Process for advising on the feasibility of implementing a patient access scheme

INTERIM

September 2009

Patient Access Schemes Liaison Unit at NICE
Contents (to be edited for public consultation)

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List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CHTE</td>
<td>Centre for Health Technology Evaluation</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>MTA</td>
<td>Multiple technology appraisal</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<tr>
<td>PAS</td>
<td>Patient Access Scheme</td>
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<tr>
<td>PASLU</td>
<td>Patient Access Scheme Liaison Unit</td>
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<tr>
<td>STA</td>
<td>Single technology appraisal</td>
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</table>
**Foreword**

This document describes the process that the National Institute for Health and Clinical Excellence (NICE) uses to advise on whether implementing a patient access scheme is feasible in the NHS in England and Wales.

A second document 'T001 PASLU Proposal Template V1-3' describes the information NICE needs for this advice.

Both documents are available on the NICE website (www.nice.org.uk).

**Acknowledgements**

NICE is very grateful to everyone who contributed to the development of this guide.
1 Introduction

The purpose of this document

1.1 This document sets out the process, including expected timescales, that NICE follows when advising whether implementation of a patient access scheme is feasible in the NHS in England and Wales.

1.2 Patient access schemes help to improve the cost effectiveness of a medicine and therefore allow NICE to recommend treatments it would otherwise have found too costly. More information on the framework for patient access schemes is provided in the 2009 Pharmaceutical Price Regulation Scheme (PPRS) (www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825).

1.3 Patient access schemes are proposed by a pharmaceutical company and referred by the Department of Health to the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation at NICE who then provide advice on the feasibility of implementing the patient access scheme in the NHS in England and Wales.

General description of NICE and the PASLU process

1.4 NICE is part of the NHS. It is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.

1.5 Within NICE, the Centre for Health Technology Evaluation (CHTE) develops technology appraisal guidance on the use of new and existing drugs and treatments (technologies or interventions) in the NHS in England and Wales.

1.6 The process for advising whether implementing a patient access scheme is feasible in the NHS in England and Wales has been specifically designed to provide robust advice to the Department of Health. This advice will inform ministerial decisions on whether NICE should consider a patient access scheme as part of its technology appraisals programme.
1.7 The Department of Health will refer patient access schemes to the PASLU at NICE to advise whether the scheme is feasible for implementation in the NHS in England and Wales. NICE will not be involved in the development of an individual patient access scheme.

1.8 Once a scheme is formally referred to the PASLU at NICE, the timeline for the topic is planned and the manufacturer or sponsor of the technology informed. NICE makes no public announcement about the topics that are under consideration by the PASLU.

1.9 Most of the evidence that the PASLU needs to advise on whether a scheme is feasible is submitted by the manufacturer or sponsor of the technology. A review of the submitted information is produced by the PASLU, and if necessary the PASLU asks for further clarification (see 2.4.2). Further input is provided by the members of the independent Expert Panel and co-optees to the panel (see table 1). The PASLU asks for advice from within or outside NICE when necessary.

1.10 When advising whether a patient access scheme is feasible the PASLU considers the 'key principles for implementation [of PASs] in England and Wales’ as outlined in the 2009 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.
- Schemes are to be discussed first and agreed in principle by the Department 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 scheme.
- The full costs to the NHS of any such arrangements should be included in the costs considered by the Appraisal Committee.
- Schemes 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 scheme 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 scheme 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 such schemes remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for the Department to take this issue into account when considering the viability of individual schemes. Priority is likely to be given to schemes that deliver the greatest benefits to patients, for example in enabling the NHS to address a previously unmet need.

• Schemes should be consistent with existing financial flows in the NHS and with local commissioning (e.g. payers must be able to calculate the effective price for their patient population, so the costs and savings accrue to those local services making commissioning and treatment decisions).

• The NHS in England and Wales must be consulted on patient access schemes, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines – for example in relation to patient numbers, or the monitoring and recording of a patient’s condition over and above that for the normal management of a patient. The Department will set out in more detail the nature of that consultation.

