

Procedure for the review of Patient Access Scheme proposals

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Patient Access Scheme Liaison Unit at NICE

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Foreword

This document describes the procedure that the Patient Access Scheme Liaison Unit (PASLU) at the National Institute for Health and Care Excellence (NICE) uses to review whether a proposed Patient Access Scheme (PAS) is feasible to implement in the NHS in England and Wales, in order to provide advice to NHS England.

Additional documents, 'T001 PASLU Proposal Template Complex Scheme' and 'T004 PASLU Proposal Template Simple Discount Scheme', describe the information the Patient Access Scheme Liaison Unit (PASLU) needs to prepare this advice.

Acknowledgements

NICE is grateful to everyone who contributed to the development of this procedure.

1 Introduction

The purpose of this document

- 1.1 This document sets out the procedure, including indicative timescales, that the Patient Access Scheme Liaison Unit (PASLU) follows when reviewing a Patient Access Scheme (PAS) proposal and assessing whether it is feasible to implement in the NHS. All references to the NHS are to the NHS in England and Wales.
- 1.2 The term 'Patient Access Scheme' refers to schemes which apply at the national level in the NHS in England and Wales (Scotland has a different mechanism; see Patient Access Scheme Assessment Group [PASAG]) and are linked specifically to technologies recommended by the NICE technology appraisal and highly specialised technologies programmes.
- 1.3 The function of such schemes is to help improve the cost effectiveness of the drug. More information on the framework for PAS is provided in Chapter 5 of the Pharmaceutical Price Regulation Scheme (PPRS) 2014.
- 1.4 A pharmaceutical company that is interested in submitting a PAS proposal must consult with NHS England as well as the PASLU.
- 1.5 As detailed in the PPRS, the commercial confidentiality of all PAS proposals will be respected while they are being considered by the NHS England and the PASLU. The content of a scheme submitted to the PASLU will remain confidential throughout the review with no public disclosure of schemes. However, the arrangements applicable at the relevant time for consultation and disclosure will apply to PAS proposals when they are considered as part of the NICE appraisal process.

General description of NICE and the PASLU

- 1.6 NICE is an independent organisation responsible for developing evidence-based guidance on the most clinically and cost-effective ways to diagnose, treat and prevent disease and ill health.
- 1.7 Within NICE, the Centre for Health Technology Evaluation (CHTE) develops guidance on the use of new and existing technology and treatments (interventions) in the NHS.
- 1.8 A submission proposing a PAS is made by a pharmaceutical company, sometimes referred to as the manufacturer or sponsor. Throughout the remainder of this document the term 'company' will be used.
- 1.9 Proposals can be made in two distinct formats, depending on whether the proposal is for a 'complex' PAS or a 'simple discount' PAS, in line with PPRS 2014. A simple discount PAS must meet the simple discount criteria, as set out in the document 'T004 PASLU Proposal Template Simple Discount Scheme'. Complex PAS include all other types of PAS, this may include financial or outcome based schemes. The PASLU's procedure for considering simple discount PAS proposals is different to that for complex PAS proposals, with a more rapid review.
- 1.10 This procedure guide details the specific routes for the review of each type of scheme proposal; section 3 covers the procedure for the review of complex PAS proposals; section 4 for simple discount PAS proposals. Unless stated specifically, sections 1 and 2 refer to both complex and simple discount PAS proposals.
- 1.11 The review of a PAS proposal by the PASLU leads to an advice document for NHS England. This document assesses the feasibility of implementing the proposed scheme in the NHS. This advice will inform ministerial decisions on whether the proposed PAS can be taken into account as part of a NICE technology appraisal.

- 1.12 The first step in this is for NHS England to refer a scheme proposal to the PASLU for review. Once a scheme proposal is formally referred to the PASLU, the timeline for the review is planned and shared with the company.
- 1.13 All information submitted to the PASLU on a proposed scheme will remain confidential while it is being considered by NHS England and the PASLU. The PASLU does not release information on scheme proposals as part of its review procedures to those who have not signed the PASLU confidentiality agreement, there are no public consultation steps, and the public are not admitted to meetings of the Expert Panel (see below for further details about the expert panel).
- 1.14 Evidence supporting the PAS proposal is provided by the company on the PASLU proposal template, which the PASLU uses to review the proposed scheme and to develop the advice for NHS England. The PASLU can ask the company for further clarification of the information provided.
- 1.15 The PASLU review incorporates the part of the PPRS which requires a formal consultation with the NHS as part of the procedure for the evaluation of complex and simple discount PAS proposals. The PASLU review of the proposal is in accordance with the 'key principles for implementation [of Patient Access Schemes] in England and Wales', as outlined in Chapter 5 of the 2014 PPRS. These principles are:
- Arrangements must respect the role of NICE in providing the NHS with an independent assessment and appraisal of the evidence on an intervention.
 - PAS proposals are to be discussed first and agreed in principle by NHS England and the company. NICE's principal role is to

assess the impact of such proposals on cost-effectiveness taking into account the details of the proposed PAS¹.

