswered business question?

2 Is an advisory board the most appropriate way of obtaining the information?

3 Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?

4 Is the number of participants limited so as to allow active participation by all?

5 Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the participants?

6 Has the company wholly and solely determined its need for the advisory board, with no input from expected attendees?

7 Is the number of delegates/meetings strictly limited to that required to answer the question?

8 Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?

9 Are the participants being paid no more than 'fair market value'?

10 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:

11 Is this the only advisory board to address the business question at issue?

12 Are the participants expected to do any preparatory work?

13 If the product/indication is unlicensed, has the PMCPA Clause 3 Guidance been taken into account?

14 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:

15 Are the arrangements (eg venue, subsistence, travel, contract) appropriate?

16 How were the participants selected?

17 Who from, or on behalf of, the company is attending? Do they have a defined role and is the ratio of company employees/others to participants reasonable?

18 Will there be a conclusions/recommendations report? What use will be made of it?

19 Have any advisory boards for the same medicine/therapy area already taken place/been planned within eg a 12 month period? If so, what is the justification for another one?

20 What follow-up, if any, is to be undertaken with participants? If so, is this appropriate given the non promotional nature of advisory boards?

21 Is this advisory board held in conjunction with any other meeting such as a learned society congress?

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