

The technology appraisal appeal process

December 2009

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1 Introduction

1.1 *Background*

1.1.1 The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. Further details about NICE and its programmes of work are available in 'NICE: our guidance sets the standard for good healthcare', which can be downloaded from the NICE website (www.nice.org.uk/aboutnice/standardsforgoodhealthcare).

1.2 *The purpose of this document*

1.2.1 This document sets out the process that NICE follows for an appeal in the context of the NICE technology appraisal process. It provides guidance for those who wish to make an appeal or who are considering doing so.

1.2.2 This document should be read in conjunction with NICE's technology appraisal process guides, available from the NICE website (www.nice.org.uk/aboutnice/howwework/devnicetech/developing_nice_technology_appraisals.jsp).

1.3 *The technology appraisal process*

1.3.1 NICE issues guidance to the NHS on the use of selected new and established health technologies. These technologies are assessed for clinical and cost effectiveness for use in the NHS. Technologies are assessed by independent appraisal committees appointed to advise NICE.

1.3.2 During NICE's technology appraisal process, consultees are organisations that accept an invitation to participate in the appraisal. They include: national groups representing patient and carers, organisations representing healthcare professionals,

manufacturer(s) or sponsor(s) of the technology, the Department of Health, the Welsh Assembly Government, specialised commissioning groups, and primary care trusts and local health boards. Consultees are invited to make submissions to the appraisal and comment on a number of consultation documents. All non-manufacturer/sponsor consultees are invited to nominate clinical specialists and/or patient experts to orally present their personal views to the Appraisal Committee. Manufacturer/sponsor consultees can also nominate clinical specialists. Representatives from the primary care trusts and local health boards invited to participate in the appraisal may also attend the Appraisal Committee meeting as NHS commissioning experts. All consultees also have the opportunity to appeal against the Appraisal Committee's final recommendations to NICE about the use of a technology (the final appraisal determination or 'FAD').

- 1.3.3 As part of the technology appraisal process, commentator organisations with an interest in the technology are invited to take part in the appraisal. They include: manufacturers of comparator technologies, NHS Quality Improvement Scotland, the relevant National Collaborating Centre (a group commissioned by NICE to develop clinical guidelines) and/or the relevant Programme Development Group for public health guidance, other related research groups and other groups (such as the NHS Confederation, Social Services and Public Safety for Northern Ireland, professional or patient organisations covering Wales only). Commentators are invited to comment on consultation documents, but are not asked to make any submission to the appraisal. Commentator organisations representing non-manufacturers/sponsors can nominate clinical specialists and patient experts to orally present their personal views to the Appraisal Committee. Comparator manufacturer/sponsor commentators can also nominate clinical specialists. These

organisations receive the FAD for information only, without right of appeal.

- 1.3.4 At the end of the technology appraisal process the Appraisal Committee produces the FAD. The FAD is considered by the NICE Guidance Executive on behalf of the NICE Board, which comprises NICE's executive directors, centre directors, implementation director and communications director. The Guidance Executive checks that the Appraisal Committee has properly appraised the technology in accordance with the terms of the Department of Health's referral and NICE's scope. NICE then sends the FAD to all consultees and commentators. Consultees have the opportunity to appeal against the FAD before it is published as guidance and disseminated to the NHS.

1.4 Patient access and flexible pricing schemes

- 1.4.1 The Association of the British Pharmaceutical Industry (ABPI) and the Department of Health published their agreement on a new Pharmaceutical Price Regulation Scheme (PPRS) in January 2009 (www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS). The 2009 PPRS allows manufacturers to submit proposals for patient access and flexible pricing schemes as part of an ongoing or published NICE technology appraisal.
- 1.4.2 Patient access schemes are proposed by a pharmaceutical company and agreed between the Department of Health (with input from NICE) and the pharmaceutical company. They improve the cost effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines.
- 1.4.3 Flexible pricing schemes recognise that the initial launch indication of a medicine may not fully reflect its longer-term value to patients in the NHS. It therefore allows a company to propose an initial price for a medicine that reflects value at launch. However, companies

retain the freedom to increase or decrease this original list price either as further evidence or as new indications for the medicine emerge and the effective value that the medicine offers to NHS patients changes.

- 1.4.4 NICE can only consider patient access and flexible pricing schemes after formal referral by the Department of Health.
- 1.4.5 Patient access schemes are designed to maximise the opportunity for access to a new technology. Therefore, within 16 weeks of guidance publication, a rapid review facility is available to consider new patient access schemes. NICE can only consider these schemes after ministerial approval and confirmation by the Department of Health. After approval, the rapid review of the guidance is planned, as a priority, into the work programme.
- 1.4.6 Appeals following the rapid review of guidance, when consideration of the impact of patient access scheme proposals on current guidance has resulted in a change to the guidance, will only be accepted on points relating to the new patient access scheme. The Appeal Panel will not consider points previously raised or points that could have been raised at earlier appeals. Subject to any appeal by consultees, the FAD forms the basis of NICE guidance on the use of the technology.
- 1.4.7 If NICE receives a flexible pricing scheme proposal for an existing indication within 12 months of guidance publication, NICE will consider the impact of new evidence and the flexible pricing scheme on the clinical and cost effectiveness of the technology.
- 1.4.8 NICE will issue the FAD to consultees, along with the consultation response to the appraisal consultation document (ACD), for appeal. Appeals will be accepted only on points relating to the flexible pricing scheme proposals. The appeal will not consider points previously raised or points that could have been raised at an earlier

appeal. Subject to any appeal by consultees, the FAD forms NICE's updated guidance on the use of the technology.

