

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY
Constitution and Procedure

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PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY
CONSTITUTION AND PROCEDURE

Operative on 1 July 2010 except for Paragraphs 2, 4.2, 5, 7, 9, 12 and 16.4 which are operative in respect of complaints and voluntary admissions received on and after 1 July 2010.

INTRODUCTION

The Code of Practice for the Pharmaceutical Industry is administered by the Prescription Medicines Code of Practice Authority. The Authority is responsible for the provision of advice, guidance and training on the Code, as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

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, though the Authority can seek evidence from third parties where necessary. 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.

Complaints made under the Code about promotional material or the promotional activities of companies are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

The names of individuals complaining from outside the pharmaceutical industry are kept confidential. In exceptional cases it may be necessary for a company to know the identity of the complainant so that the matter can be properly investigated. Even in these instances, the name of the complainant is only disclosed with the complainant's permission.

Complaints about the promotion of medicines should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

STRUCTURE AND RESPONSIBILITIES

1 Prescription Medicines Code of Practice Authority

1.1 The Prescription Medicines Code of Practice Authority (the 'Authority') is responsible for the administration of the Code of Practice for the Pharmaceutical Industry (the 'Code') including the provision of advice, guidance and training on the Code. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

1.2 The Authority also administers the complaints procedure by which complaints made under the Code are considered by the Code of Practice Panel (the 'Panel') and, where required, by the Code of Practice Appeal Board (the 'Appeal Board').

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1.3 The Authority is appointed by and reports to the Board of Management of The Association of the British Pharmaceutical Industry (ABPI) (the 'ABPI Board') and consists of the Director, Deputy Director, Secretary and Deputy Secretary.

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Notwithstanding the above, the Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI for administrative purposes.

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In the absence of the Director, the Deputy Director is authorized to act on his behalf. In the absence of the Director and the Deputy Director, the Secretary is authorized to act on the Director's behalf.

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1.4 To facilitate the complaints procedure by ensuring that the requisite information is available, the Director may 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.

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1.5 The Director may consult the Appeal Board upon any matter concerning the Code or its administration.

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2 Code of Practice Panel – Constitution and Procedure

2.1 The Panel consists of the members of the Authority and meets as business requires to consider complaints made under the Code.

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The member of the Authority who acted as case preparation manager for a particular case must not participate when the Panel considers it or be present when it does so.

The parties have no right to appear or be represented before the Panel.

2.2 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 Deputy Director or, in his absence, the Secretary, acts as Chairman of the Panel and has both an original and a casting vote.

