

Introduction

The purpose of this document is to give guidance about declarations of interest, in particular for members of the Code of Practice Appeal Board. It is vital for effective self-regulation that conflicts of interest are appropriately managed to maintain fairness and confidence.

Requirements in the Constitution and Procedure

The requirements for members of the Appeal Board are given in Paragraph 4.8 of the Prescription Medicines Code of Practice Authority's (PMCPA) 2024 Constitution and Procedure which includes:

'If a member of the Appeal Board is involved in a case either as complainant or respondent, that member will not receive copies of the papers circulated in connection with the case or be present while the Appeal Board considers the case.

The complainant and the respondent will be told the membership of the Appeal Board, including potential co-optees, before the Appeal Board meeting, and asked if they have any objections to particular members and the grounds for such objections. The Chair will determine whether objections are valid.

Any member in respect of whom there are valid objections must withdraw from the Appeal Board while it considers the case.

Members of the Appeal Board must declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chair will determine whether it is appropriate for a particular member to remain for the consideration of the case.'

The fact that a member of the Appeal Board works for a company that has a competitor product to one the subject of a complaint is not necessarily sufficient to require that member to withdraw from the consideration of that case.

Brief details of all interests declared are recorded in the minutes of the Appeal Board meeting.

Requirements in the Constitution and Procedure for the ABPI Board

Paragraph 14.3 of the Constitution and Procedure has similar requirements for members of the ABPI Board with the President having a similar role to the Chair of the Appeal Board.

What is meant by declaring 'other interests'?

The Appeal Board includes independent members and members from pharmaceutical companies which can give rise to very different conflicts of interests.

Potential conflicts fall into four categories: personal interests, non-personal interests,

company interests and miscellaneous.

Personal interests

Personal interests involve a payment to a member personally. For example:

- consultancy payment within last 12 months;
- fee paid work within last 12 months;
- any meaningful shareholding in a company.

Non-personal interests

Non personal interests involve payment to an organisation or department for which the member is responsible or has some link with but which is not received by the member personally. For example, support from a pharmaceutical company within the last 12 months by means of:

- a grant, including a charitable grant
- sponsorship of a post
- commission for research work
- commission for advice
- current applications for support.

Company interests

Company interests involve the activities of the member's current or previous employer. For example:

- competitor licensed products or products for which a licence application in the UK has been submitted and is in the public domain
- relevant UK co-marketing or co-promotion agreements
- the company has made a similar complaint to the respondent
- the member may have specialist knowledge of the product beyond that in the public domain
- the member has been commercially involved with the product within the last 12 months
- if a member had previously worked for a company involved in an appeal.

Miscellaneous interests

Miscellaneous interests do not fit into any of the above three categories. For example:

- the member knows the complainant (if not a pharmaceutical company)
- the member was present when the activity in question took place.

Process for declaring interests

Parties appearing before the Appeal Board are provided before the meeting with a list of members (including potential co-optees) and, in the case of industry members, the pharmaceutical companies for which they currently work.

Members are only required to give details of the nature of their interests if they wish the Chair to consider whether they can take part in the consideration of the matter. Members who do not wish to give details of the nature of the interests cannot remain for the consideration of the matter in question.

If a member had previously worked for a company involved in an appeal or a report, then that member should not participate in the consideration of the appeal for at least three years from the date that the member finished working for the company. Depending on the nature of the case, a longer time period may be required.

The Chair will consider each declaration and ask that member if the interest prevents them from bringing an independent mind to the matter and judging the case on the evidence presented. Even if the member is confident that the interest is not one that precludes participation, the Chair still has the right to ask that member to leave if they consider the nature of the interest is such that a fair-minded and reasonable observer in possession of the facts would consider it inappropriate for that member to remain.

If the Chair decides that a member with an interest can remain the parties appearing before the Appeal Board will be advised and asked for comment. If there are such comments the Chair has the final decision.

Members should identify potential conflicts of interest in relation to appeals, audits and reported cases when preparing for meetings and should contact the Operations and Governance Manager (pclift@pmcpa.org.uk) for advice. That means that, if necessary, alternative arrangements can be made to ensure that the Appeal Board remains quorate despite their absence.

Members are advised that if there is any doubt about an interest then it should be declared. It may be that a member becomes aware of a conflict of interest only during the appeal process or the hearing of a report. In such circumstances, the member should immediately inform the Chair who will determine next steps.

February 2025