PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

DRAFT FOR CONSULTATION DECEMBER 2023

Introduction to the PMCPA Constitution and Procedure

OPERATIVE ON XX Month 2024 (Provisional) ~~JANUARY 2019~~

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. The system is designed so that both parties can participate fully in the process. Although anonymous complaints are accepted, it is preferable if complainants from outside the industry provide a name, contact details and relevant information about their interests in the matter of complaint. 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.

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 are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Case reports are ~~on cases are~~ published ~~by the Authority~~ and are available ~~on request and~~ on the Authority's website www.pmcpa.org.uk.

Complaints should be submitted via the complaints portal on the Authority's website. If this is not possible, complaints may be submitted via email to complaints@pmcpa.org.uk or sent to the Director of the Prescription Medicines Code of Practice Authority, 2nd Floor Goldings House, Hay's Galleria, 2 Hays Lane, London, SE1 2HB ~~7th Floor, Southside, 105 Victoria Street, London SW1E 6QT~~, ~~telephone 020 7747 8880, 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').

1.3 The Authority is appointed by and reports to the Board of the Association of the British Pharmaceutical Industry (ABPI) (the 'ABPI Board') and consists of the Director and at least three other individuals appropriately qualified to be a member of the Panel~~, Deputy Director and two Managers~~.

1.4 ~~In the absence of t~~The Director may nominate a senior individual within the Authority ~~the Deputy Director is authorized~~ to act on their ~~his/her~~ behalf. ~~In the absence of the Director and Deputy Director, one of the Managers is authorized to act on the Director's behalf.~~

1.5 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 authorising any such material and copies of relevant briefing material for representatives.

1.6 The appointment of the Director and Deputy Director(s) are made by a panel including representatives from the Appeal Board, ABPI Board and ABPI Leadership Team, and in consultation with the MHRA.

~~Notwithstanding the above,~~ The Director reports to the Appeal Board for guidance on the interpretation of the Code. Further, the Appeal Board has a supervisory role in relation to the operation of the complaints process and the Director must provide a regular status report to the Appeal Board on all complaints submitted under the Code and details of the action taken on them. If the Appeal Board has concerns about the operation of the complaints procedure those concerns should be raised with the Director and, at the Appeal Board's discretion, may be escalated to the President of the ABPI through the Chair of the Appeal Board. ~~and the operation of the complaints procedure~~ The Director reports to the ~~and to the~~ President of the ABPI (and/or, where a conflict of interest is identified to ~~at the President's discretion,~~ the Vice President of the ABPI) for administrative purposes. The Director does not report to the President in relation to decisions and actions taken within the complaints procedure. The Chair of the Appeal Board must be consulted by the President before setting any aspect of the Director's annual performance review which relates to the operation of the complaints procedure. Feedback from the Chair of the Appeal Board should be obtained to assist the President's consideration of the Director's performance.

1.7 Members of the Panel are required to declare any conflicts of interest prior to appointment to the Authority, and before involvement in a case including acting as Case Preparation Manager or adjudicating on a complaint. Members of the Panel previously employed by a pharmaceutical company are restricted from taking any decision-making role as described above on a matter relating to their former employer for a minimum period of three years.

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

Overriding Objective

1.9 The overriding objective of this constitution is to ensure that cases are dealt with fairly and justly while protecting patient safety. When making procedural and discretionary decisions, the Case Preparation Manager, Code of Practice Panel, Director, Appeal Board, Chair of the Appeal Board and any independent referee shall all act in a way they consider most likely to further the overriding objective.

All parties are required to take all reasonable steps to assist the PMCPA and the Appeal Board to further the overriding objective

Dealing with cases fairly and justly includes:

dealing with each case in ways which are proportionate to the importance of the case and the complexity of the issues;

avoiding unnecessary formality and adopting flexibility in the proceedings where appropriate;

ensuring, so far as practicable, that the parties are able to participate fully in the proceedings; and

avoiding delay to the case in hand and other cases, so far as compatible with proper consideration of the issues.

Case Management Directions

The Director may give a case management direction (as defined below) at any time prior to an appeal, including a direction amending, suspending, or setting aside an earlier direction.