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

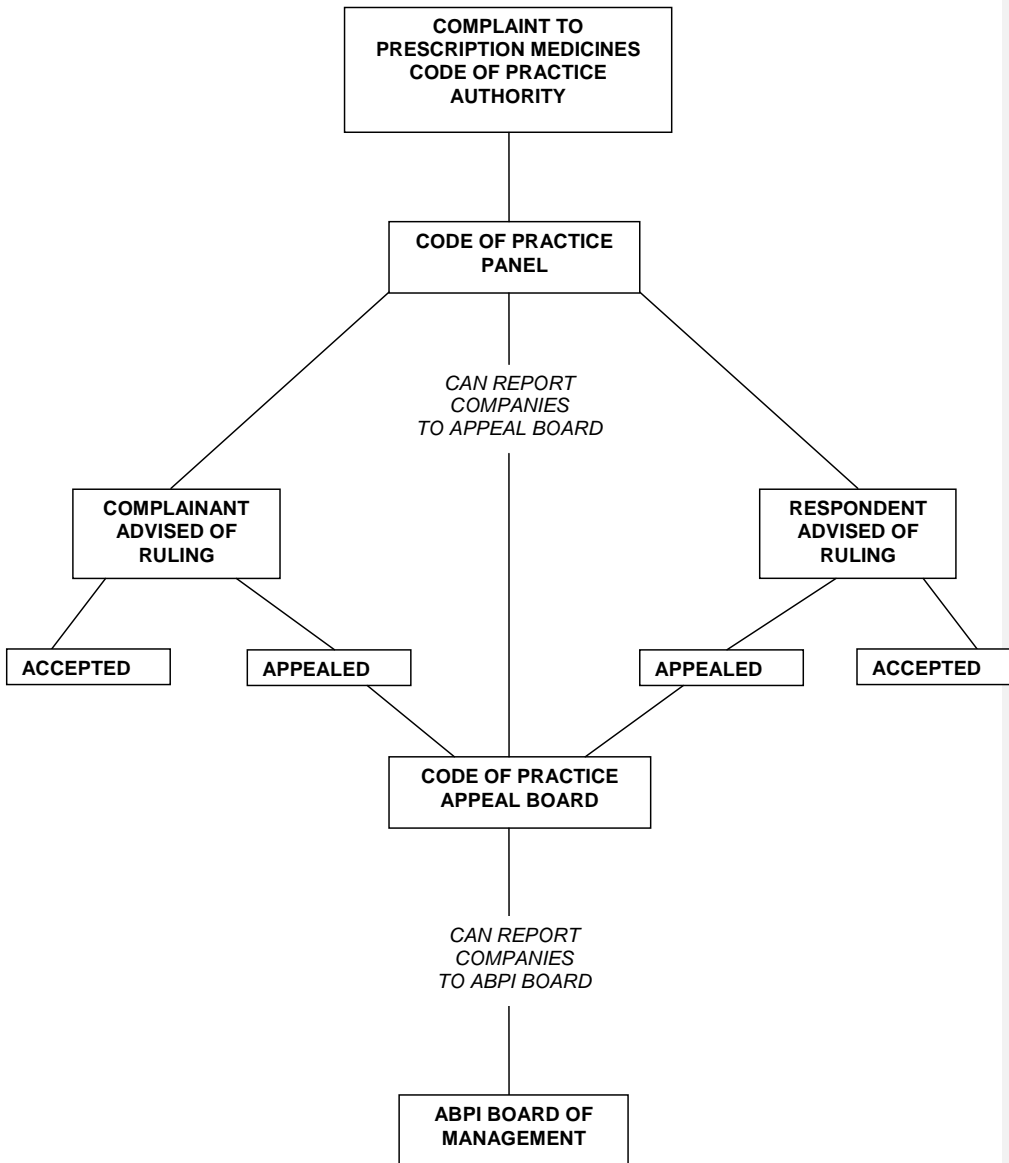
2.3 The Director may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but have no voting rights.

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3 Code of Practice Appeal Board – Constitution

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

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The Appeal Board and its Chairman are appointed by the ABPI Board. 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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3.2 The Appeal Board comprises:

- an independent, legally qualified Chairman
- 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 treating patients
- one independent practising registered pharmacist appointed following consultation with the Royal Pharmaceutical Society of Great Britain
- one independent registered nurse prescriber appointed following consultation with the Royal College of Nursing
- one independent member representative of the interests of patients
- one member from an independent body involved in providing information on medicines
- one independent lay member
- four registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
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One of the members from pharmaceutical companies may be retired, provided that the initial appointment is made within one year of the date of retirement.

3.3 The Chairman of the Appeal Board is appointed for a term of five years which may be renewed.

Members of the Appeal Board are each appointed for a term of three years. Members may be reappointed but may serve for no more than two consecutive terms. In exceptional circumstances the Chairman may nominate a member who has served two terms for reappointment for a third term. A member of the Appeal Board who has served two or, following the Chairman's nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.

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A member of the Appeal Board appointed prior to 1 January 2006 is eligible to serve for two or, following the Chairman's nomination, three further consecutive terms following completion of their current term and is eligible for reappointment after a minimum interval of one year.

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3.4 The Director is responsible for providing appropriate administrative support to the Appeal Board including the provision of case papers.

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The Director, Deputy Director, Secretary, and Deputy Secretary of the Authority may be present as observers at a meeting of the Appeal Board during the consideration of an appeal, or a report under Paragraph 11 below, only at the invitation of the Chairman and with the agreement of the party or parties involved in the appeal or report in question.

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4 Code of Practice Appeal Board – Procedure

4.1 The Appeal Board meets as business requires to consider appeals under the Code and any other matter which relates to the Code. The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them.

