



*National Institute for
Clinical Excellence*

Guidance for

Appellants

Guidance for

Appellants

This document can be made available in large print, braille or audio format on application

Guidance for Appellants

Issue date: June 2001

About the technology appraisal series

This document is one of a set of five, which describe the process the Institute uses to undertake technology appraisals and provide guidance to the organisations invited to contribute to these appraisals.

When a submission to the Institute is being considered or prepared, the statement of process should be read in conjunction with the guidance documents referred to below. All five documents are available on the Institute's website: www.nice.org.uk

Note: Documents 1, 2 and 5 replace the Institute's publication entitled *Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers And Sponsors December 1999*.

Ordering information

These publications can be ordered by telephoning the NHS Response Line on 0870 1555 455 and quoting the relevant reference number below. The price is £10.50 each with a 10% discount for orders between 5 and 50. Discounts for orders over 50 by application to NICE. The five technology appraisal documents are:

Title	Ref. No.
1. Guide to the Technology Appraisal Process	N0010
2. Guidance for Appellants	N0011
3. Guidance for Patient/Carer Groups	N0012
4. Guidance for Healthcare Professional Groups	N0013
5. Guidance for Manufacturers and Sponsors	N0014

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Guidance for Appellants

The National Institute for Clinical Excellence issues guidance to the National Health Service (NHS) on the use of selected new and established health technologies. These technologies are assessed for their clinical effectiveness, cost effectiveness and the wider impact of their use on the NHS. This assessment is carried out by an Appraisal Committee appointed by the Institute to provide advice to the Institute's board. Full details of the appraisal process are contained in the Institute's *Guide to the Technology Appraisal Process*.

At the end of the appraisal process the Appraisal Committee produces a Final Appraisal Determination (FAD) and submits it to the Institute. The FAD will then be considered by the Institute's guidance executive to satisfy itself that the Appraisal Committee has properly appraised the technology in accordance with the terms of the Department of Health/National Assembly for Wales (DH/NAW)'s reference and the Institute's scope. The Institute will distribute the determination, as the Institute's final determination and guidance to the NHS, to all consultees. There is then an opportunity to appeal before the guidance to the NHS is made public and disseminated to the NHS itself. This document provides guidance for those who wish to make an appeal or who wish to consider doing so.

The appeal period

The guidance to the NHS will be provided to consultees to the appraisal ['consultees' are the manufacturer(s) or sponsor(s), the patient/carer and professional groups identified by the Institute at the beginning of the appraisal process, the Department of Health and the National Assembly for Wales, the Health Technology Board for Scotland and selected health authorities]. There will be a period of 15 working days from the day the guidance to the NHS is received by the consultees during which a consultee may appeal to the Appeal Panel ("the appeal period"). The letter from the Institute which accompanies the guidance to the NHS will state the deadline for any appeal. In calculating the deadline Saturdays, Sundays and public holidays in England and Wales will not be counted.

The Health Technology Board for Scotland and the health authorities selected as consultees, do not have the right of appeal.

Confidentiality during the appeal period

The Institute will not publish its guidance to the NHS until the expiry of the appeal period or, if an appeal is lodged, the determination of the appeal. The guidance will be placed, for information only, on the Institute's website 5 working days after it has been sent to the consultees who have appeal rights.

Introduction

Right of appeal

Who can appeal?

An appeal may be made by any of the consultees other than the Health Technology Board for Scotland and the health authorities selected as consultees.

What is the scope of an appeal?

An appeal may relate either to the guidance to the NHS or the way in which the appraisal process has been conducted.

How is an appeal lodged?

An appellant who wishes to appeal should lodge their appeal with the chief executive of the Institute within the appeal period. The documents lodged by the appellant must include the following information:

1. The aspect(s) of the guidance to the NHS or appraisal process being appealed against;
2. The ground(s) of appeal;
3. The basis for the appeal.

The Institute may refuse to entertain an appeal which does not include all of the above information.

On what grounds can an appeal be made?