- The full costs to the NHS of any such arrangements should be included in the costs considered by the Appraisal Committee¹.
- PAS should be clinically robust, clinically plausible, appropriate and monitorable (e.g. if it is a responder scheme, there must be a relatively straightforward way to measure a patient's clinical response).
- Any PAS should be operationally manageable for the NHS without unduly complex monitoring, disproportionate additional costs and bureaucracy. Any burden for the NHS should be proportionate to the benefits of the PAS for the NHS and patients. Clarity is also required on the exact duration of any agreement and the circumstances in which it might be terminated.
- It is important that the cumulative administrative burden of PAS remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for NHS England to take this issue into account when considering the viability of individual PAS proposals. Priority is likely to be given to PAS proposals that deliver the greatest benefits to patients, for example in enabling the NHS to address a previously unmet need.
- PAS should be consistent with existing financial flows in the NHS and with commissioning arrangements (for example, payers must be able to calculate the effective price for their patient population, so the costs and savings accrue to those services making commissioning and treatment decisions).
- The NHS in England and Wales must be consulted on PAS proposals, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines - for example, in relation to patient

¹ This bullet refers to the evaluation principally by the technology appraisal and highly specialised technologies programmes, not the review by the PASLU.

numbers, or the monitoring and recording of a patient's condition over and above that for the normal management of a patient.

The PASLU has been established to advise on the feasibility of PAS proposals, and the PASLU submission review procedure includes arrangements for consultation with the NHS.

1.16 After reviewing the evidence submitted by the company, the PASLU develops draft advice on the feasibility of implementing the proposed scheme in the NHS. Where the proposal is for a simple discount PAS the PASLU reaches a conclusion on whether or not the proposal meets the simple discount PAS criteria.

1.17 The criteria for simple discount PAS are that the scheme must:

- offer a price² for the product that is lower than the list price, applies to all supplies and preparations of the product, and is valid for all current and future indications (for the duration of the PAS), and in all settings
- offer a reduction from the list price through a discount applied to all original invoices for the product
- require no additional administration; 'additional' means over and above the administration required to purchase the product without a PAS (a single simple agreement is allowed)
- remain in place until NICE next reviews the guidance³ on the product and a final decision has been published on the NICE website.

1.18 All complex PAS proposals are considered by PASLU's independent Expert Panel. The Expert Panel can ask for clarification from the company during the Expert Panel meeting. Simple discount PAS proposals are not normally reviewed by the

² The discounted price may be a specified maximum price or a discount (expressed as a fixed amount or a percentage), that tracks any changes to the UK list price. The approach used should be stated.

³ The discount should remain until NICE issues new guidance following the review. The review date specified in the technology appraisal guidance indicates the date that the guidance is to be considered for review; this does not necessarily lead to the guidance being reviewed.

full Expert Panel. A simple discount PAS proposal may be referred to the Expert Panel where it might, directly or indirectly, introduce complexities and/or administrative burden into the NHS or if there are particular considerations that would benefit from input from the full Expert Panel.

- 1.19 The Chair or Vice Chair of the Expert Panel reviews and comments on simple discount PAS proposals to assess whether the proposal complies with the simple discount scheme criteria.
- 1.20 The final advice is signed-off by the Director of the Centre for Health Technology Evaluation at NICE (complex PAS), or the Programme Director for the technology appraisals and highly specialised technologies programme (simple discount PAS).
- 1.21 The company has the opportunity to provide clarification and address factual errors at scheduled points in the procedure before the advice is submitted to NHS England.
- 1.22 The PASLU submits the final advice to NHS England. Ministers make the final decision about whether a PAS proposal can be considered as part of the technology appraisals or highly specialised technologies programme.