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4.2 The Chairman and seven members of the Appeal Board constitute a quorum. Four of those present, in addition to the Chairman, must be independent members, at least one of whom must be a registered medical practitioner, and there must also be present two members from pharmaceutical companies, at least one of whom must be a registered medical practitioner.

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For the consideration of any particular case, or a report under Paragraph 11 below, independent members, including the Chairman, must be in a majority.

In the event that a quorum cannot be attained for the consideration of a case because of the number of members barred under Paragraph 4.4 below, or for any other reason, the Chairman may co-opt appropriate persons who are former members of the Appeal Board, or who are on a list of persons approved for co-option to the Appeal Board, so as to enable a quorum to be achieved. The list of persons approved for co-option is drawn up following procedures similar to those for appointing members of the Appeal Board.

No one may be co-opted in relation to any case in which he has acted as a referee in accordance with Paragraphs 5.1, 5.2, 5.3, 7.2, 7.4, 7.5 and 7.6 below.

4.3 Decisions are made by majority voting. The Chairman has both an original and a casting vote. Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

4.4 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.

The complainant and the respondent are advised in advance of the membership of the Appeal Board, including potential co-optees, 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 must 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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4.5 The Chairman may obtain expert assistance in any field. Expert advisers may be invited to attend a meeting of the Appeal Board but have no voting rights.

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4.6 When an appeal is considered by the Appeal Board, both the complainant and the respondent company are entitled to appear or be represented. The first presentation in relation to a ruling which is appealed is made by the appellants.

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A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the case in question.

4.7 Where an appeal is brought which is concerned with an issue of fact between a complainant and the company concerned which cannot be properly resolved without the oral evidence of the persons directly involved, the Chairman may invite such persons to attend and give evidence.

COMPLAINTS PROCEDURE

5 Action on Complaints

5.1 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 Director must assign a member of the Authority (who may be the Director) to be the case preparation manager to process the matter and, if appropriate, prepare case papers for the Panel.

The case preparation manager must not divulge to other members of the Authority details of matters being processed until the formal case papers are provided to the Panel for consideration as provided for in Paragraph 5.5 below.

The Director is responsible for ensuring that the preparation of a case and the adjudication of it are carried out by different members of the Authority and must take steps to make certain that this separation is maintained in the event of absences of those involved.

The Director may delegate to a case preparation manager one or more of his responsibilities under this Constitution and Procedure when he considers it appropriate and necessary to do so.

The case preparation manager:

- determines whether a case should go before the Panel
- may dismiss a complaint which he considers frivolous
- may invite evidence from third parties when considered to be appropriate even though the primary responsibility for the provision of evidence lies with the parties to a case.
- may delay processing a complaint if the facts are essentially similar to those before an external forum, such as an employment tribunal; this does not apply to matters before the Medicines and Healthcare products Regulatory Agency
- may amalgamate a complaint with an ongoing complaint or complaints where two or more complaints are based on essentially the same evidence.

When a complaint is amalgamated, delayed or dismissed, as above, the complainant may appeal against the amalgamation, delay or dismissal to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

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

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

If a complaint is received about a company other than one of those referred to in 5.1 above, it is invited **by the case preparation manager** to agree to comply with the Code and accept the jurisdiction of the Authority (unless it has previously declined to do so). In the absence of such agreement, the complaint is not proceeded with and the complainant is advised to refer the matter to the Medicines and Healthcare products Regulatory Agency.

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.

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 Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.

If a complainant does not accept a decision of the Director that a complaint should not be proceeded with because a similar complaint has been adjudicated upon previously and nothing has changed in the meantime, then the matter is referred to **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination** which is final.

If, in the view of the Director, a complaint does not show that there may have been a breach of the Code, the complainant **will** be so advised. If the complainant does not accept that view, the matter is referred to **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination** which is final.

5.3 When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

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

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unsuccessful. A formal statement detailing the actions taken must be provided. This requirement does not apply where the allegation is that a company has failed to comply with an undertaking that it has given and is in breach of Clause 25 of the Code.

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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 18.2 below. Information about conciliation is available from the Director.