An appeal must be made on one or more of the specific grounds upon which an appeal can be heard. It is not possible to appeal against the guidance to the NHS simply because the appellant does not agree with it. An appeal will only be heard if it falls under one or more of the following grounds:

1. The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's *Guide to the Technology Appraisal Process*;
2. The Institute has prepared guidance which is perverse in the light of the evidence submitted;
3. The Institute has exceeded its powers.

The Appeal Panel will not consider appeals unless the grounds for appeal are clearly identified and fall within one or more of the grounds set out above.

Will there be an oral hearing?

At the discretion of the Institute's chairman appellants will be given the opportunity to make oral submissions to the Appeal Panel, in addition to any written submissions they may wish to make.

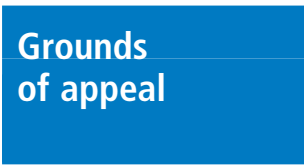
What is the timescale for an appeal?

The Appeal Panel will endeavour to hear an appeal within 28 days of the appeal being lodged.

The Appeal Panel will aim to send its decision to the Institute within 21 days of the hearing, but there may be some circumstances in which a longer interval is necessary. The Institute will then make the full text of the decision available to the appellants and within one week it will be posted on the Institute's website.

The date for hearing any appeal will be confirmed to appellants in the letter accompanying the guidance to the NHS.

An appeal is not an opportunity to reopen arguments and issues upon which the Appraisal Committee has reached a determination. The Appeal Panel will not substitute its own judgment for that of the Appraisal Committee or look afresh at the evidence submitted to the Appraisal Committee. The Appeal Panel has the restricted role of hearing appeals which fall within one or more of the three strictly limited grounds upon which interested parties may appeal. An appeal on any other ground will not be considered.



These grounds are:

1. The Institute has failed to act fairly and in accordance with the appraisal procedure set out in the Institute's *Guide to the Technology Appraisal Process*;
2. The Institute has prepared guidance which is perverse in the light of the evidence submitted;
3. The Institute has exceeded its powers.

Ground One:

The Institute has failed to act fairly and in accordance with the appraisal procedure set out in the Institute's *Guide to the Technology Appraisal Process*

The Institute is committed to following a fair procedure throughout the appraisal process. An appellant who believes they have not been treated fairly by the Institute or the Appraisal Committee may appeal on this ground. This ground relates to the procedure followed and not directly to the content of the Guidance to the NHS and it should be noted that Guidance to the NHS with which the appellant does not agree is not necessarily unfair.

Ground Two:**The Institute has prepared guidance which is perverse in the light of the evidence submitted**

The Institute will not normally entertain an appeal against the merits of the determination reached by the Appraisal Committee or the guidance to the NHS. However, an appellant may appeal where the guidance to the NHS is perverse in the light of the evidence submitted. To be 'perverse' means to be obviously and unarguably wrong, to be in defiance of logic or so absurd that no reasonable Appraisal Committee could have reached such conclusions. The Appeal Panel will not substitute its own judgment for that of the Appraisal Committee but will review the decisions of the Appraisal Committee to see whether or not they are perverse. It should be noted that it is hypothetically possible that two different Appraisal Committees could reach different conclusions on the same evidence without either acting perversely and appellants should not appeal on this ground simply because they disagree with the views or conclusions expressed in the guidance to the NHS.

Ground Three:**The Institute has exceeded its powers**

The Institute is a public body which carries out appraisals in accordance with the Statutory Instruments under which it is established and Directions and guidance issued by the Secretary of State for Health and the National Assembly for Wales. An appellant may appeal on the ground that the Institute has acted outside its remit or has acted unlawfully in any other way.

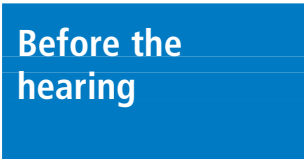
**The Appeal Panel****Who will sit on the Appeal Panel?**

The Board of the Institute will appoint the members of the Appeal Panel. The panel will comprise of 5 members drawn from the Institute's Appeals Committee all of whom will have had no prior involvement in the appraisal in question. The panel will consist of at least one non executive director of the Institute who will chair the appeal, at least one member from within the NHS, one member with experience of the relevant industry or clinical field and one member with experience of patient or carer organisations. The provisional membership of the Appeal Panel will normally be published in advance on the Institute's website. The Institute also intends to inform the appellant(s) of the membership of the Appeal Panel as soon as possible after an appeal has been lodged.