- 1.4.9 For further details, see NICE's technology appraisal process guides (see www.nice.org.uk/aboutnice/howwework/devnicetech/developing_nice_technology_appraisals.jsp).

1.5 Overview of the appeal process

- 1.5.1 Figures 1 and 2 outline the steps involved in the oral and written appeal process.
- 1.5.2 NICE has a standing Appeal Committee, which is appointed by the NICE Board. The Appeal Committee is chaired by the vice chair of NICE and consists of non-executive directors of NICE, NHS representatives, representatives with experience of the relevant industry or clinical field, and representatives with experience of patient or carer organisations. Each appeal is considered by an Appeal Panel, the members of which are appointed from the Appeal Committee.
- 1.5.3 Consultees have 15 working days from the day the FAD is issued to consultees and commentators in which to make an appeal. Appeals must be submitted in writing, in the manner described in this document, and must fall within one or more of the three grounds of appeal. Appeals lodged are initially considered by the chair of the Appeal Committee.
- 1.5.4 Assuming that the appeal is valid (see section 3.4), the Appeal Panel will aim to hold the appeal hearing within 10 weeks of the end of the appeal period.
- 1.5.5 An appeal can be considered at an oral hearing or by written submission alone.
- 1.5.6 After both the oral and written appeal hearing, the Appeal Panel will aim to send its decision to NICE within 15 working days of the

hearing. The NICE Guidance Executive will then consider any actions that need to be taken.