5.4 Upon receipt of a complaint, the company concerned has ten working days in which to submit its comments in writing.

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

5.6 When a company advises the Authority that it may have breached the Code, the Director will treat the matter as a complaint. The company's response is invited. The case preparation manager may suggest the clauses of the Code to be addressed. When the response is received the procedure under Paragraph 5.5 above will be followed.

5.7 The parties must be notified that a case has been referred to the Panel.

6 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 will be followed.

7 Code of Practice Panel - Rulings

7.1 Where the Panel rules that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

The respondent company has five working days to provide a written undertaking that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must

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be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/or the last date on which the promotional activity took place.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

7.2 Where the Panel rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision. Where the complaint is from a pharmaceutical company, the complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

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 **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board for his determination** which is final.

7.3 The complainant or the respondent company may appeal against a ruling of the Panel to the Appeal Board. Appeals must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be circulated to the Appeal Board.

Notice of appeal must be given within five working days of notification of the Panel's ruling and the appeal must be lodged within ten days of notification of the Panel's ruling.

Where the respondent company gives notice of appeal it must, within five working days of notification of the Panel's ruling, suspend the use of the promotional material or activity at issue, pending the final outcome of the case and must notify the Authority that such action has been taken.

If the respondent company accepts one or more of the Panel's rulings of breaches of the Code, but appeals one or more other such rulings, then within five working days of notification of the Panel's rulings it must provide the undertaking required by Paragraph 7.1 above in respect of the ruling or rulings which it is not appealing.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

7.4 Where an appeal is lodged by the complainant, 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.

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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.

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 **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine** whether those particular comments can be included in the evidence which goes before the Appeal Board. The **referee's** decision is final.

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7.5 Where an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

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.

In the event that the respondent company objects to certain details of its appeal 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 **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine** whether those particular details can be included in the evidence which goes before the Appeal Board. The **referee's** decision is final.

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Where an appeal is lodged by the respondent company, the complainant is sent a copy of the initial 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 **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination, which is final.**

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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.

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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 **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.**

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The complainant may appeal against the **Panel's** ruling to **an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member**

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of the Appeal Board, for his determination which is final. An appeal must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be provided to the referee. The appeal must be lodged within ten working days of notification of the ruling of the Panel.

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

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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 provided to the respondent company and the referee.

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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 the referee must decide whether he can take those comments into consideration when making his determination.

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In such an appeal, the referee must consider no more than whether or not the matter of complaint is within the scope of the Code. If the referee determines that the matter is not within the scope of the Code the complainant and the respondent company are so advised in writing.

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If the referee determines 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 will be followed.

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

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8 Code of Practice Panel - Reports to the Code of Practice Appeal Board

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8.1 Failure to comply with the procedures set out in Paragraphs 5 and 7 above will be reported to the Appeal Board.

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8.2 The Panel may also report to the Appeal Board any company whose conduct in relation to the Code, or in relation to a particular case before it, or because it repeatedly breaches the Code such that it raises concerns about the company's procedures, warrants consideration by the Appeal Board. Such a report to the Appeal Board may be made notwithstanding the fact that a company has provided an undertaking requested by the Panel.

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9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

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In the event of the Medicines and Healthcare products Regulatory Agency making a complaint which relates to the safety or proper use of a medicine, and requesting that an advertisement be withdrawn, the respondent company has five working days to respond with its comments. The procedure in Paragraph 5.5 above will be followed.

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10 Code of Practice Appeal Board - Rulings

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10.1 Where the Appeal Board rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

Where a complainant pharmaceutical company appeals and the Appeal Board upholds the ruling that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where a respondent company appeals and the Appeal Board rules that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

10.2 Where the Appeal Board rules that there is a breach of the Code, the respondent company is so advised in writing and is given the reasons for the decision. The respondent company then has five working days to provide a written undertaking providing **relevant** information **as** specified in Paragraph 7.1 above.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

10.3 Where the Appeal Board rules that there is a breach of the Code, **it may 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. Written details of the action taken must be provided to the Appeal Board.**

10.4 Where the Appeal Board rules that there is a breach of the Code, **it may require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code. These could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period. The Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material. All of the costs of pre-vetting must be met by the company concerned.**

The Appeal Board may also require an audit if a company repeatedly breaches the Code.