If a party has lodged an appeal, the Director or the Chair of the Appeal Board may give a direction at any time before an appeal has been heard in relation to the conduct of proceedings.

"Case management directions" are directions as to the manner in which proceedings will be conducted which may include, but are not limited to, directions about: (i) what material may go in front of the Panel or Appeal Board; (ii) what material may be redacted; (iii) whether a hearing is conducted remotely or in person; (iv) providing dictation to support to an individual who is unable to submit a complaint in writing; and (v) directions in response to the conduct of any parties, for example where such conduct is not in line with the parties obligation to provide reasonable assistance to the PMCPA to further the overriding objective.

Set Aside for procedural error

The Director may give a direction at any time before an appeal has been heard setting aside the decision of a Panel where there has been an error in complying with the procedure for dealing with cases set out in this Constitution (a "procedural error").

The Chair of the Appeal Board may give a direction at any time before an appeal has been heard setting aside the decision of the Panel where there has been a procedural error, and may give a direction at any time setting aside a decision of the Appeal Board where there has been a procedural error.

The directions described above should be given in writing with a brief explanation of the procedural error. Before making a final decision to set a matter aside, the Director or Chair of the Appeal Board must give parties an opportunity to make written submissions. In all cases where a decision is set aside for procedural error, the decision which is set aside will have no effect and the case will proceed as if that decision had not been made. All decisions to set aside may be referred to an independent referee if any party so requests.

Non-Compliance

Failure of any party to comply with: (i) its obligation to assist the PMCPA and Appeal Board to further the overriding objective; (ii) any requirement in this Constitution and Procedure, or (iii) with a direction issued by the Director, Chair of the Appeal Board or Appeal Board, may be reported to the Chair of the Appeal Board. The Chair of the Appeal Board may take such action as they consider just, in line with the overriding objective, which may include waiving the requirement, requiring compliance, restricting a party's participation in the proceedings or determining that a case should not proceed. The Chair of the Appeal Board may refer a determination that a case should not proceed to an Independent Referee if any party so requests.

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.

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 most senior individual present acts as Chair of the Panel, ~~Director or, in his/her absence, the Deputy Director or, in his/her absence, one of the Managers, acts as Chair of the Panel~~ and has both an original and a casting vote.

If necessary, the Director or in their ~~his/her~~ absence, an individual authorised to act on the Director's behalf ~~the Deputy Director,~~ may co-opt an appropriate person to be a member of the Panel. The Director should seek the agreement of the Chair of the Appeal Board prior to any co-option.
The list of persons approved for co-option is drawn up following procedures similar to those in place for appointing the Authority.

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 independent expert assistance in any field. Independent expert advisors who are consulted may be invited to attend a meeting of the Panel but have no voting rights.

3 Code of Practice Appeal Board – Constitution

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

The Appeal Board and its Chair are appointed by the ABPI Board. The appointment of independent members to the Appeal Board, including the Chair, is made following consultation with the Medicines and Healthcare products Regulatory Agency. Appointments of industry members are proposed by their UK Chief Executive or equivalent and are initially appointed by the ABPI Board as co-opted members of the Appeal Board before being appointed for a fixed-term.

3.2 The Appeal Board comprises:

- an independent, legally qualified Chair;
- three independent registered medical practitioners appointed following a check of the individual's history and credentials as stated on the medical register, held on the General Medical Council website ~~following consultation with the British Medical Association and (~~one of the three appointees must have ~~with~~ recent experience as a general practitioner and one ~~with~~ must have recent experience as a hospital consultant treating patients);
- one independent registered pharmacist appointed following a check of the individual's history and credentials as stated on the pharmacy register, held on the General Pharmaceutical Council website ~~consultation with the Royal Pharmaceutical Society~~
- one independent registered senior nurse practitioner ~~prescriber~~ (minimum Band 7 or equivalent) appointed following a check on the individual's credentials and history as held on the Nursing and Midwifery Council website. ~~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
- four directors or senior executives of pharmaceutical companies.

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 Chair 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 Chair of the Appeal Board 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 Chair's nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.

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

~~The Director, Deputy Director and the two Managers 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 Chair and with the agreement of the party or parties involved in the appeal or report in question.~~

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.

