

GUIDANCE ON APPEAL PROCEDURES

Paragraph 7.3 of the Constitution and Procedure for the Authority states that the complainant and the respondent company in a case may appeal to the Code of Practice Appeal Board against rulings made by the Code of Practice Panel.

These notes are intended for guidance to assist the complainant and the respondent company when lodging an appeal or responding to one. The Authority and the Appeal Board will expect the recommendations below to be followed as closely as possible. The numbers in brackets refer to the relevant paragraphs of the Constitution and Procedure.

1 Lodging an appeal

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 working days of notification of the Panel's ruling. An appeal must be accompanied by detailed reasons as to why the ruling is not accepted (7.3) and which clauses are appealed. When drafting the appeal it should be noted that the Appeal Board will review the whole of the documentation relating to an appealed ruling (see point 5 below).

An extension to the five and ten working days allowed can be granted at the discretion of the Director of the Authority but only in exceptional circumstances.

Non-industry complainants who have difficulty in responding within the time allowed because of professional commitments or holidays etc, should contact the Director as soon as possible after they receive notice of the Panel's ruling so that alternative arrangements can be made.

If a company ruled in breach of the Code in relation to a number of allegations appeals some rulings but accepts others, then it must provide, within five days of notification of the rulings, the requisite undertaking and assurance in respect of those rulings of breaches of the Code which it accepts, ie those which it is not appealing (7.3).

In certain circumstances the Panel can decide that, if there is an appeal, the company ruled in breach must suspend the use of the material or activity pending the final outcome (7.1). Where this is the case, suspension must take place within five days of notification of the Panel's ruling and the company must notify the Authority that such action has been taken.

2 What should be said?

Brevity may not always be possible when complex matters are appealed but a clear and concise exposition of the facts should be aimed at. Repetition of the same point should be avoided. All points should be covered in the main text without the use of footnotes.

In a multi-issue case, the letter setting out the appeal must follow the numbering system used by the Authority in its notification of the Panel's rulings and matters must be dealt with in the same order, if more than one ruling is appealed.

When preparing an appeal it should be borne in mind that members of the Appeal Board will have before them, and will read, all of the prior documentation in full (see point 5 below).

It should also be borne in mind that it must have been possible to substantiate a claim etc on the day it was made.

When a published paper etc is referred to, it must be provided and it assists the Appeal Board if an indication is given as to what members are expected to glean from it and whereabouts in it they should look. There is little merit in merely submitting a large number of published papers without any commentary on them.

Foreign language documents must be accompanied by an English translation.

Websites may be cited but digital copies of the relevant web pages must be provided.

When submitting an appeal, or responding to one, pharmaceutical companies should submit digital copies of all of the documentation to be considered. This should include the covering letter together with its attachments. Wherever possible there should be no restrictions on editing.

Regardless of which party appeals, respondent companies should provide good quality digital copies of the material at issue together with copies of relevant summaries of product characteristics (SPCs) (see point 5 below).

When audio only or audio-visual material is referred to, a transcript must be provided.

3 An appeal by the complainant – further documentation

Where an appeal is lodged by the complainant, the respondent company has five working days to comment on the reasons given for the appeal. The complainant then has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal (7.4). Both sets of comments go before the Appeal Board and the complainant's comments are also sent to the respondent company for information.

If 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, it will be referred to an independent referee identified by the Director of the Authority and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, who will decide whether those particular comments can be included in the evidence which goes before the Appeal Board. It should be noted that the general principle is that anything which the respondent company wishes the Appeal Board to consider has to be made available to the complainant.

The points relating to the extensions of the time allowed set out at 1 above and the comments on documentation at 2 above apply equally here.

4 An appeal by the respondent company – further documentation

When an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons for the appeal (7.5). These comments will go before the Appeal Board and are also sent to the respondent company for information.

The points relating to confidentiality of material set out at 3 above and extensions of the time allowed at 1 above, and the comments on documentation at 2 above, all apply equally here.

5 What papers go before the Appeal Board?

The Appeal Board will have been sent in advance of the appeal hearing a digital volume (or volumes) including the following:

- the complaint and its attachments
- the authority's letter notifying the respondent of the complaint
- the response and its attachments
- the Code of Practice Panel minute
- the Authority's letters notifying the outcome to the parties
- the appeal and its attachments
- subsequent comments by the parties arising from points 3 and 4 above, and their attachments

- copies of published case reports referred to by the parties.