None of the members of the Appeal Panel will have had any prior involvement in the appraisal of the relevant health technology. In appointing the members of the Appeal Panel, the Board will endeavour to ensure that no member has any interest which may give rise to a real danger of bias. Once appointed the Appeal Panel will act impartially and independently of any party to the appraisal including the Appraisal Committee. If an appellant believes that a member of the Appeal Panel has an interest which gives rise to a real danger that he or she may unfairly regard with favour or disfavour the submissions of any appellant then the Appeal Panel should be informed immediately. In these circumstances and if the Appeal Panel considers it necessary, the Appeal Panel may ask the Board to change the membership of the Appeal Panel. Alternatively and with the permission of all those involved the Appeal Panel may proceed with only four members, the member whom it is alleged may be biased standing down.

What will happen before the hearing?

An appeal received from an appellant will be acknowledged by the Institute. The Institute also intends to inform the appellant(s) of the membership of the Appeal Panel as soon as possible. The appellant will be asked to provide the names and positions of the persons who will be attending the hearing on its behalf. It may sometimes be necessary to limit the number of persons attending the appeal.



Initial scrutiny by the chairman of the Board

The appeal documents lodged by an appellant will be scrutinised by the chairman of the Board, who will look to see that they contain the necessary information. The appeal documents must contain the following information:

1. The aspect(s) of the guidance to the NHS or appraisal process being appealed against;
2. The ground(s) of appeal;
3. The basis for the appeal.

If the notice of appeal does not contain the necessary information, or if the appeal does not appear to the chairman of the Board to fall under any one or more of the grounds of appeal, he or she will write to the appellant to request further information or clarification. An appeal will only be referred to the Appeal Panel if, after giving the appellant an opportunity to elaborate or clarify the grounds of appeal, the chairman of the Board is satisfied that the appeal falls under one or more of the grounds upon which the Appeal Panel can hear an appeal. The chairman of the Board may allow the appeal to go ahead on certain grounds but not others.

At the appeal hearing (one party only)

Can new data be submitted to the Appeal Panel?

The grounds of appeal do not allow the Appeal Panel to reconsider the merits of the decision reached by the Appraisal Committee. All data that manufacturers, sponsors, professional organisations and patient organisations consider relevant to the appraisal should be submitted to the Appraisal Committee as part of the appraisal process as set out in the guide to the Technology Appraisal Process. New data or evidence that was not presented before the Appraisal Committee will almost certainly not be relevant to the grounds of appeal, and if this is the case will not be considered by the Appeal Panel.

The Appeal Panel will consider representations in private but its findings will be made public.

Who may attend the hearing?

The appellant may be represented at the hearing by a team comprised of whoever it thinks appropriate. It may sometimes be necessary to limit the number of persons attending the appeal. The appellant may be legally represented if it so desires. The Appeal Panel may also ask representative(s) of the Appraisal Committee and the Institute to attend the hearing if it considers that this would be helpful, but it is not intended that the hearing will be conducted in an adversarial manner. The Appeal Panel may have its own legal adviser present. The role of the Appeal Panel’s legal adviser will be to advise the Appeal Panel on any procedural or legal issues which may arise. The legal adviser will not make any submissions or question any party at the hearing.

Members of the public and the press will not be admitted to the hearing. The Appeal Panel may expel any person from the hearing if the Appeal Panel considers that that person is disrupting proceedings.

How will the hearing be conducted?

