

**AMENDMENTS**  
**TO THE**  
**CONSTITUTION AND PROCEDURE**  
**FOR THE**  
**PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY**  
**2006 EDITION**

**INTRODUCTION**

***Amendment***

Additional text is added:

'The Authority is not an investigatory body as such. It asks the respondent company for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company. A complainant has the burden of proving their complaint on the balance of probabilities. Anonymous complaints are accepted and like all complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.'

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**PARAGRAPH 1**

**Paragraph 1.4 Prescription Medicines Code of Practice Authority**

***Current text***

'The Director has the authority to request copies of any relevant material from a pharmaceutical company, including copies of the certificates authorizing any such material and copies of relevant briefing material for representatives.'

***Amendment***

Changed to:

'To facilitate the complaints procedure by ensuring that the requisite information is available, the Director has the authority to request ...'

\* \* \* \* \*

**PARAGRAPH 2**

**Paragraph 2.2 Code of Practice Panel – Constitution and Procedure**

***Current text***

‘Two members of the Authority form a quorum for a meeting of the Panel. Decisions are made by majority voting. The Director or, in his absence, the Secretary, acts as Chairman of the Panel and has both an original and a casting vote.’

***Amendment***

A further paragraph is added:

‘Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.’

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**PARAGRAPH 3**

**Paragraph 3.1 Code of Practice Appeal Board – Constitution**

***Current text***

‘The Code of Practice Appeal Board and its Chairman are appointed by the Board of Management of the ABPI. The appointment of independent members to the Appeal Board is made following consultation with the Medicines and Healthcare products Regulatory Agency.’

Vacancies for independent members other than the Chairman are advertised in appropriate journals and/or the national press.’

***Amendment***

Changed to:

‘Vacancies for independent members of the Code of Practice Appeal Board, including the Chairman, are advertised in appropriate journals and/or the national press.’

The Appeal Board and its Chairman are appointed by the Board of Management of the ABPI. The appointment of independent members to the Appeal Board, including the Chairman, is made following consultation with the Medicines and Healthcare products Regulatory Agency.’

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**Paragraph 3.2 Code of Practice Appeal Board - Constitution**

**Current text**

Paragraph 3.2 states, *inter alia*:

'The Appeal Board comprises

- three independent registered medical practitioners appointed following consultation with the British Medical Association, one with recent experience as a general practitioner and one with recent experience as a hospital consultant
- one independent member who is not a health professional'

**Amendment**

'... as a hospital consultant' is changed to '... as a hospital consultant treating patients'

'one independent member who is not a health professional' is changed to 'one independent lay member'

\* \* \* \* \*

**PARAGRAPH 4**

**Paragraph 4.3 Code of Practice Appeal Board – Procedure**

**Current text**

'Decisions are made by majority voting. The Chairman has both an original and a casting vote.'

**Amendment**

A further paragraph is added:

'Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.'

\* \* \* \* \*

**Paragraph 4.4 Code of Practice Appeal Board – Procedure**

**Current text**

'If a member of the Appeal Board is concerned in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the Appeal Board during its consideration.'

Members of the Appeal Board are also required to declare any other interest in a case prior to its consideration. The Chairman determines whether it is appropriate for that member to remain for the consideration of the case.'

***Amendment***

The second paragraph is deleted and replaced with:

'The complainant and respondent are advised in advance of the membership of the Appeal Board and asked if they have any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Appeal Board during consideration of the case. The Chairman determines whether objections are valid.

Members of the Appeal Board are also required to declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chairman determines whether it is appropriate for a particular member to remain for the consideration of the case.'

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**PARAGRAPH 5**

**Paragraph 5.1 Action on Complaints**

***Current text***

The first paragraph states:

'When the Director receives information from which it appears that a company (being either a member of the ABPI or a company which, although not a member, has agreed to comply with the Code and accept the jurisdiction of the Authority) may have contravened the Code, the managing director or chief executive or equivalent of the company concerned is requested to comment on the matters of complaint.'

***Amendment***

Changed to:

'... the managing director or chief executive or equivalent of the company concerned is requested to provide a complete response to the matters of complaint.'