Figure 1 Summary of the oral appeal process

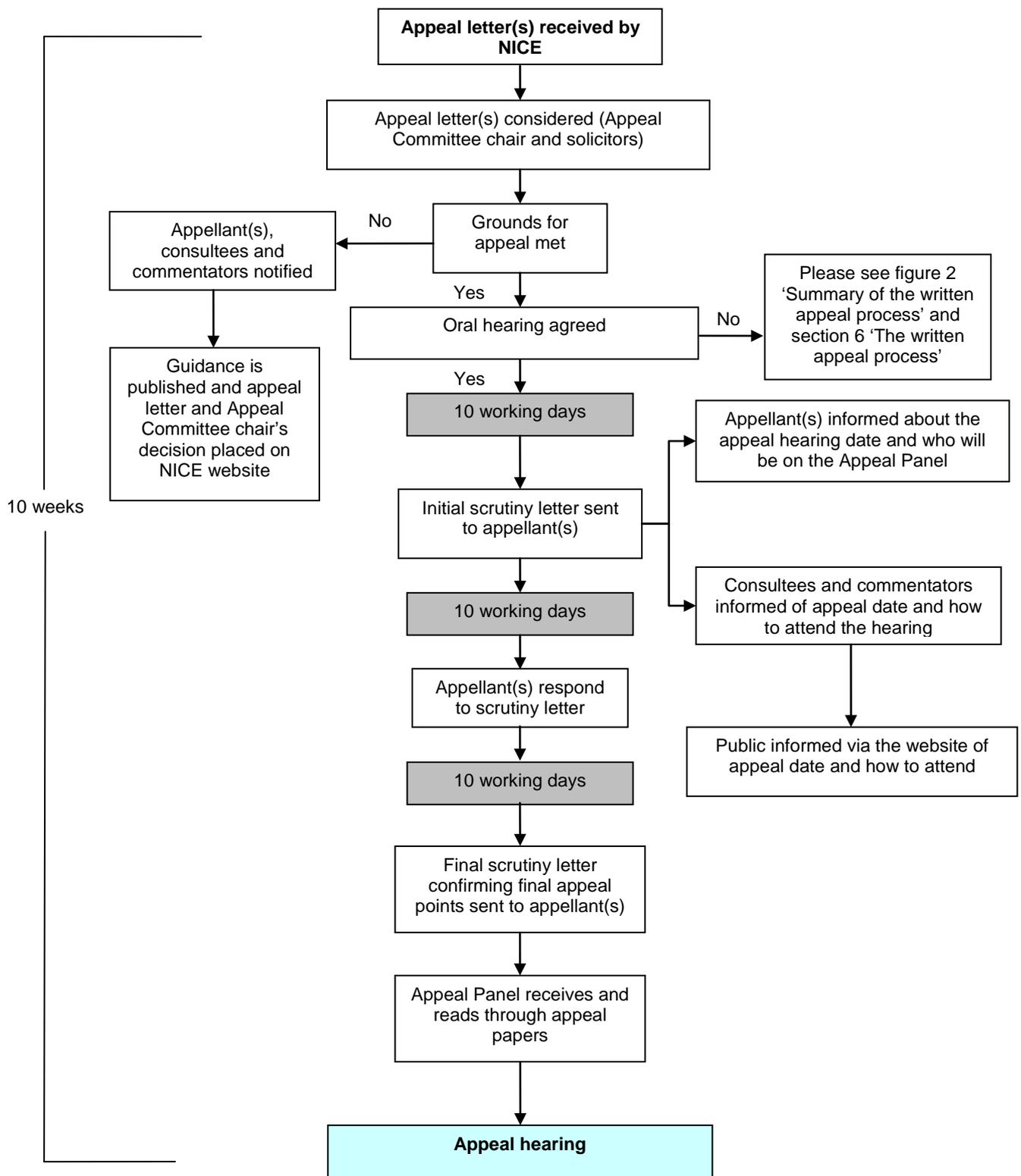
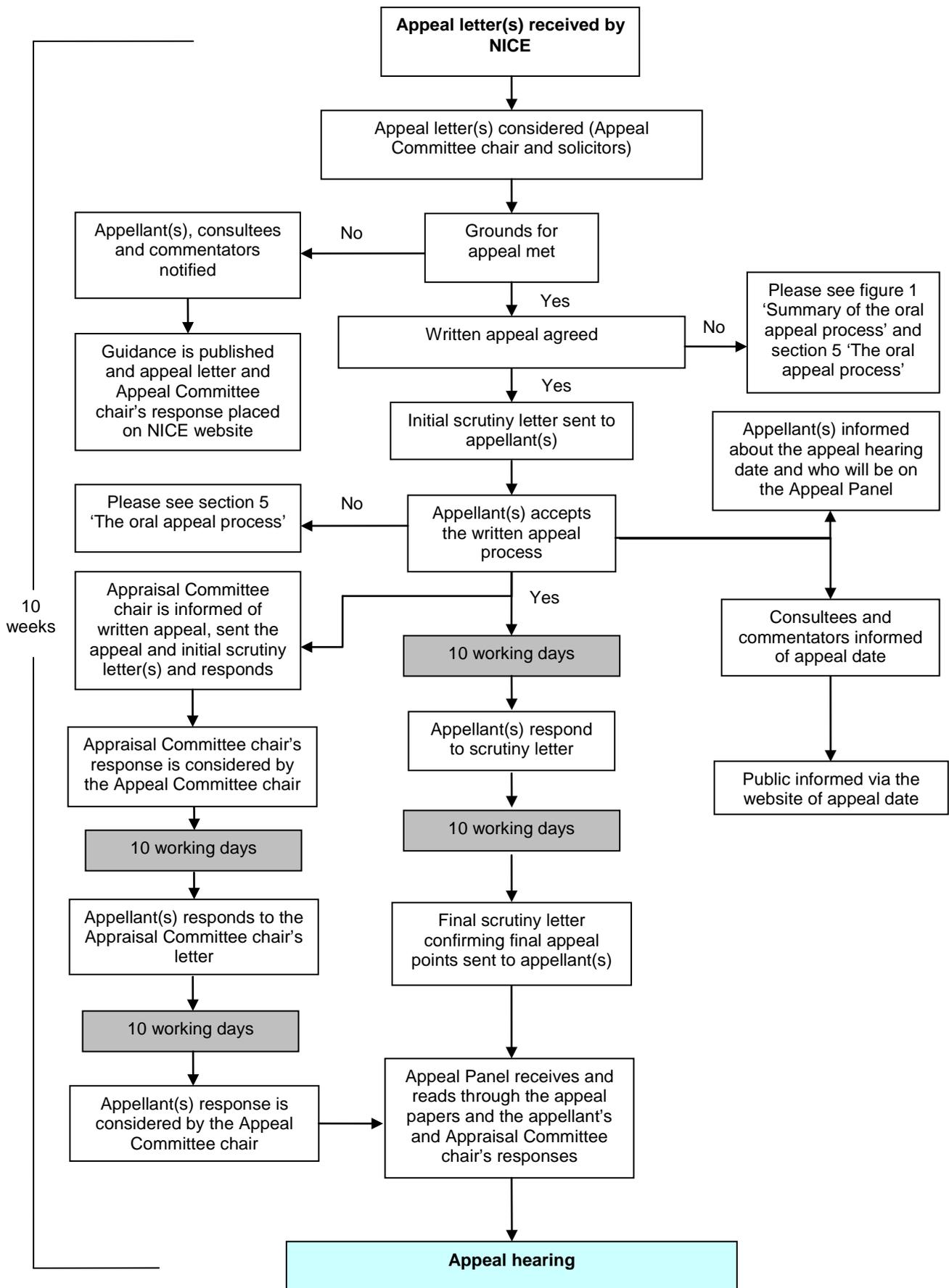


Figure 2 Summary of the written appeal process



2 The appeal period

- 2.1.1 A consultee may appeal to NICE within 15 working days from the day the FAD is issued to consultees and commentators. This is the appeal period. The letter from NICE that accompanies the FAD states the deadline for appeal.
- 2.1.2 The FAD is placed, for information only, on the NICE website 5 working days after it has been sent to the consultees and commentators.
- 2.1.3 NICE does not issue technology appraisal guidance to the NHS until after the appeal period or, if an appeal is lodged, until after the resolution of the appeal.