10.5 Where the Appeal Board rules that there is a breach of the Code, **it may** reprimand the company and publish details of that reprimand.

10.6 Where the Appeal Board rules that there is a breach of the Code, **it may require the company to issue a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use.**

11 Reports to the Code of Practice Appeal Board

11.1 Where the Panel reports a company to the Appeal Board under the provisions of Paragraphs 8.1 and 8.2 above, or where the Panel reports the failure of a company to comply with the procedure set out in Paragraph 9 above, or where the Authority reports the failure of a company to comply with the procedures set out in Paragraph 10 above, the procedures set out below shall apply. These procedures also apply if the Appeal Board, having received a report on

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a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.

11.2 The company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's case.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the matter in question.

11.3 The Appeal Board may:

- reprimand the company and publish details of that reprimand
- require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code; these could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period; the Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material; **all of the costs of pre-vetting must be met by the company concerned**
- require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use
- 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; **written** details of the action taken must be provided to the Appeal Board.

11.4 Where a company not in membership of the ABPI fails to comply with the procedures set out in Paragraphs 5, 7, 9 or 10 above and indicates that it no longer wishes to accept the jurisdiction of the Authority, the Appeal Board may decide **to remove** the company from the list of non member companies which have agreed to comply with the Code and **advise** the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

The **ABPI Board** must be advised that such action has been taken.

12 Code of Practice Appeal Board - Reports to the ABPI Board of Management

12.1 Where the Appeal Board considers that the conduct of a company in relation to the Code or a particular case before it warrants such action, it may report the company to the **ABPI Board**. Such a report may be made notwithstanding the fact that the company has provided an undertaking requested by either the Panel or the Appeal Board.

12.2 Where such a report is made to the **ABPI Board**, the **ABPI Board** may **suspend or expel the company from the ABPI**.

In the case of a company not in membership of the ABPI, the ABPI Board may remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

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To assist it in deciding whether to suspend or expel a company or, in the case of a company not in membership of the ABPI, to remove the company from the list of non member companies which have agreed to comply with the Code, the ABPI Board may require an audit of the company's procedures in relation to the Code to be carried out by the Authority.

12.3 If a member of the ABPI Board 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 ABPI Board during its consideration.

The company concerned is advised in advance of the membership of the ABPI Board 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 ABPI Board during consideration of the report. The President (or Chairman in the absence of the President) determines whether objections are valid.

Members of the ABPI Board must 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.

12.4 Where a report is made to the ABPI Board under Paragraph 12.1 above, the company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the ABPI Board to state the company's case.

13 Case Reports

13.1 At the conclusion of any case under the Code, the complainant is advised of the outcome and a report is published summarising the details of the case.

13.2 The respondent company and the medicine concerned are named in the report.

In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual.

Where expert assistance has been obtained by either the Panel or the Appeal Board, the report will include the name and qualifications of the expert concerned.

Where a company has been required to issue a corrective statement, the report will reproduce its text and provide details of how the corrective statement was disseminated.

13.3 A copy of the report on a case is sent to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Director, consulting with the other party where appropriate. If either party does not accept the Director's decision as to whether or not a report should be amended, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

13.4 Copies of all case reports are submitted to the Appeal Board prior to publication. Copies of the reports are sent to the ABPI Board for information following publication.

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13.5 Full case reports in printed form are published each quarter by the Authority,

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Copies of the reports are sent to the Medicines and Healthcare products Regulatory Agency, the Office of Fair Trading, the British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Royal College of Nursing and the Editors of the BMJ, The Pharmaceutical Journal and the Nursing Standard. Copies are also available to anyone on request.

13.6 In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints 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.

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

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Access to the Authority's website is unrestricted.

13.7 Following publication of the relevant case reports, the Authority advertises in the medical, pharmaceutical and nursing 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. The companies concerned are required to contribute to the cost of the press advertisements.

GENERAL PROVISIONS

14 Time Periods for Responding to Matters under the Code

The number of working days within which companies or complainants must respond to enquiries etc, from the Authority, as referred to in the above procedures, is counted from the date of receipt of the notification in question.

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An extension in time to respond to such notifications may be granted at the discretion of the Director.