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

For the consideration of any particular case, or a report under Paragraph 13 ~~11~~ below, independent members, including the Chair, must be in a majority.

In the event that a quorum cannot be attained for the consideration of a case, audit or case report because of the number of members barred under Paragraph 4.4 below, or for any other reason, the Chair 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/she 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.

The Director, and other members 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 13 below only at the invitation of the Chair of the Appeal Board, and with the agreement of the party or parties involved in the appeal or report in question, and only for the purposes of understanding the work of the Appeal Board. Where a member of the Authority provides any assistance to the Chair of the Appeal Board in relation to a matter of procedure , their presence and any assistance provided will be minuted.

Any other person may observe, but may not participate in, an Appeal Board meeting at the invitation of the Chair, and with agreement of the party or parties involved in the appeal or report in question.

Appeal Board meetings may be recorded solely for the purpose of producing accurate minutes of meetings and will be deleted once the minutes are approved.

Records of procedural decisions at prior Appeal Board meetings may be shared with Appeal Board members at the Chair's discretion

4.3 Decisions are made by majority voting. The Chair 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 while it considers the case. ~~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 while it considers the case ~~during consideration of the case~~. The Chair 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 Chair determines whether it is appropriate for a particular member to remain for the consideration of the case.

4.5 The Chair may obtain independent expert assistance in any field. Independent expert advisors may be invited to attend a meeting of the Appeal Board for the consideration of the case but have no voting rights.

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 appellant.

A company may not be represented before the Appeal Board in any matter by a representative who is also a member of the Appeal Board except with the consent of the Chair. Such consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within their ~~his/her~~ company can properly represent it in the matter 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 Chair 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 their ~~his/her~~ responsibilities under this Constitution and Procedure when they ~~he/she~~ consider it appropriate and necessary to do so.

The case preparation manager:

- must determine~~s~~ whether a case ~~should~~ proceeds through the full complaints process and goes before the Panel, whether it meets the criteria for the abridged process (described in Paragraph 6 below), or whether the complaint should not proceed.
- 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 at any time where two or more complaints are based on essentially the same evidence.

When a complaint is delayed or amalgamated, as above, the parties shall be notified and ~~the complainant~~ may appeal against the delay or amalgamation to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their ~~his/ her~~ determination, which is final.

Complaints that the PMCPA does not proceed

When the Case Preparation Manager receives information from which it appears that the matter being complained about does not fall within the scope of the Code but potentially within the jurisdiction of another UK authority (e.g., MHRA, GMC, GPhC), the assigned Case Preparation Manager may inform the complainant and provide the details of the relevant UK authority. If the complainant is non-contactable, the Case Preparation Manager may forward the information to the relevant UK authority. When referring the complainant to another UK authority, the complainant will be informed that they may not appeal this decision with the PMCPA but may provide further information for consideration by the Case Preparation Manager if they disagree with the decision. The Case Preparation Manager must then consider the further information and may revise their previous decision if they consider it appropriate to do so.

If a complainant does not accept a decision of the Case Preparation Manager that a complaint should not be proceeded with, and it is not considered as potentially within the jurisdiction of another UK authority, then the matter is referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their ~~his/her~~ determination, which is final.

If, in the view of the Case Preparation Manager, 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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their ~~his/her~~ determination, which is final.

If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, the Director may direct at any time before the complaint is determined by the Panel that the complaint should not proceed. In making that

determination the Director will bear in mind the overriding objective, and will additionally consider whether: (i) new relevant evidence has been adduced by the complainant or; (ii) 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.

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.

In the event that the Case Preparation Manager does not agree that (a) clause(s) cited by the complainant is relevant to the complaint, the grounds relating to those clauses will be removed from the complaint and the complainant will be informed, with written reasons given. For cases going through the full complaints process, if the complainant does not agree with the Case Preparation Manager's decision, the clauses will be cited as alleged and provided to the company to provide a response.

If a complaint is received about a company other than one of those referred to in Paragraph 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. If the complainant is non-contactable, the complaint will be referred to the Medicines and Healthcare products Regulatory Agency if the matter is covered by UK law.