3 Making an appeal

3.1 *Who can appeal?*

- 3.1.1 An appeal can be made by any of the appraisal's consultees. A consultee is referred to as an appellant once an appeal has been lodged.

3.2 *What is the scope of an appeal?*

- 3.2.1 Generally the Appeal Panel will not rehear evidence or be persuaded by repetition of points previously made by the appellant and considered by the Appraisal Committee unless it can be shown that one or more of the three grounds of appeal (see section 3.4) is also valid.
- 3.2.2 An appeal may relate only to sections 1–4 of the FAD itself, or the way in which the appraisal process was conducted. An appeal cannot be lodged against other documents produced during the appraisal (for example, the ACD, overview or scope), nor against

sections 5–8 of the FAD because they do not relate directly to the guidance.

- 3.2.3 Requests for corrections of minor factual or typographical errors are not normally considered at an appeal and will be looked at separately. For full details of correction of factual errors, see NICE’s technology appraisal process guides (www.nice.org.uk/aboutnice/howwework/devnicetech/developing_nice_technology_appraisals.jsp).

3.3 *How is an appeal lodged?*

- 3.3.1 Consultees must lodge appeals in writing with the appeal project manager or by email to appeals@nice.org.uk within the appeal period.

3.4 *On what grounds can an appeal be made?*

- 3.4.1 The Appeal Panel can only consider appeals that fall within one or more of the three strictly limited grounds listed below. Appeals on any other grounds will not be considered.

The grounds of appeal are:

Ground one: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute’s technology appraisals process guides.

Ground two: NICE has formulated guidance which cannot reasonably be justified in light of the evidence submitted.

Ground three: The Institute has exceeded its powers.

3.5 *The grounds of appeal*

Ground one – The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute’s technology appraisals process guides

- 3.5.1 NICE is committed to following a fair process throughout the technology appraisal process. An appellant who believes that they have not been treated fairly by NICE or the Appraisal Committee because the process has not been followed as set out in the NICE technology appraisal process guides may appeal on this ground. This ground relates only to the fairness of the process followed and not to the content of the FAD. It should be noted that a FAD with which an appellant does not agree is not unfair for that reason. For example, although it would be unfair to exclude a relevant data set from the appraisal process, it would not be unfair if the FAD does not itself set out the arguments for and against a particular data set.
- 3.5.2 This ground of appeal does not cover unfairness in the colloquial sense, for instance that it is ‘unfair’ to patients not to provide a treatment.
- 3.5.3 Unsubstantiated allegations of general unfairness, for example the alleged inability to understand a conclusion, will not be accepted as a valid appeal point. Details and evidence must be provided in every case. For example, if it is claimed that an appellant cannot understand the reasons for a conclusion, and so could not respond to a consultation, the appellant must first set out the range of possible reasons that they considered may have applied, then explain why they are unable to distinguish which was the correct reason, and finally indicate why that has affected their ability to participate fairly in the consultation.
- 3.5.4 NICE requires appellants to explain what steps they took to resolve any unfairness promptly at the time it arose, and the Appeal Panel

may interpret the absence of any such steps, without sufficient reason, as evidence that there was in fact no such unfairness.

- 3.5.5 Appellants will need to demonstrate why the expert and professional resources available to them did not enable them to resolve any unfairness at the time it is said to have arisen.

Ground two – NICE has formulated guidance which cannot reasonably be justified in light of the evidence submitted

- 3.5.6 NICE will not accept an appeal because a consultee does not agree with the views or conclusions in the FAD. However, a consultee may appeal if they consider that the guidance in a FAD cannot reasonably be justified. This ground means that the guidance is obviously and unarguably wrong, illogical, or so absurd that a reasonable Appraisal Committee could not have reached such conclusions. The Appeal Panel will not make new judgements about the technology, but will review the Appraisal Committee's decisions to see if they can reasonably be justified, based on the evidence that was available to the Appraisal Committee. It should be noted that it is possible that two different appraisal committees could reach different conclusions based on the same evidence without acting unreasonably.

Ground three – The Institute has exceeded its powers

- 3.5.7 NICE is a public body. It carries out technology appraisals in accordance with the statutory instruments under which it was established and directions and guidance issued by the Secretary of State for Health. An appellant may appeal on the ground that NICE has acted outside its remit or has acted unlawfully.

3.6 *What must the appeal letter contain?*

- 3.6.1 The appeal letter is the appellant's first opportunity to present their appeal to the chair of the Appeal Committee. It is important that the appeal letter is submitted correctly, is presented clearly and contains the necessary information, as explained below. If the letter

received is not appropriate (for example, the letter does not have sufficient supporting information or the relevance of the appeal points is unclear), there is a possibility that the appeal will be dismissed as 'not valid' because it does not fall within one or more of the grounds of appeal. The appeal letter requirements are stated in this section.