Table 1 Key participants in the PASLU review procedure

Body	Composition
Expert Panel	The Expert Panel has a core membership and invites co-optees to join for consideration of specific topics.
NHS Review Group	The NHS Review Group is a group of people with expert knowledge (clinical, pharmacy, NHS finance, NHS commissioning) who are involved in the review of the proposed Patient Access Scheme.
Topic specialists	Topic specialists with expert knowledge relevant to the technology are invited to the meeting(s) of the Expert Panel to support the Panel's assessment of the information gathered during the review.
NICE staff	Responsibilities
Centre director	The Centre Director is accountable for the delivery of all programmes within the Centre for Health Technology Evaluation.
Programme director	The Programme Director is responsible for the delivery of the technology appraisals and highly specialised technologies programmes, and the work programme of the PASLU. The Programme Director is responsible for

	approving documents at specific stages of the review procedure.
Programme manager	The programme manager is responsible for planning timelines for individual PASLU reviews and projects, ensuring the timelines and procedure are followed, and liaising with manufacturers or sponsors and other individuals or organisations contributing to the procedure.
Technical lead	The technical lead is responsible for the technical aspects of the PASLU review procedure, including liaising with the Chair of the Expert Panel to prepare for the meeting. The technical lead prepares the draft advice and advises the Expert Panel on technical aspects of the review.
Technical adviser	The technical adviser is responsible for the technical quality of each PASLU review. This involves providing leadership on technical issues, and reviewing and assuring the quality of work of the technical lead. The technical adviser also ensures that a consistent approach is taken across the PASLU programme.
Public Involvement Programme (PIP)	PIP is the team at NICE that supports and develops public involvement across NICE's work programmes. A PIP public involvement adviser is assigned to the PASLU programme. They liaise with representatives of patient and carer organisations and individual patients or carers in providing appropriate input to the review of individual PAS proposals and to other parts of the PASLU review procedure as required. The public involvement adviser also helps to recruit, and provide support for, lay members on the PASLU Expert Panel.

2 Procedure points

- 2.1 All correspondence from the company about an individual PAS proposal should be sent to the PASLU programme manager. The PASLU sends correspondence to the company by email; this is to one key contact nominated by the company. It is therefore essential that the company notifies the PASLU programme manager of any change in contact details during the PASLU review procedure.
- 2.2 The PASLU review procedure begins when a scheme proposal is referred to the PASLU by NHS England. This can occur before the technology receives a marketing authorisation.

The submission

- 2.3 The submission is a completed proposal template and supporting documentation: this is known as the proposal.

- 2.4 The PASLU is able to provide guidance about the review procedure and answer general queries but will not comment formally on any proposal during its preparation and before it is referred by NHS England to the PASLU for review.
- 2.5 Substantial or significant revisions to the proposal after formal referral from NHS England to the PASLU are not accepted. In exceptional circumstances, when a company needs to make such a revision, they should discuss this with the PASLU as soon as possible. The PASLU can then advise on the best course of action.

Information handling

- 2.6 The PASLU adheres to the principles and requirements of the Data Protection Act and the Freedom of Information Act when dealing with information it receives during the PASLU review procedure.
- 2.7 The PASLU will not put into the public domain any documents that are being considered as part of the PASLU review procedure. The PASLU considers it essential that schemes can be received and considered in confidence. The PASLU also understands that companies may suffer commercial harm if information on the detail of proposed schemes were made publically available at this point. Therefore, the PASLU will treat all details of a proposed scheme as confidential during the PASLU review procedure.
- 2.8 The review of the proposed scheme may involve consultation with NHS staff and other consultees who have signed the PASLU confidentiality and acknowledgement undertaking form. This includes members of the Expert Panel, members of the NHS Review Group, the topic specialists and patient experts (co-optees). Conflicts of interest are handled in accordance with the NICE [code of practice](#) for declaring and dealing with conflicts of interest.

- 2.9 The PASLU invites people working in the NHS who have relevant knowledge and/or experience of working with PAS to join the PASLU NHS Review Group. Potential reviewers are approached with a standard invitation which explains the work of the NHS Review Group and invites them to opt-in to the reviewer pool. Those who agree to take part may serve for one or more three year term(s). All reviewers sign a general declaration of interest (DOI) form to join the pool and a specific DOI form to review each specific proposal.
- 2.10 For each PAS proposal the PASLU will invite comments from the NHS reviewers. They become the NHS Review Group for that proposal.
- 2.11 The PASLU does not release the information collected during the course of its work to the technology appraisals programme at NICE.
- 2.12 Companies should take care when submitting information relating to individual patients and clinicians. Identifiable personal and sensitive information (for example, information that allows identification of any individual) should not be submitted. All patient-related information submitted must be anonymised.
- 2.13 Information submitted to the PASLU must meet the requirements of copyright legislation. If information includes full journal articles, the company must ensure that it is legally entitled to send a copy of the article. Journal articles will be passed to the PASLU team, Expert Panel and reviewers in the format they are received (printed or electronic). Any articles sent by email must be to a NICE email account or NHS Net email account. The PASLU will not copy, print or store submitted articles. The PASLU will act only as an intermediary by passing on the article. If the PASLU needs to make

further copies of an article it will first ensure that it is legally entitled⁴ to do so.