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, or in a competitor.

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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her 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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.~~

5.3 When the complaint is from an individual, the Authority encourages complainants to be contactable in order to fully participate in the complaints process. The Authority does not share the identity or any personally identifiable information with other parties including the respondent company unless certain information is considered necessary to enable the company to respond to the complaint, and then it will only be shared with the prior permission of the complainant.

Complainants are strongly encouraged, but not required, to initially attempt to resolve the complaint using the company's internal or external whistleblowing and/or dispute resolution procedures.

5.4 When the complaint is from a pharmaceutical company, the complaint must be signed or authorised 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 Case Preparation Manager ~~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.
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 3.3 of the 2024 Code ~~Clause 29 of the 2019 Code (Clause 3.3 of the 2021 Code).~~

If, in the view of the Case Preparation Manager ~~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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for ~~their his/her~~ 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.

5.5 Upon receipt of a complaint, the company concerned has fifteen ~~ten~~ working days in which to submit its comments in writing. An extension in time to respond may be granted at the discretion of the Case Preparation Manager.

5.6 When the respondent company's response is received, the case preparation manager must determine whether there is a *prima facie* case to answer under the Code. If, in the view of the case preparation manager, no *prima facie* case has been established, the complainant and the respondent company are so advised. If the complainant does not accept that view, the matter is referred to the Code of Practice Panel to determine whether or not there has been a breach of the Code. If the complainant submits further evidence, then the respondent company shall be invited to comment on that further evidence before the matter is referred to the Panel.

5.7 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.

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

6 Abridged Complaints Procedure

6.1 On receipt of a complaint or a voluntary admission, and where it is likely in the Case Preparation Manager's view that there has been a breach of the Code for all matters alleged, the Case Preparation Manager may offer the responding company the option to follow an abridged complaints procedure.

6.2 The Case Preparation Manager will notify the respondent company that the complaint is being handled through the abridged complaints procedure. The allegations must relate to the clauses in the Authority's approved list published on the PMCPA website for use of the abridged procedure, and the clauses to be cited in the complaint will be determined by the case preparation manager.

6.3 Where a complaint comprises multiple allegations, the complaint will follow the full complaints process if any of the allegations do not fall within the scope of the abridged process.

In the event that the Case Preparation Manager does not agree that a clause(s) cited by the complainant are relevant, the complainant will be informed with written reasons. If the complainant does not agree with their decision they may request that the matter is referred to an independent referee, identified by the Director and Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their determination, which is final.

6.4 The respondent company has fifteen working days from the date on which it is notified by the Director of the complaint in which to conduct its investigation and respond. An extension in time to respond may be granted at the discretion of the Director.

6.5 When the response from the respondent company is received, the case preparation manager must assess that the response satisfies the following criteria;

- The respondent company accepts the breach(es) of the Code and submits a written undertaking that the 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; and
- The respondent company confirms that, as a result of its investigation, it has not identified a systemic compliance issue in relation to the matters alleged.

6.6 If the Case Preparation Manager assesses that the respondent company's response does not satisfy the criteria in [6.5] the case will follow the full complaints procedure. The case preparation manager has the discretion to raise additional clauses, where appropriate to do so.

7 Complaints Arising from Media Criticism

7.1 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.

7.2 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.

8 Code of Practice Panel – Rulings

8.1 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.

If the material or activity at issue is considered by the Panel to be likely to prejudice public health and/or patient safety, and/or it represents a serious breach of the Code, the Panel must decide whether, if there is subsequently an appeal by the respondent company, it would be required to suspend the use of the material or activity pending the final outcome of the case. If suspension would be required, the company must be so notified when it is advised of the Panel's ruling of a breach of the Code.

The respondent company has five working days to provide a written undertaking that the 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/her authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the material was finally used or appeared and/or the last date on which the 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 thirty ~~twenty working~~ days an administrative charge based on the number of matters ruled in breach of the Code.

8.2 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 thirty ~~twenty working~~ days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

8.3 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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

8.4 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.

If the Panel has so required in accordance with Paragraph 7.1 above, 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.

8.5 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.

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 Chair 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.