- 3.6.2 The appeal letter must contain an introductory statement clearly indicating the FAD that is to be appealed and on which of the permitted grounds the appeal is being made. For complex appeals, or if a notice of appeal is longer than five A4 pages, appellants are asked to produce an executive summary of the appeal. This should be no longer than one page of A4.
- 3.6.3 The appeal letter must clearly and succinctly set out the appellant's points of appeal in detail. Appeal points must be made in order of the ground to which they relate, that is, all appeal points made under ground one must be made first, followed by all points made under ground two, and concluding with all points made under ground three.
- 3.6.4 Appeal letters must be sufficiently comprehensive that the Appeal Panel can understand all points being raised.
- 3.6.5 Each point must be headed with the appeal ground to which it relates, and a one-sentence description of the appeal point. For example:
- 1.1 *Ground one: the Appraisal Committee's refusal to base its recommendations on a comparison with [name of drug], a routine treatment for the condition in question, is contrary to NICE's procedures [relevant section of the technology appraisal process guide]*

- 3.6.6 Appellants who wish to appeal under ground one must refer to the relevant NICE process document (including the specific paragraph number) that has allegedly been contravened.
- 3.6.7 Each appeal point must be numbered so that the first appeal point under ground one is numbered 1.1 with subsequent ground one points numbered 1.2, 1.3, and so on. The same numbering will apply for ground two and three points. It is not necessary to number individual paragraphs in the appeal letter, but if the appellant considers that this aids clarity, the numbering should follow the numbering of the appeal point in question. For example, if there are three paragraphs detailing the argument under appeal ground one, they should be numbered 1.1, 1.2 and 1.3.
- 3.6.8 The Appeal Panel only considers the exact grounds and arguments as set out in the appeal letters, and appellants should prepare their appeal letters accordingly. The grounds for appeal are quite distinct and are set out in section 3.4. Appellants are therefore advised to consider carefully which ground of appeal any given complaint relates to. In particular, it is unhelpful to submit complaints that are essentially about the substance of guidance under ground one. If the context for different appeal points overlaps, it is not necessary to repeat the same facts under more than one appeal point, but appellants must set out the argument they wish to make under each ground in detail. They must not refer the Appeal Panel to earlier text without clearly indicating how that text relates to the current appeal point. For instance, it is not acceptable to state under ground two: *'The appellant repeats the points made under point 1.1 above.'* But it is acceptable to state *'The appellant argues that the facts set out at point 1.1 above also demonstrate perversity in that...'*
- 3.6.9 The chair of the Appeal Committee will not consider appeals unless the grounds for appeal are clearly identified, fall within one or more of the grounds set out in sections 3.4 and 3.5, and are arguable.

- 3.6.10 If the appeal letter contains commercial-in-confidence or academic-in-confidence information, the appellant will be responsible for ensuring that this information is clearly labelled or that a second version of the appeal letter is submitted with the commercial-in-confidence or academic-in-confidence information removed.
- 3.6.11 The letter must conclude with a final statement indicating whether the appellant wishes to be heard at an oral or a written appeal, should one take place. The chair of the Appeal Committee will make this decision at their discretion; however the appellant's preference will be taken into account.
- 3.6.12 In summary the appeal letter must include the following information:
- the ground(s) of the appeal
 - the aspect(s) of the guidance or appraisal process being appealed against
 - the reasons why the aspect(s) of the guidance or appraisal process being appealed against fall within the specified ground(s) of appeal, in enough detail to demonstrate an arguable case
 - the concluding statement indicating whether the appellant wishes to be heard an at oral or written appeal.
- 3.6.13 The chair of the Appeal Committee will respond to each appeal letter to indicate his or her preliminary view of the arguability and validity of each of the points made by the appellant, as set out in section 4.4. This response is known as an initial scrutiny letter.

3.7 *Can new data be submitted to the Appeal Panel?*

- 3.7.1 All data that consultees consider relevant to the appraisal should be submitted to the Appraisal Committee as part of the appraisal process as described in the NICE technology appraisal process guides. New evidence or information that was not before the Appraisal Committee, or re-analysis of existing evidence or

information, must not be presented in the appeal letter, and will not be considered by the Appeal Panel.

3.7.2 An appeal is not an opportunity to reopen arguments and issues that the Appraisal Committee has decided on. It is not possible to appeal against a FAD because a consultee does not agree with it.

3.7.3 Generally the Appeal Panel will not rehear evidence or be persuaded by repetition of points previously made by the appellant and considered by the Appraisal Committee unless it can be shown that one or more of the three grounds of appeal (see section 3.4) is also valid.

4 Conduct of an appeal

4.1 *Will there be a hearing?*

4.1.1 The chair of the Appeal Committee decides whether an oral hearing or written appeal would be appropriate. Appeals may be conducted using a written process if this is fair. This is more likely for appeal points that are discrete and/or where few points are in dispute.

4.2 *What is the timescale for an appeal?*

4.2.1 Assuming that the appeal is valid (see section 3.5), the Appeal Panel aims to hold the appeal within 10 weeks of the end of the appeal period.

4.3 *Who sits on the Appeal Panel?*

4.3.1 The Appeal Panel comprises five members drawn from NICE's Appeal Committee. Each Appeal Panel is chaired by a non-executive director of NICE. It includes two other non-executive directors of NICE, or one non-executive director of NICE and one NHS representative. In addition, the Appeal Panel includes someone with experience of the relevant industry or clinical field,

and someone with experience of patient or carer organisations. NICE informs appellants who will be in the Appeal Panel as soon as possible.