• The more systematic use of such schemes will need to be reviewed in light of experience. The timing of such a review will be jointly agreed but will be initiated not later than 2 years after the commencement of this agreement.

1.11 After reviewing the evidence submitted by the manufacturer or sponsor of the technology, the PASLU develops draft advice on whether the implementation of the patient access scheme is feasible in the NHS in
England and Wales. The draft advice will not be subject to public consultation.

1.12 The draft advice, together with the evidence submitted by the manufacturer or sponsor, is considered by PASLU’s independent Expert Panel (see table 1). The Expert Panel can ask for clarification from the manufacturer or sponsor of the technology. Expert Panel meetings are held in private. Final advice is developed with input from the Expert Panel and approved by the Director of the Centre for Health Technology Evaluation or, in their absence, Director of the Technology Appraisals Programme.

1.13 The final advice is shared with the manufacturer or sponsor of the technology before it is submitted to the Department of Health. There is an opportunity for the manufacturer or sponsor of the technology to review the PASLU’s final advice for factual errors before the advice is submitted to the Department of Health.

1.14 The consideration of the Patient Access Scheme in the context of a technology appraisal is subject to Ministerial approval.
### Table 1 Key participants in the Patient Access Scheme Liaison Unit (PASLU) process

<table>
<thead>
<tr>
<th>Body</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert Panel</td>
<td>The Expert Panel has a core membership and invites co-opteees to join for the consideration of specific topics. Panel members are recruited through open advertising, are appointed initially for a 3-year term, and have a clinical, pharmacy, NHS finance, NHS commissioning, patient or pharmaceutical industry background.</td>
</tr>
<tr>
<td>Clinical and pharmaceutical specialists and NHS and patient co-optees</td>
<td>Clinical, pharmaceutical, NHS and patient experts are selected by the Chair of the Expert Panel from people nominated by the PASLU. They are invited to the Expert Panel meeting and are asked to support the Panel in their review of the information submitted by the manufacturer or sponsor.</td>
</tr>
<tr>
<td>NICE staff</td>
<td>Responsibilities</td>
</tr>
<tr>
<td>Centre Director</td>
<td>The Centre Director is accountable for the delivery of all programmes within the Centre for Health Technology Evaluation.</td>
</tr>
<tr>
<td>Programme Director</td>
<td>The Director of the Technology Appraisals Programme is responsible for the delivery of the technology appraisals programme and the work programme of the PASLU. The Programme Director is responsible for approving documents at specific stages of a project.</td>
</tr>
<tr>
<td>Associate Director</td>
<td>The Associate Director of the PASLU is responsible for the delivery of individual pieces of PASLU advice and has responsibility for approving documents at specific stages of an individual project.</td>
</tr>
<tr>
<td>Project Manager</td>
<td>The project manager is responsible for planning timelines for individual PASLU projects, for ensuring the timelines and process are followed, and for liaising with manufacturers or sponsors and other individuals or organisations contributing to the project.</td>
</tr>
<tr>
<td>Technical lead</td>
<td>The technical lead is responsible for the technical aspects of the PASLU project, including liaising with the Chair of the Expert Panel to prepare for the meeting. The technical lead writes the draft advice and advises the Expert Panel on technical aspects of the project.</td>
</tr>
<tr>
<td>Technical Adviser</td>
<td>The technical adviser is responsible for the technical quality of each PASLU project. 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.</td>
</tr>
<tr>
<td>Editorial lead</td>
<td>The editorial lead is responsible for ensuring that all PASLU documents (from draft advice to final advice) are accurate, clear and consistent.</td>
</tr>
<tr>
<td>Patient and Public Involvement Programme (PPIP)</td>
<td>PPIP is the team at NICE that supports and develops patient and public involvement across NICE’s work programme. A PPIP project manager is assigned to the PASLU programme and supports patient and carer organisations, their representatives and individual patients or carers, throughout their involvement with the PASLU project. This may include making it easier to attend workshops or meetings; giving advice on completing submissions, or other documentation; and nominating experts.</td>
</tr>
</tbody>
</table>
2 The PASLU process

The PASLU process and timelines are summarised in figure 1 and appendix A. The process consists of three distinct phases:

- Phase 1 – initiation and submission of documentation by the manufacturer or sponsor.
- Phase 2 – review of submitted evidence (including initial clarification) and drafting of advice.
- Phase 3 – consideration of the draft advice by the Expert Panel and submission of the final advice to the Department of Health.