8.6 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. The parties can introduce new reasons at Appeal stage in their written submissions described above but may not introduce new or different allegations that have not been ruled upon by the Panel. 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 Chair 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.

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 Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their ~~his/ her~~ determination which is final.

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

The complainant may appeal against the Panel's ruling to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for their ~~his/her~~ 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.

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.

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.

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 they ~~he/she~~ can take those comments into consideration when making their ~~his/her~~ determination.

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.

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.

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

9 Abridged Procedure – Rulings, Sanctions and Reporting

9.1 Where the case preparation manager has determined that the abridged procedure will be applied, the case preparation manager will inform the complainant that the company has accepted a breach of the Code and provide details of the undertaking.

9.2 The case preparation manager will draft a case summary for publication detailing the allegation, acceptance of the breach by the company and that the company has provided its undertaking and assurances.

9.3 The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them.

9.4 There is no right of appeal by either the complainant or the respondent company under the abridged procedure.

9.5 Administrative charges equal to 50% of the cost of a complaint going through the full complaints process will be payable by the respondent company.

9.6 The case summary will be published on the PMCPA website which is open access.

~~10 Code of Practice Panel – Reports to the Code of Practice Appeal Board~~

~~10.1~~ ~~Failure to comply with the procedures set out in Paragraphs 5 and 7 above will be reported to the Appeal Board.~~

~~10.2~~ ~~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.~~

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

11.1 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.

11.2 If the Panel upholds the complaint, the company is required to suspend the advertisement or practice forthwith pending the final outcome of the case.

12 Code of Practice Appeal Board – Rulings and Sanctions

12.1 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 thirty ~~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 thirty ~~twenty working~~ days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

12.2 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 thirty ~~twenty working~~ days an administrative charge based on the number of matters ruled in breach of the Code.

12.3 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.

12.4 ~~Where t~~ 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, a specific scope audit, a requirement that the respondent company provide updates regarding implementation of their commitments to improve 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. Neither the Authority or its third-party can ~~but it cannot~~ approve such material; in the event of a complaint about such material, it will be handled in accordance with the Constitution and Procedure in the normal way.

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.

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

12.6 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.

12.7 Where the Appeal Board rules that there is a breach of the Code, it may take other administrative steps as appropriate in line with the Overriding Objective such as inviting a Senior representative of a particular company to future meetings of the Appeal Board to report on progress, or requesting written confirmation that appropriate action has been taken.

13 Reports to the Code of Practice Appeal Board

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

13.2 The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them. Where a case has been completed at Panel level, the Appeal Board shall consider whether additional sanctions may be appropriate. The Appeal board can also determine whether additional sanctions may be appropriate in relation to rulings which are accepted at the Panel level in cases which are before the Appeal Board in relation to other matters.

13.3 The Panel may also report to the Appeal Board any company whose conduct warrants consideration by the Appeal Board because:

(i) its conduct in relation to the Code, or in relation to a particular case before it raises concerns about the company's procedures; and/or ~~that it repeatedly breaches the Code such that it~~

(ii) it repeatedly breaches the Code such that it raises concerns about the company's procedures

~~about the company's procedures, warrants consideration by the Appeal Board.~~

This includes failure to sign an undertaking or to suspend an advertisement or practice as required by Paragraphs 8.1 and 11.2. Such a report to the Appeal Board may also be made, notwithstanding the fact that a company has provided an undertaking requested by the Panel.

13.4 Where a report has been made to the Appeal Board, and in the case of completed cases where the Appeal Board considers that additional sanctions may be appropriate, the procedure below is followed. ~~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 a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.~~

13.5 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 Chair. Such consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within his/her company can properly represent it in the matter in question.~~

13.6 Upon hearing the representations of the respondent company and considering the appropriate course to take, 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.

- Report the company to the ABPI Board with a recommendation for suspension or expulsion in line with Paragraph 14 below

13.7 Where a company not in membership of the ABPI fails to comply with the procedures set out in Paragraphs 5, 7, 9 or 12 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.

14 Code of Practice Appeal Board – Reports to the ABPI Board

14.1 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.

14.2 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~~ MHRA that responsibility for that company under the Code can no longer be accepted.