4.3.2 None of the members of the Appeal Panel will have had any previous involvement in the technology appraisal being appealed against. Before being appointed to the Appeal Panel, members must declare conflicts of interest in accordance with NICE's code of practice. When appointing the Appeal Panel, the Appeal Committee chair ensures that no member has any interest that may give rise to bias. Once appointed, the Appeal Panel acts impartially and independently of any party involved with the appraisal, including the Appraisal Committee. If an appellant believes that a member of the Appeal Panel has an interest that means that he or she may favour or disfavour the submissions of any appellant, they should inform the chair of the NICE Board within 10 working days of receiving the letter, listing the relevant Appeal Panel members. In these circumstances, if the Appeal Panel considers it necessary, it may ask the chair of the NICE Board to change its membership.

4.3.3 All five members of the Appeal Panel must be present for the appeal. However, if a member is unable to attend or has to stand down at short notice, the chair of the Appeal Panel will consult with the appellant(s). If the appellant(s) agree, the appeal will continue with only four members of the Panel, and this will be noted in the Appeal Panel decision.

4.4 *Initial scrutiny by the chair of the Appeal Committee*

4.4.1 NICE acknowledges receipt of appeal within 2 working days of the deadline for appeals. The chair of the Appeal Committee writes to the appellant within 10 working days of receiving the notice of appeal.

4.4.2 The chair of the Appeal Committee will respond to each appeal letter to indicate his or her preliminary view of the arguability and

validity of each of the points made by the appellant. In doing so he or she may take legal advice. This response is known as the initial scrutiny letter. Following this, the appellant will be informed whether the Appeal Committee chair has decided the appeal should be oral or whether it could take the form of a written appeal (see section 4.4.9).

- 4.4.3 If the notice of appeal does not contain the necessary information or if the chair of the Appeal Committee does not believe it presents an arguable case under one or more of the grounds of appeal, he or she may request further information or clarification in the initial scrutiny letter. Appeals are only referred to an Appeal Panel if, after giving the appellant an opportunity to elaborate or clarify the grounds of appeal, the chair of the Appeal Committee is satisfied that the appeal falls into one or more of the grounds as set out in sections 3.4 and 3.5, and are arguable. The chair of the Appeal Committee has the discretion to allow the appeal to go ahead on one or more grounds presented in any appeal letter but not others.
- 4.4.4 In determining the prospects of success of appeal points, the chair of the Appeal Committee has regard to and is guided by past decisions of the Appeal Panel, but is not strictly bound by them. The chair gives greater weight to past decisions on legal or quasi-legal issues, and less weight to decisions on factual issues. For example, a finding that guidance should consider any significant groups of patients with disabilities who may be unable to take a treatment being recommended is likely to be given weight in future appeals. This is a finding on a legal issue. A finding that some specific aspect of guidance was or was not perverse is unlikely to be given much weight in a future appeal. This is only a finding about the facts of one appraisal.
- 4.4.5 The chair of the Appeal Committee will not suggest reallocating grounds of appeal if the issues raised seem weak under the nominated ground, and may be stronger under a different ground,

unless the chair considers that an appellant may genuinely be in need of assistance.

- 4.4.6 Appellants are given 10 working days to respond to the initial scrutiny letter. Responses to this letter must not contain new points of appeal. Responses must deal only with requested clarifications, or arguments or comments about the chair of the Appeal Committee's concern that an appeal point raised has no reasonable prospect of success, is unsupported by evidence, or is outside the scope for an appeal. Existing appeal points may be elaborated and further evidence in support of existing appeal points may be given. Responses received after the deadline may not be considered, and a final decision may be taken without their being taken into account. There may be occasions when further clarification is needed and more than one scrutiny letter may be sent.
- 4.4.7 The appellant must not submit a revised appeal letter in response to comments in the initial scrutiny letter (for example, the appellant must not move and renumber appeal points to clarify what appeal points were being made if the original letter was insufficiently clear), unless invited to do so.
- 4.4.8 If the appellant is invited to submit a revised appeal letter, it must not contain new grounds of appeal. The numbering of the original letter should be preserved as far as possible or clearly indicate when an appeal point has changed number (for example, 2.4 [formerly 1.2] if an appeal point changes from ground one to ground two) or held to have no reasonable prospect of success (for example, 2.3 [not used]).
- 4.4.9 During the scrutiny process the chair of the Appeal Committee may suggest that the appeal could be conducted appropriately by reviewing the papers, without the need for an oral hearing. This

process will only be adopted after consultation with the appellant(s) involved and will result in a written appeal.

4.5 *What happens after initial scrutiny?*

- 4.5.1 If the initial scrutiny letter indicates that there are valid appeal points, NICE informs the appellant(s) who will be on the Appeal Panel, the NICE Panel (representatives of the Appraisal Committee and members of NICE), and the date of the appeal hearing, as soon as possible. This occurs whether the hearing is oral or written. In the case of an oral appeal hearing the appellant is asked to provide the names and job titles of the representatives who will be attending the hearing. It may be necessary to limit the number of representatives attending the appeal.
- 4.5.2 NICE informs consultees and commentators that an appeal has been received and the date of the appeal hearing. NICE publishes a notice on its website announcing that an appeal will take place at least 2 working days after consultees and commentators are informed of the date of the appeal hearing.