- 2.14 The PASLU requires all companies to sign a statement declaring that all material relevant to the proposed PAS has been disclosed.
- 2.15 The PASLU requires all companies to sign a statement that they will treat all material they receive from the PASLU, which is relevant to the review of their PAS, as confidential and not disclose any information or make public statements.
- 2.16 NICE will not comment on a scheme being considered by the PASLU until the review procedure has been completed and the final advice has been sent to NHS England. NICE will only comment in the circumstances set out below:
- NICE reserves the right to make public comment if there has been an unauthorised disclosure from a confidential PASLU document. The decision will be taken by the Chief Executive of NICE on the recommendation of two NICE Directors. Companies will be informed of this decision as soon as possible.
 - NICE reserves the right to issue a correction if a public comment that could mislead or misinform is made about PASLU advice.
- 2.17 To note - It is the responsibility of all those involved with the PASLU review procedure to make sure that documents that are not otherwise available in the public domain remain confidential and secure at all times. The PASLU considers individuals within an organisation that employs a member of the Expert Panel, the NHS Review Group, or topic specialists and patient experts (co-optees) to be bound by the terms of the confidentiality agreement signed by the designated contact.

⁴ Note that it either owns the copyright of the article or subscribes to the journal in which the article is published or has obtained a copy of the article for which they have paid a copyright fee.

- 2.18 Any organisation or individual who does not work directly with a member of the Expert Panel, the NHS Review Group or the topic specialists and patient experts (co-optees) is considered to be a third party. Expert Panel members or co-optees may release documentation to third parties when:
- the third party has no conflicts of interest as per the NICE code of practice for declaring and dealing with conflict of interests and
 - it is necessary to enable the expert to contribute to the advice and
 - the third party has seen and agreed to be bound by the terms of the PASLU confidentiality and acknowledgement undertaking agreement.
- 2.19 Members of the Expert Panel and co-optees may discuss confidential documentation with other PASLU Expert Panel members but, before doing so, they must be satisfied that the other experts have signed and returned their confidentiality agreements to the PASLU.
- 2.20 The PASLU may include any material submitted during the PASLU review procedure in the final advice to NHS England.

Submission and clarification

- 2.21 On receipt of the company's proposal, the PASLU checks that the proposal is complete and whether any points need clarification.
- 2.22 If the proposal is incomplete (for example, information considered central to the review is not provided), or clarification is needed, the PASLU forwards a request for clarification to the company. The company has a maximum of 5 working days to respond. The PASLU may organise a meeting with the company to discuss any issues that cannot be resolved by other means.

2.23 Legal advice will be sought by the PASLU on the proposed scheme if considered necessary.

3 Complex PAS proposals

3.1 The PASLU review procedure and minimum timeline is summarised below:

Stage 1	Stage 2	Stage 3
Week 1	Weeks 1–6	Weeks 7–12
Proposal submission	Clarification Input from NHS Review Group Draft advice prepared	Factual error checks Expert Panel Meeting Final advice to NHS England

3.2 This information is given for guidance only. It is not possible to set absolute timescales for all stages of the PASLU review procedure because the time needed for each stage can vary depending on the nature of the particular proposal. Detailed timings can be discussed with the PASLU.

Stage 1: Submission of proposal template

3.3 The review procedure begins when NHS England refer a scheme proposal to the PASLU for review.

Stage 2: Review of proposal documentation

Submission and clarification

3.4 When the PASLU raises points that require clarification the company has a maximum of 5 working days to respond.

Preparation of draft advice

3.5 Once the clarification stage is complete, consultation with the PASLU NHS Review Group is started. A summary of the proposal, extracts, and supporting information are sent to the PASLU NHS

Review Group. The participants are asked specific questions about the proposal and also given the opportunity to provide further comments.

- 3.6 The company will be sent the draft PASLU advice which includes the summarised input of the NHS Review Group to check for factual errors (for example, errors in the figures, incorrect quotes from the proposal or text that does not describe the facts accurately). The company has 5 working days to respond. The company cannot submit additional evidence at this stage unless it is in support of the response to the factual error check, or it is specifically requested by the PASLU.