To assist it in deciding whether or not 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.

The ABPI Board must ratify the recommendation made by the Appeal Board unless there was an error made by the Appeal Board in formulating its recommendation, or the recommendation is manifestly disproportionate. The ABPI Board should share minutes of decisions with the Appeal Board.

14.3 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 Chair of the ABPI Board 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 Chair of the ABPI Board in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.

14.4 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.

15 Case Reports

15.1 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.

15.2 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 independent 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.

15.3 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 Chair of the Appeal Board for ~~his/her~~ their decision which is final.

15.4 Copies of all case reports are submitted to the Appeal Board prior to publication for it to review as part of its supervisory role in relation to the operation of the complaints process and to determine if any additional sanctions may be appropriate. ~~Copies of the reports are sent to the ABPI Board for information following publication.~~

15.5 ~~Full case reports in printed form are published each quarter by the Authority.~~

Copies of the reports may be ~~are~~ sent to the Medicines and Healthcare products Regulatory Agency, the Competition and Markets Authority, the Serious Fraud Office, the British Medical Association, the Royal Pharmaceutical Society, 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.

15.6 ~~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, any public reprimands and the texts and modes of dissemination of any corrective statements that companies have been required to issue for at least the past ~~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.

Access to the Authority's website is unrestricted.

15.7 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. A press release is also issued to the media and other stakeholders. Such advertisements also appear on the Authority's website. The companies concerned are required to contribute to the cost of the press advertisements, and the additional administrative burden to the Authority.

A copy of the Clause 2 advert is sent to the respondent company prior to publication. Any requested amendments to the advertisement are considered by the Director. If the respondent company does not accept the Director's decision as to whether or not an advertisement should be amended, the matter is referred to the Chair of the Appeal Board and their decision is final.

General Provisions

16 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.

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

17 Withdrawal of Complaints and Notices of Appeal

17.1 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. If the complaint is withdrawn prior to the company being requested to provide a response then the withdrawal does not require the consent of the respondent company.

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

17.3 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.

18 Code of Practice Levy and Charges

18.1 An annual Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 8, 9 and 12 ~~7 and 10~~ above, the charges for audits carried out in accordance with Paragraphs 12.4, 13.6 and 14.2 ~~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.

18.2 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.

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

18.3 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.

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

18.5 The number of administrative charges which apply in a case is determined by the Director and is based upon the number of matters. If a company does not agree with the Director's decision, the matter is referred to the Chair of the Appeal Board for their ~~his/her~~ decision which is final.

18.6 Failure to pay any of the charges provided for by this paragraph must be reported by the Director to the Appeal Board or the ABPI Board as appropriate.

19 Scrutiny

19.1 The Authority may arrange~~s~~ 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 may not adjudicate on a case relating to a material or activity that they have reviewed as part of scrutiny.

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

Neither the Authority nor its third-parties can approve such material.

19.2 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.

19.3 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 8.11~~7.1~~ above. No administrative charge will be payable in these circumstances and there will be no case report on the matter in question.

19.4 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.

19.5 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.

20 Provision of Advice and Assistance with Conciliation

20.1 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.

20.2 Companies and complainants wishing to seek the assistance of a conciliator with the view to reaching agreement on ~~inter-company~~ differences about materials and activities in scope of the Code ~~promotion~~ may contact the Director for advice and assistance.

21 Amendments to the Code of Practice and Constitution and Procedure

21.1 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.

Notwithstanding the above, where a proposal to amend the Code or this Constitution and Procedure arises solely from the ABPI's obligation to comply with any code promulgated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), then the ABPI Board may decide that formal approval at an ABPI General Meeting is not necessary. ABPI member companies must nonetheless be consulted in relation to the proposed texts of the changes.

21.2 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 Competition and Markets Authority, the Serious Fraud Office, the British Medical Association, the Royal Pharmaceutical Society and the Royal College of Nursing must also be invited.

Notwithstanding the above, where the ABPI Board has decided, in accordance with Paragraph 19.1 above, that formal approval of the proposal at an ABPI General Meeting is not necessary, then the bodies referred to above need only be informed of the changes which are to be made.

21.3 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.

22 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.