2.1 General points

2.1.1 All correspondence relating to an individual patient access scheme should be sent to the PASLU project manager to ensure it is dealt with effectively. NICE sends correspondence by email or post to one key contact identified by the manufacturer or sponsor of the technology. It is therefore essential that manufacturers and sponsors notify the PASLU project manager of any change in contact details or in organisation or company name throughout the PASLU process.

2.1.2 NICE will not publish information related to schemes being considered by the PASLU on its website or make such information available to those that request it. Individual manufacturers or sponsors will receive information about the timing and progress of the assessment of their scheme from the PASLU project manager.
2.2 Phase 1: Initiation and submission of documentation

2.2.1 Phase 1 begins when a patient access scheme is referred to NICE by the Department of Health to advise on whether its implementation is feasible. This can occur before ministerial referral of the topic to the technology appraisals programme and before the technology receives a marketing authorisation.

2.2.2 Documents must usually be received by the PASLU 8 weeks before the Expert Panel meeting. Each topic is assigned to a project team at the PASLU. The PASLU project manager will inform the manufacturer or...
sponsor of the technology of the team members. The roles of key members of the project team are summarised in table 1.

Submission of documentation by the manufacturer or sponsor

2.2.3 The manufacturer or sponsor of the technology provides documentation on the implementability of the patient access scheme using a template and specification (see www.nice.org.uk). The specification is derived from the criteria listed in the 2009 PPRS.

2.2.4 NICE is unable to review proposals during their preparation. Only minor amendments to the proposal are accepted during the PASLU process. Resubmissions because of significant changes to the outline of the patient access scheme will only be accepted after a renewed referral of the scheme by the Department of Health.

2.2.5 No submissions or statements are invited from other parties.

Information handling

2.2.6 NICE 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 process.

2.2.7 NICE will not put into the public domain any documents that are considered in the PASLU process. NICE considers it essential that schemes can be received and considered in confidence. NICE also understands that manufacturers may suffer commercial and other harm if information on the detail of proposed schemes were made publically available at this point. Therefore, NICE will treat all details of proposed schemes as confidential and will not release any information relating to it under the Freedom of Information Act or in any other circumstance, unless the manufacturer has agreed to the release. Those involved in the assessment of patient access schemes will be subject to a confidentiality agreement; this includes members of the Expert Panel and clinical and pharmaceutical specialists and NHS and patient experts (co-optees).
There are no separate arrangements for the submission of information designated as commercially or academically confidential.

2.2.8 The PASLU will not release the information collected during the course of its work to the technology appraisals programme. Manufacturers or sponsors of the technology should consult the relevant process documents for multiple and single technology appraisals (see www.nice.org.uk) for arrangements for release of information pertaining to PASs in the context of a subsequent technology appraisal.

2.2.9 Manufacturers and sponsors should take care when submitting information relating to individual patients and clinicians. Identifiable personal and sensitive information (for example, information that allows identification of an individual’s clinician) should not be submitted without being anonymised.

2.2.10 Information submitted to NICE must meet the requirements of copyright legislation. If information includes full journal articles, the manufacturer or sponsor must ensure that they have copyright clearance. Journal articles in electronic format will be accepted only if they are provided on CD-ROM. Copyright-controlled material may not be provided by email or other internet-based means. Journal articles will be passed to the PASLU team and Expert Panel in the format they are received (printed or electronic). NICE will not copy, print or store submitted references because this would be in breach of copyright legislation.

2.2.11 NICE requires manufacturers and sponsors of technologies that are considered by the PASLU to sign a statement declaring that all material relevant to the patient access scheme has been disclosed.