4.6 *Final scrutiny by the chair of the Appeal Committee*

- 4.6.1 The chair of the Appeal Committee writes to the appellant with the final decision on the admissibility of the appeal points raised after considering the appellant's response to the initial scrutiny letter. This is known as the final scrutiny letter.
- 4.6.2 The final scrutiny letter is the chair's final word and a further response cannot be submitted by the appellant. That letter will outline all of the appeal points that will be considered at the appeal and may also make specific directions for the conduct of an appeal, if necessary.

5 The oral appeal process

5.1 *Who may attend the hearing?*

5.1.1 Oral appeal hearings are open to consultees, commentators, members of the public and the press. Holding appeal hearings in public is part of NICE's commitment to openness and transparency. It enables stakeholders and the public to better understand the appeal hearing process at NICE.

5.1.2 To promote public attendance NICE publishes a notice on its website announcing that an appeal will be heard for a technology appraisal, and opens the registration to attend the appeal hearing at least 20 working days before the hearing. At this point, consultees, commentators, members of the public and press may register on the NICE website to attend the hearing. Up to 20 places will be available, depending on the size of the venue. Once registration has closed, NICE will contact all the applicants. The successful applicants will receive an invitation to the hearing and documents related to the technology appraisal under discussion. Requests to attend are granted on a first-come, first-served basis, although priority is given to members of the public who are not employed by the appellant(s). To allow wide public access, NICE reserves the right to limit the number of representatives per organisation. The press and public are not allowed to participate in the discussions, record the appeal proceedings (video or audio), or take photographs in the premises in which the hearing is held. The Appeal Panel chair may exclude any person from the hearing if the Panel considers that that person is disrupting proceedings.

5.1.3 Each appellant is allowed up to five representatives at the hearing, including legal representation if they wish. This number may be reduced if there are more than three appellants against the FAD. If appellants intend to make similar statements, the Appeal Panel will

encourage them to be jointly represented, particularly if they have legal representation.

- 5.1.4 The Appeal Panel may have its own legal adviser present to advise on any procedural or legal issues that may arise.

5.2 *How is the hearing conducted?*

- 5.2.1 On the morning of the appeal, the notice of appeal, the scrutiny letters from the Appeal Committee chair and responses to these letters are placed on the NICE website. Any confidential information and personal data are removed before publication on the website.

- 5.2.2 At the appeal hearing, each appellant is allowed to make a brief 5-minute introductory statement. Visual aids such as Microsoft PowerPoint presentations are not accepted. The NICE Panel is also invited to make an introductory statement of similar length. The order in which appellants present appeal points is at the discretion of the Appeal Panel chair. Statements are made in the presence of the other appellants, the public and the press unless there are issues of confidentiality (see section 5.3). Appellants are treated impartially and will each be given a fair opportunity to make their statement, but are not necessarily allowed a similar total amount of time to make statements. The amount of time given to each appellant is determined by the nature of the statements they wish to make and the need for the Appeal Panel to manage the hearing efficiently and fairly. The chair of the Appeal Panel may stop appellants from making statements that are irrelevant, or that repeat something already said by that or another appellant. Each appellant and the NICE Panel are also invited to make a brief concluding statement before the hearing ends.

- 5.2.3 Hearings are conducted in an inquisitorial rather than an adversarial style. This means that members of the Appeal Panel may ask appellants questions on any relevant issue. All questions must be made to the chair; appellants and NICE Panel

representatives do not question each other directly. Appellants' statements should be relevant to the grounds of appeal, avoid repetition and be as clear and concise as possible.

5.2.4 Appellants should not expect to be allowed to make a statement in connection with every appeal point. Points may be dealt with by way of questions from the Appeal Panel, or, if the Panel is confident it has understood the arguments on each side, may not be specifically raised in oral argument at all.

5.2.5 The NICE Panel may be asked at any time to comment on the appellants' statements. Any such comments are made in the presence of the appellant and the appellant is given an opportunity to respond.

5.3 Confidential submissions

5.3.1 If an appellant wishes to make statements that involve disclosing confidential information, the Appeal Panel will allow them to be heard in private (that is, in the absence of the other appellants, the public and the press) if they fall within the conditions set out in section 5.3.2.

5.3.2 An appellant who intends to make confidential submissions should inform the appeals project manager 15 working days before the appeal hearing. The Appeal Panel will be sensitive to the need to protect confidential and commercially sensitive information, but will balance this against the fact that a private hearing would deny the other appellants and the public of the opportunity to listen (and in the case of any other appellants, to respond) and would reduce the transparency of the process. Appellants should not rely on confidential information in their appeal letters and statements if their appeal could be supported equally strongly by information in the public domain. The Appeal Panel will only allow a statement to be made in private if it is satisfied that the disclosure of confidential information is necessary for an effective appeal hearing. In

addition, a private hearing will only be granted for specific submissions for which that test is satisfied; any other submissions will be heard in public.