Stage 3: Consideration of draft advice by the Expert Panel and submission of final advice to NHS England

- 3.7 A proposal (which here means the proposed scheme and the evidence collected by PASLU as summarised in the draft advice) will be reviewed at a meeting of the Expert Panel a minimum of 8 weeks after receipt by the PASLU.
- 3.8 The Expert Panel's remit is to consider the draft advice developed by the PASLU. The Panel will review proposals according to the principles detailed in Chapter 5 of the PPRS and provide a view on the proposal which will be included in the final advice document to NHS England. Panel members are recruited through open advertising and are appointed initially for a 3 year term. All members of the Expert Panel attend the Expert Panel meetings as individuals and not as representatives of organisations. Members include:
- Staff from the NHS with expert knowledge (clinical, pharmacy, NHS finance, NHS commissioning) relevant to the operation of PAS.
 - People with experience of patient representation.
 - People with experience of the pharmaceutical industry.

3.9 The Expert Panel meetings are not held in public.

Preparing for the Expert Panel meeting

3.10 Once the company has provided a response (which may be a nil return) to the factual error check on the draft advice, the factual error check response is sent to the Expert Panel for consideration at the meeting of the Expert Panel.

3.11 Approximately 2 weeks before the Expert Panel meeting the draft advice and supporting documents are circulated to all Expert Panel members who do not have any conflicts of interest (as indicated in their annual declaration of interests). The draft advice pack includes:

- the company's completed proposal template and supporting documents
- clarification requests and the company's responses
- an overview of the review of the evidence submission by the PASLU project team, which includes the summarised input of the NHS Review Group
- an initial position on the feasibility of implementing the proposed PAS in the NHS.

Participation of topic specialists and patient experts

3.12 Topic specialists are selected by the PASLU for each proposed scheme and invited to the meeting of the Expert Panel as co-optees to the Panel for that meeting. Topic specialists are identified by the PASLU team based on their relevant experience and found through a thorough search or recommendation and check process.

3.13 The criteria used to select the topic specialists include:

- They have specialist expertise and/or experience in the area of the indication relevant to the PAS proposal.
- They have a good working knowledge of the NHS.

- They agree to be bound by the terms and conditions of the PASLU's confidentiality and acknowledgement undertaking agreement.
- They hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with the company or any manufacturer or sponsor of a directly competing technology.
- They agree to their name and affiliation appearing in the PASLU advice.
- They are prepared to declare any interests they have in the technology under consideration at the Expert Panel meeting.
- They do not have any conflicts of interest that would prevent them from advising on whether the proposed PAS is feasible.

3.14 Patient input is normally provided as a written statement. Patient experts are not normally expected to attend the Expert Panel meeting. Patient experts would be invited to attend the meeting where their input might help to clarify uncertainty surrounding impact of the technology on patients. The PASLU will seek statements from patients and bodies representing patients who have relevant experience of the indication(s) for which technology is being appraised through the NICE Patients and Involvement Programme. Where possible this will be requested in parallel with the technology appraisal programme.

Participation of company or sponsor representatives

3.15 Representatives of the company are invited to attend part of the Expert Panel meeting to provide clarification on any points that members of the Expert Panel might raise about the proposal under consideration. A maximum of 5 representatives can attend the meeting.

Expert Panel meeting to consider the draft advice

- 3.16 Members of the Expert Panel and individuals having direct input into the Panel discussions declare any interests at each meeting. For further information on how the PASLU deals with conflicts of interest, please see 'A [code of practice for declaring and dealing with conflicts of interest](#)'. The PASLU project team usually introduces the proposed scheme to members of the Expert Panel. This introduction is constructed to promote discussion. The PASLU team answer questions from the members of the Expert Panel and provide clarification on the draft advice.
- 3.17 Topic specialists in attendance also present a resume on the proposed PAS from their respective viewpoints and respond to questions from the members of the Expert Panel and provide clarification.
- 3.18 Patient experts input may be provided as written statements or by the patient representatives at the meeting. The decision to invite patient experts to attend is taken by the programme manager in discussion with the Chair of the Expert Panel under circumstances where there is a clear need for patient input.
- 3.19 The Expert Panel considers and discusses the information provided. The Expert Panel formulates its views on the proposed schemes in a private session after the topic specialists and representatives of the company have left the meeting.
- 3.20 Decisions made by the Expert Panel are normally based on consensus. Panel members discuss the key points and formulate an agreed position on the proposed scheme and make Panel comments and recommendations which will feature in the views of the Expert Panel section of the final advice to NHS England. Where the Panel might fail to reach a consensus during the time allocated for the meeting, the Chair may call for a vote in which the Chair may elect to use a second, casting vote.