6 Cases appealed by both the complainant and the respondent company

All of the stages described above are followed in relation to cases which involve appeals by both parties. In such a case the Appeal Board will have before it a composite bound volume (or volumes) covering both of the appeals.

7 Hearing by the Appeal Board

When an appeal is considered by the Appeal Board, both the complainant and the respondent company are entitled to appear or be represented (4.6). Neither party is obliged to attend, although respondent companies are usually represented. Although the Appeal Board considers it extremely helpful if appellant companies attend, cases can be dealt with on the basis of written submissions.

The parties are advised in advance of the membership of the Appeal Board (including potential co-opted members) 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 during the consideration of the case. The Chair determines whether objections are valid (4.4). Independent members, including the Chair, are always in a majority. Occasionally the Chair co-opts members so that a quorum can be achieved. Not all members will necessarily be present at any particular meeting.

A member of the Appeal Board who is concerned in a case either as complainant or respondent is not sent the papers and withdraws before consideration commences. Other members are required to declare any interest in a case before it is considered. Having consulted the parties (if present), the Chair decides whether it is appropriate for any particular member to remain for the consideration of the case (4.4).

The members of the Authority, including the Director, Deputy Director and PMCPA managers, are normally present although this is only at the invitation of the Chair and with the prior agreement of the parties involved (3.4). The Executive Officer to the Authority is also present.

Advance notification of the names and job titles of those who will be representing the parties should be given to the Authority. Where there is more than one representative from a party, it is helpful if someone is clearly designated as the leader and that this is made known to the Chair.

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 (4.6). Such consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within the company can properly represent it in the case in question.

If both the complainant and the respondent company appear or are represented, the procedure is that the appellant (whether that be the complainant or the respondent company) is invited to make the first presentation. If more than one point is appealed, they will be taken in the same order as in the Panel's rulings. It is not obligatory to make a presentation though it is customary to do so; sometimes representatives just answer any questions that members of the Appeal Board may have. After the appellant's presentation the other party is invited to make a presentation if they wish and the appellant can then make brief closing comments.

Where both the complainant and the respondent are appellants, the above procedure is still followed. In these circumstances, the points appealed by the complainant are taken first, in the same order as in the Panel's rulings. The points appealed by the respondent are then taken, again in the order in the Panel's rulings.

Where only one party is represented then that party is invited to make a presentation if they wish.

Presentations should be concise, clear and to the point. It should be borne in mind that members of the Appeal Board will already have read the papers in the case (see point 5 above). New material, ie material which has not been included in the papers submitted in relation to the case, cannot be introduced at the hearing (7.4 and 7.5). If there is a possibility that a presentation introduces new material, the relevant party will be asked to identify where in the submitted papers the information can be found. If the information cannot be found in the submitted papers, the relevant party will be asked to remove it from the presentation.

Presentations should normally last no longer than fifteen minutes. If it is considered that fifteen minutes will not be long enough, then this should be raised with the Director as far in advance of the hearing as is possible. Representatives are likely to be asked questions by the Appeal Board after they have made their presentations.

If necessary, the Chair can be asked to adjourn the

hearing for a few minutes so that the representatives of a party can consult between themselves.

If either of the parties at a hearing has any concerns or questions about the Appeal Board's procedures, they must be raised with the Chair at the time rather than after the hearing.

Appeals are heard by the Appeal Board in the offices of the PMCPA or an appropriately chosen venue. Members of the Appeal Board are identifiable by nameplates. The parties are seated opposite the Chair. If both parties are represented, they are seated on either side of the projection screen.

8 Audio-visual aids

Powerpoint projection facilities are available and if they are to be used the numbered slides, to which no subsequent amendments can be made, must be emailed to the Authority three working days before the hearing.

Although there is no obligation, the Chair of the Appeal Board considers it appropriate for each party to have advance sight of any slides which the other party intends to show. When the Authority has received both sets of slides it exchanges them between the parties.

If parties wish to use any audio-visual aids other than Powerpoint they should contact the Authority for guidance.

9 Notification of the outcome of an appeal

When the hearing has been completed, and the representatives have left the meeting, the Appeal Board determines whether the appeal in relation to each particular ruling has been successful or not.

Informal notification of the result is given by telephone soon after the hearing. Formal written notification follows in due course after the minutes of the meeting have been agreed by the Chair.

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself. The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England and Wales, no 09826787 registered office: 7th Floor Southside, 105 Victoria Street, London SW1E 6QT

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