6 The written appeal process

6.1 *How is the written appeal process conducted?*

6.1.1 All communication for written appeals is done in writing. The chair of the Appeal Committee scrutinises the notice of appeal and requests clarification. The appellant has the opportunity to respond to the initial scrutiny letter to clarify and confirm the grounds to be discussed during the appeal process. Once the grounds for appeal have been determined and the appellants have been consulted on a written appeal, the correspondence is forwarded to the chair of the Appraisal Committee, who has the opportunity to respond to the notice of appeal with respect to the grounds agreed in the scrutiny letter. This response is sent to the appellant, who is given the opportunity to respond to the Appraisal Committee chair's comments. All of this correspondence, along with the technology appraisal documents, is then provided to the Appeal Panel. The Appeal Panel meets to consider the submissions received.

6.1.2 On the morning of the appeal, the notice of appeal, the Appeal Panel scrutiny letter and responses to these letters are placed on the NICE website. Any confidential information and personal data are removed before publication on the website.

6.2 *Who may attend the appeal?*

6.2.1 The Appeal Panel convenes to discuss the appeal lodged and the Appraisal Committee chair's response. This meeting may be in person or via teleconference. The Appeal Panel may take legal advice if necessary. No appellants, Appraisal Committee members, NICE staff, press or public will be in attendance at this meeting.

7 Rejected appeals

- 7.1.1 If all grounds of appeal have been rejected at initial scrutiny and an appeal hearing (oral or written) will not be held, the appellant and consultees and commentators will be informed and the appeal letter and Appeal Committee chair's response will be placed on the NICE website at the time of guidance publication.

8 Multiple appeals against a FAD

- 8.1.1 Following the outcome of an appeal, a consultee may choose to lodge another appeal against the FAD of the same technology appraisal. This can only happen if, following the appeal hearing, the Appeal Panel decides that the FAD is to be returned to the Appraisal Committee for consideration.
- 8.1.2 The technology appraisal will be returned to the technology appraisal process and work will start on redeveloping the guidance as advised by the Appeal Panel and agreed by the NICE Guidance Executive.
- 8.1.3 The Appraisal Committee will meet to consider the Appeal Panel's decision. The technology appraisal will either return to the Appraisal Committee meeting to redevelop the ACD or to redevelop the FAD. When a FAD is produced, it will be distributed to consultees and commentators, as previously stated (section 1.3.4). Consultees will have another opportunity to appeal against this FAD before it is published as guidance and disseminated to the NHS. They can also highlight any factual errors.
- 8.1.4 If an appellant from the first appeal lodges another appeal, the appeal letter must not raise the same points presented in the first appeal or those points presented by another appellant at the first appeal hearing. The Appeal Panel will have already determined the outcome on these points.

- 8.1.5 If an appellant who did not participate in the first appeal hearing lodges an appeal, the appeal will need to satisfy that one or more of the grounds have been met and have reasonable prospect of success. The appeal process will follow its usual process as set out in section 4 and continue as either an oral or written appeal.

9 After the appeal hearing

9.1 *What is the timescale for the appeal decision?*

- 9.1.1 In both the oral and written appeal processes, the Appeal Panel will aim to send its decision in writing to the NICE Chief Executive within 15 working days of the appeal hearing. There may be circumstances in which more time is needed. The appeal decision is then considered by the Guidance Executive. Figure 3 summarises the appeal process from the release of the appeal decision to its publication as well as the publication of the guidance.

9.2 *Outcome of an appeal*

Appeal upheld and FAD returned to the Appraisal Committee

- 9.2.1 If one or more of the appeal points are upheld and it is necessary for the FAD to be returned to the Appraisal Committee, the Guidance Executive will aim to consider the appeal decision within 10 working days. The appeal decision is normally published within 15 working days of its consideration by the Guidance Executive. Consultees (including appellants) and commentators are informed of the appeal decision and details of when the FAD will be reconsidered by the Appraisal Committee 2 working days before publication of the appeal decision.

Appeal Panel requests changes to the FAD but no further consideration by the Appraisal Committee

- 9.2.2 If the Appeal Panel requests that the Guidance Executive makes changes to the FAD that do not require further consideration by the Appraisal Committee, the Guidance Executive will aim to consider

the appeal decision within 10 working days. The final guidance is normally published on NICE's website within 15 working days after the Guidance Executive meeting. Consultees (including appellants) and commentators are informed of the date of publication, and are sent the Appeal Panel's decision and a copy of the final guidance 2 working days beforehand.

Appeal dismissed

9.2.3 If the appeal is dismissed and the Appeal Panel has not requested changes to the FAD, the Guidance Executive receives the Appeal Panel's decision. The final guidance is normally published on NICE's website within 15 working days after the Guidance Executive meeting. Consultees (including appellants) and commentators are informed of the date of publication, and are sent the Appeal Panel's decision and a copy of the final guidance 2 working days beforehand.

9.3 *What happens after the appeal decision is published?*

9.3.1 There is no possibility of further appeal against the decision of the Appeal Panel. However, this decision and NICE's decision to issue the final guidance may be challenged by applying to the High Court for permission to apply for a judicial review. Any such application must be made within 3 months of publishing the final guidance.

Figure 3 Summary of process for publishing the appeal decision and guidance