Final advice

- 3.21 After the Expert Panel meeting, the PASLU develops the final advice, taking account of views provided by members of the Expert Panel.
- 3.22 The PASLU notifies the company by email after the Expert Panel meeting to advise when the final advice will be sent to them for a factual error check.
- 3.23 The director of the Centre for Health Technology Evaluation signs-off the final advice.
- 3.24 The final advice is sent to the company for a factual error check. The final advice is not subject to public consultation.
- 3.25 Following the factual error check, the final advice is issued to NHS England. The final advice is also sent to members of the Expert Panel for information.
- 3.26 The final advice package usually consists of, but is not limited to:
- the company's submission
 - clarification requests and the company's responses
 - the PASLU review of the proposed scheme
 - company's completed proposal template and supporting documents
 - the views provided by the members of the Expert Panel
 - final conclusions on the feasibility of implementing the proposed PAS in the NHS.

4 Simple discount PAS proposals

4.1 The PASLU review procedure and minimum timeline is summarised below:

Week 1	Week 2	Week 3	Week 4
Proposal submission Review process begins	Review Continues Clarification input from NHS Review Group (if required)	Review by Chair of Expert Panel for comment	Programme Director sign off and advice finalised and sent to NHS England

4.2 This information is given for guidance only. It is not possible to set absolute timescales for all stages of the PASLU procedure because the time needed for each stage can vary depending on the nature of the particular proposal. Detailed timings can be discussed with the PASLU.

Procedure points

4.3 Where a PAS proposal is submitted as a simple discount PAS proposal, it needs to be in accordance with the 'key principles for implementation [of PAS] in England and Wales' as outlined in Chapter 5 of the 2014 PPRS (see 1.15), and fulfil the following four criteria:

- offer a price⁵ for the product that is lower than the list price, applies to all supplies and preparations of the product, and is valid for all current and future indications (for the duration of the PAS), and in all settings
- offer a reduction from the list price through a discount applied to all original invoices for the product

⁵ The discounted price may be a specified maximum price or a discount (expressed as a fixed amount or a percentage), that tracks any changes to the UK list price. The approach used should be stated.

- require no additional administration; ‘additional’ means over and above the administration required to purchase the product without a PAS (a single simple agreement is allowed)
- remain in place until NICE next reviews the guidance⁶ on the product and a final decision has been published on the NICE website.

Week 1: Submission of proposal template, review begins

4.4 The review procedure begins when NHS England refers a submission for a proposed scheme to the PASLU for review.

Week 2: Review of proposal documentation, clarification and consultation

4.5 When the PASLU raises points that require clarification the company has a maximum of 2 working days to respond.

4.6 The review procedure timeline does not allow for a prolonged period of clarification. If the company requires more than 2 working days then the review procedure will stop until the clarification is complete. Once the clarification stage is complete and the company has addressed all the points raised, a consultation with the PASLU NHS Review Group may take place if areas of uncertainty remain around whether any of the essential criteria are met.

Week 3: Review by the Chair of the PASLU Expert Panel

4.7 The initial PASLU advice and the company’s proposal are sent to the Chair of the PASLU Expert Panel.

4.8 The Chair of the PASLU Expert Panel provides comments on the proposal in relation to the criteria for simple discount PASs and raises relevant questions. When it is considered that additional

⁶ The discount should remain until NICE issues new guidance following the review. The review date specified in the technology appraisal guidance indicates the date that the guidance is to be considered for review; this does not necessarily lead to the guidance being reviewed.

input on specific points of the proposed PAS would be helpful, the Chair may propose that PASLU invite other members of the Panel to comment.

Week 4: Advice finalised and sent to the DH

- 4.9 During the final week of the review procedure the advice is finalised. The programme director for the technology appraisals and highly specialised technologies programmes signs-off the final advice.
- 4.10 The final advice is issued to the DH.
- 4.11 The final advice package usually consists of, but is not limited to:
- the company's submission
 - clarification requests and the company's responses
 - an overview of the review of the submission by the PASLU project team
 - the Chair of the Expert Panel's comments
 - final conclusions on whether or not the PAS proposal meets the simple discount PAS criteria.

Appendix A: complex PAS