The appellant will be allowed a reasonable opportunity to make oral submissions. The Appeal Panel may restrict the amount of time the appellant has to present its submissions. The hearing will be conducted in an inquisitorial rather than an adversarial style. This means that the members of the Appeal Panel may ask the appellant questions on any relevant issue. The appellant’s submissions should be relevant to the grounds of appeal, avoid repetition and be as clear and concise as possible. The Appeal Panel may stop the appellant from making submissions which are irrelevant or repetitious. The representative(s) of the Appraisal Committee or the Institute (if any) may be

asked to comment on the submissions made by the appellant. Any comments made by the representative(s) of the Appraisal Committee or the Institute will be in the presence of the appellant and the appellant will be given an opportunity to respond.

Who may attend the hearing?

Each appellant may be represented at the hearing by a team comprised of whoever it thinks appropriate and may be legally represented if it so desires. If appellants intend to make similar submissions the Appeal Panel will encourage appellants to be jointly represented, particularly if the appellants have legal representation. The Appeal Panel may also ask representative(s) of the Appraisal Committee or the Institute to attend the hearing if it considers that this would be helpful. The Appeal Panel may have its own legal adviser present. The role of the Appeal Panel's legal adviser will be to advise the Appeal Panel on any procedural or legal issues which may arise. The legal adviser will not make any submissions or question any party at the hearing.

At the appeal hearing (multiple parties)

Members of the public and the press will not be admitted to the hearing. The Appeal Panel may expel any person from the hearing if the Appeal Panel considers that that person is disrupting proceedings.

How will the hearing be conducted?

Each appellant will be allowed a reasonable opportunity to make oral submissions. Submissions will be made in the presence of the other appellants unless there are issues of confidentiality (see below). The Appeal Panel may restrict the amount of time an appellant has to present its submissions. This will particularly be the case when there are multiple appellants. The appellants will be treated impartially and with equal regard but will not necessarily be allowed a similar amount of time to make submissions. The relative amount of time allowed to each appellant will be determined by the nature of the submissions they wish to make. The order in which the appellants make their submissions will be determined by the Appeal Panel.

The hearing will be conducted in an inquisitorial rather than an adversarial style. This means that the members of the Appeal Panel may ask the appellant questions on any relevant issue. The appellant's submissions should be relevant to the grounds of appeal, avoid repetition and be as clear and concise as possible. The Appeal Panel may stop the appellant from making submissions which are irrelevant or which repeat what has already been said by that appellant or another appellant.

The representative of the Appraisal Committee (if any) may be asked at any time to comment on the submissions made by the appellants. Any comments made by the representative of the Appraisal Committee will be in the presence of the appellants and the appellants will be given an opportunity to respond.

Dealing with confidential submissions

If an appellant wishes to make submissions which are likely to involve the disclosure of confidential information the Appeal Panel will consider allowing those submissions to be heard in the absence of the other appellants. If an appellant wishes to make such submissions it should inform the Appeal Panel as soon as possible prior to the hearing. The Appeal Panel will be sensitive to the need to protect information in the possession of an appellant which may be confidential and commercially sensitive but will balance this consideration against the counter-consideration that a hearing in the absence of the other appellants will deprive the other appellants of the opportunity to respond. If the Appeal Panel is convinced that the disclosure of confidential information is likely to be necessary in order to make an effective submission it will allow the submission to be made in the absence of the other appellants. Such a hearing will only be granted in relation to specific submissions and any other submissions will be heard in the presence of the other appellants.

After the appeal hearing

After the hearing the Appeal Panel will withdraw to deliberate in private. The appellants will be notified of the Appeal Panel's decision in writing by the Institute.

What happens next?

The Appeal Panel will aim to send its decision to the Institute within 21 days of the hearing, but there may be some circumstances in which a longer interval is necessary. The Institute will then make the full text of the decision available to the appellants and within one week it will be posted on the Institute's website.

If the appeal is dismissed the Institute will make arrangements to issue the guidance to the NHS. If the appeal is upheld the Institute will consider the appropriate course of action. In most cases the Appraisal Committee will be asked to reconsider the evidence and the appraisal process will resume at Step 15 as described in *Guide to the Technology Appraisal Process* (the second meeting of the Appraisal Committee, following consultation on the appraisal consultation document).

The Technology Appraisals Process Series

1. Guide to the Technology Appraisal Process
2. **Guidance for Appellants**
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