An additional paragraph is added:

'To assist companies in ensuring that a complete response is submitted the Director may suggest relevant supporting material to be supplied. It is the responsibility of the respondent to ensure that a full response is submitted. If the complainant is not a pharmaceutical company the Director may suggest the clauses of the Code to be addressed.'

\* \* \* \* \*

**Paragraph 5.1 Action on Complaints*****Current text***

Paragraph 5.1 states, *inter alia*:

'If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Code of Practice Panel which was not the subject of appeal to the Code of Practice Appeal Board.'

***Amendment***

The second sentence is amended to read:

'The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Code of Practice Panel where no breach of the Code was ruled and which was not the subject of appeal to the Code of Practice Appeal Board.'

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**Paragraph 5.1 Action on Complaints*****Amendment***

Additional text added (to be the fifth and sixth paragraphs):

'Unless the information is disclosed in the complaint, a complainant other than a pharmaceutical company is asked whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned, such as whether the complainant is an employee or ex-employee.

Such interests will be disclosed to the respondent company and will normally be included in the case report.'

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**Paragraph 5.2 Action on Complaints**

**Current text**

Paragraph 5.2 states, *inter alia*:

'A complaint from a pharmaceutical company will be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful. A formal statement detailing the actions taken must be provided.'

**Amendment**

An additional paragraph is added:

'If, in the view of the Director, that condition has not been met, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to the Chairman of the Appeal Board for his decision which is final.'

\* \* \* \* \*

**Paragraph 5 Action on Complaints**

**Amendment**

An additional paragraph is added (to be Paragraph 5.5):

'When the respondent company's response is received, the case is referred to the Code of Practice Panel to determine whether or not there has been a breach of the Code.'

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**PARAGRAPH 6**

**Paragraph 6 Establishment of *Prima Facie* Case and Consideration by the Code of Practice Panel**

**Amendment**

Paragraph 6 is deleted in entirety.

References to Paragraph 6 are deleted from Paragraphs 8.1 and 11.4.

The words '*prima facie*' are deleted from Paragraphs 18.4 and 18.5 [now to be Paragraphs 17.4 and 17.5] and replaced by the word 'possible' in Paragraph 18.2 [now to be Paragraph 17.2].

Changes are made to Paragraph 5.4 to remove references to '*prima facie*' and to refer to procedures under Paragraph 5.5 (new).

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## **NEW PARAGRAPH 6**

### ***Amendment***

A new paragraph is added (to be Paragraph 6):

Titled '**Complaints arising from media criticism**'

**6.1** When it appears to the Director from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter is treated as a complaint.

The author of the article, or the editor where no author is named, is treated as the complainant.

The author, or editor, is asked if they want to be involved in the case and whether they have any additional information to submit. The consequences of not being involved (no right of appeal and no right to comment on a respondent's appeal or the proposed text of the case report) must be explained in writing. If the author or editor declines involvement, this is stated in the case report.

**6.2** A published letter from which it appears that a company may have breached the Code is dealt with as a complaint with the author being treated as the complainant. The procedure set out in Paragraph 6.1 above shall be followed.'

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## **PARAGRAPH 7**

### **Paragraph 7.4 Code of Practice Panel - Rulings**

#### ***Current text***

Paragraph 7.4 deals with an appeal by the complainant against a ruling of the Code of Practice Panel.

#### ***Amendment***

An additional paragraph is added:

'Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal

Board to consider must be submitted in writing with the appeal, with the respondent company's comments on the reasons given by the complainant for the appeal or with the complainant's comments on the respondent company's comments on the reasons given by the complainant for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.'

\* \* \* \* \*

### **Paragraph 7.5 Code of Practice Panel - Rulings**

#### ***Current text***

Paragraph 7.5 deals with an appeal by the respondent company against a ruling of the Code of Practice Panel.

#### ***Amendment***

An additional paragraph is added:

'Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal or with the complainant's comments on the reasons given by the respondent company for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.'

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### **Paragraph 7 Code of Practice Panel: Rulings**

#### ***Amendment***

A new paragraph is added (to be Paragraph 7.6):

'Where the Panel rules no breach of the Code because it considers the matter of complaint is not within the scope of the Code the complainant and the respondent company are so advised in writing.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Code of Practice Appeal Board for his decision which is final.

The complainant may appeal against the ruling to the Code of Practice Appeal Board. An appeal must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be circulated to the Appeal Board. The appeal must be lodged within ten working days of notification of the ruling of the Panel.

The respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeal Board.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Code of Practice Appeal Board who will decide whether those particular comments can be included in the evidence which goes before the Appeal Board. The Chairman's decision is final.

In such an appeal, the Appeal Board must consider no more than whether or not the matter of complaint is within the scope of the Code.

If the Appeal Board considers that the matter is not within the scope of the Code the complainant and the respondent company are so advised in writing.

If the Appeal Board considers that the matter is within the scope of the Code the complainant and the respondent company are so advised in writing. The case is referred back to the Panel for it to be considered on its merits and the procedure in Paragraph 5.5 above onwards shall be followed.'

No administrative charges apply in relation to proceedings under Paragraph 7.6 and there shall be no case reports.'

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## **PARAGRAPH 11**

### **Paragraph 11.3 Reports to the Code of Practice Appeal Board**

#### ***Current text***

'The Appeal Board may decide [*inter alia*]:

- to take steps to recover items given in connection with the promotion of a medicine; details of the action taken must be provided in writing to the Appeal Board.'

#### ***Amendment***

The text is changed to:

- 'to require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like; details of the action taken must be provided in writing to the Appeal Board.'

The same reference to health professionals is added to Paragraph 10.3.

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**Paragraphs 11.4 and 12.2**

***Amendment***

'abide by the Code' is changed to 'comply with the Code'.

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**PARAGRAPH 12**

**Paragraph 12.3 Code of Practice Appeal Board: Reports to the ABPI Board of Management**

***Current text***

'If a member of the Board of Management is concerned in a case which has led to the report, as either complainant or respondent, that member does not receive a copy of the report and is required to withdraw from the Board of Management during its consideration.

Members of the Board of Management are also required to declare any other interest in a report prior to its consideration. The President (or Chairman in the absence of the President) determines whether it is appropriate for that member to remain for the consideration of the report.'

***Amendment***

The second paragraph is deleted and replaced with:

'The company concerned is advised in advance of the membership of the Board of Management and asked if it has any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Board of Management during consideration of the report. The President (or Chairman in the absence of the President) determines whether objections are valid.

Members of the Board of Management are also required to declare any other interest in a report prior to its consideration. Having consulted the company representative(s) (if present), the President (or Chairman in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.'

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**PARAGRAPH 13****Paragraph 13.6 Case Reports*****Current text***

'In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints in which a *prima facie* case has been established and which are currently under consideration but not yet resolved and the texts and modes of dissemination of any corrective statements that companies have been required to issue during the previous twelve months.

Access to the Authority's website is unrestricted.'

***Amendment***

The second sentence of the first paragraph is changed to:

'The website also carries brief details of all complaints which are currently under consideration but not yet resolved ...'

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**Paragraph 13.6 Case Reports*****Current text***

'In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints in which a *prima facie* case has been established and which are currently under consideration but not yet resolved and the texts and modes of dissemination of any corrective statements that companies have been required to issue during the previous twelve months.

Access to the Authority's website is unrestricted.'

***Amendment***

A further paragraph is added to be the second paragraph:

'The Authority's website also carries interim case reports in respect of cases where publication of the final report is delayed because either the Code of Practice Appeal Board or the Board of Management of the ABPI has required an audit of the respondent company's procedures in relation to the Code.'

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**Paragraph 13.7 Case Reports**

***Current text***

'Following publication of the relevant case reports, the Authority advertises in the medical and pharmaceutical press brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. Such advertisements also appear on the Authority's website.'

***Amendment***

Amended to state:

'... the Authority advertises in the medical, nursing and pharmaceutical press...'

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**PARAGRAPH 17**

**Paragraph 17 Possible Breaches identified by the Code of Practice Panel or Code of Practice Appeal Board**

***Amendment***

Paragraph 17 is deleted in entirety.

There is consequential re-numbering of the subsequent paragraphs.

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**DATE OF IMPLEMENTATION**

The following statement will appear at the beginning of the Constitution and Procedure:

'Operative on 1 July 2008 except for paragraphs 4.4, 5.1, 5.2, 5.4, 5.5, 7.6, 12.3, 13.6 and 13.7 which are operative in respect of complaints received on and after 1 July 2008.'

1 May 2008