15 Withdrawal of Complaints and Notices of Appeal

15.1 A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Authority, but not thereafter.

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15.2 Notice of appeal may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the reasons for the appeal have been received by the Authority, but not thereafter.

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15.3 Notice of appeal may be withdrawn by a respondent company at any time but if notice is given after the papers relating to its appeal have been circulated to the Appeal Board, then the higher administrative charge will be payable.

16 Code of Practice Levy and Charges

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16.1 An annual Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 7 and 10 above, the charges for audits carried out in accordance with Paragraphs 10.4, 11.3 and 12.2 above and the contributions to the cost of press advertisements referred to in Paragraph 13.7 above are determined by the ABPI Board, subject to approval at a General Meeting of the ABPI by a simple majority of those present and voting.

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16.2 Administrative charges are payable only by pharmaceutical companies and companies are liable for such charges whether they are members of the ABPI or not.

There are two levels of administrative charge.

The lower level is payable by a company which accepts either a ruling of the Panel that it was in breach of the Code or a rejection by the Panel of its allegation against another company. The lower level is also payable by a complainant company if a ruling of the Panel that there was a breach of the Code is subsequently overturned by the Appeal Board and by a respondent company if a ruling of the Panel that there was no breach of the Code is subsequently overturned by the Appeal Board.

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The higher level is paid by a company which unsuccessfully appeals a ruling of the Panel.

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16.3 Where two or more companies are ruled in breach of the Code in relation to a matter involving co-promotion, each company will be separately liable to pay any administrative charge which is payable.

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16.4 Where a company advises the Authority that it may have breached the Code, and it is subsequently ruled in breach, any administrative charge payable will be one half of that which would otherwise have been due.

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17 Scrutiny

17.1 The Authority arranges for the scrutiny of samples of advertisements, detail aids, leavepieces, other promotional items and meetings on a continuing basis in relation to the requirements of the Code.

Members of the Authority must not carry out scrutiny.

To facilitate such scrutiny, the Director may request relevant material from pharmaceutical companies, including copies of the certificates authorizing such material, and companies must respond to such requests within ten working days.

17.2 Where a possible breach of the Code is identified under this procedure by the scrutineer, the company concerned is requested to comment in writing within ten working days of receipt of the notification.

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17.3 If the company accepts that there is a breach of the Code, the company is requested to provide an undertaking providing the information specified in Paragraph 7.1 above. No administrative charge ~~will~~ be payable in these circumstances and there ~~will~~ be no case report on the matter in question.

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17.4 If the company does not accept that there is a breach of the Code and, having considered the company's comments, the ~~scrutineer~~ decides that there is no case to answer under the Code, then the procedure is brought to a close. There ~~will~~ be no case report on the matter in question.

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17.5 If the company does not accept that there is a breach of the Code but, having considered the company's comments, the ~~scrutineer~~ considers that a case has been established, the ~~matter will be dealt with as a complaint~~.

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18 Provision of Advice and Assistance with Conciliation

18.1 The ~~Authority~~ is willing and able to provide informal guidance and advice in relation to the requirements of the Code and, where appropriate, may seek the views of the ~~Appeal Board~~.

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18.2 Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences about promotion may contact the Director for advice and assistance.

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19 Amendments to the Code of Practice and Constitution and Procedure

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19.1 The Code ~~and~~ this Constitution and Procedure may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

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19.2 The views of the ~~Authority~~ and the ~~Appeal Board~~ must be sought on any proposal to amend the Code or this Constitution and Procedure. The views of the Medicines and Healthcare products Regulatory Agency, the British Medical Association, the Royal Pharmaceutical Society of Great Britain and the Royal College of Nursing must also be invited.

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19.3 The ~~Authority~~ and the ~~Appeal Board~~ may, in the light of their experience, make recommendations for amendment of the Code and this Constitution and Procedure.

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20 Annual Report

An annual report of the ~~Authority~~ is published each year with the approval of the ~~Appeal Board~~. This report includes details of the work of the Authority, the ~~Panel~~ and the ~~Appeal Board~~ during the year and provides a list of all companies ruled in breach of the Code during the year which specifically identifies those ruled to have breached Clause 2.

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