2.2.12 NICE will not comment on a scheme being considered by the PASLU until the process has been completed and its final advice has been produced and sent to the Department of Health. And only then will it 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 Directors. Manufacturers or sponsors will be informed of this decision as soon as possible after it has been taken.
• NICE reserves the right to issue a correction if a public comment that could mislead or misinform is made about PASLU advice.
• It is the responsibility of those involved with the PASLU process to make sure that documents not otherwise in the public domain remain confidential and secure at all times. NICE considers individuals within an organisation related to a member of the Expert Panel or a clinical and pharmaceutical specialists and NHS and patient experts (co-optees) to be bound by the terms of the confidentiality agreement signed by the designated contact.
• Any organisation or individual who does not work directly with a member of the Expert Panel or the clinical and pharmaceutical specialists and NHS and patient experts (co-optees) is a third party. Expert Panel members or co-optees may release documentation to third parties when:
  – 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 confidentiality agreement.
• Members of the Expert Panel and co-optees may discuss confidential documentation with other Panel members but, before doing so, they must be satisfied that the other experts have signed and returned their confidentiality agreements to NICE.
• NICE may include in the final advice to the Department of Health any material submitted during the PASLU process.

2.3 **Process timelines**
2.3.1 It is not possible to set absolute timescales for all stages of the PASLU process. The time needed for each stage can vary depending on the nature of the particular patient access scheme proposed. The timings set
out in tables 2 and 3 and Appendix A indicate the minimum number of weeks for each stage of the PASLU process.

2.3.2 Throughout the PASLU process, the manufacturer or sponsor may request up-to-date information about timing and progress from the PASLU project manager.

2.4 **Phase 2: Review of documentation**

**Submission and clarification**

2.4.1 On receipt of the manufacturer or sponsor’s proposal, the PASLU checks that the proposal is complete with reference to the criteria included in 2009 PPRS and the proposal template.

2.4.2 If the received proposal is incomplete, the PASLU forwards a request for clarification to the manufacturer or sponsor (normally within 10 working days of receiving the proposal). The manufacturer or sponsor has a maximum of 5 working days to respond. NICE will organise a face-to-face meeting with the manufacturer or sponsor to discuss any issues that cannot be resolved by other means.

**Draft advice**

2.4.3 When a manufacturer or sponsor provides an adequate proposal, the documentation submitted is reviewed by the PASLU. The PASLU then prepares draft advice on the feasibility of implementing the patient access scheme in the NHS in England and Wales. This draft advice is based on a review of the manufacturer’s or sponsor’s proposal and, if necessary, further discussion of the PAS with clinical and pharmaceutical specialists, and NHS and patient experts. The PASLU will seek legal advice if necessary.

2.4.4 Before presenting the draft advice to the Expert Panel, the PASLU sends it to the manufacturer or sponsor. The manufacturer or sponsor has 5 working days to check that the draft advice does not contain factual errors (for example, errors in the figures, incorrect quotes from the
proposal and text that does not describe the facts accurately). A document highlighting factual errors is prepared by the manufacturer or sponsor for consideration by the Expert Panel. The manufacturer or sponsor cannot submit additional evidence at this stage unless this has been agreed before the initial submission, or it is requested by PASLU.

**Participation of clinical and pharmaceutical specialist, NHS and patient co-optees**

2.4.5 While the draft advice is being written, NICE prepares for phase 3 of the PASLU process (consideration of the draft advice by the Expert Panel and submission of the final advice to the Department of Health). This involves organising the Expert Panel meeting. The Expert Panel meeting is held in private.

2.4.6 Clinical and pharmaceutical specialists, NHS and patient experts are selected by the PASLU in conjunction with the Chair of the Expert Panel. These experts act as co-optees to the Expert Panel for the consideration of a specific patient access scheme.

2.4.7 Clinical and pharmaceutical specialists, and NHS and patient experts are selected according to the nature of their experience of the technology and the disease, and the services provided by the NHS to patients with the conditions that the technology is designed to treat. Whenever possible the clinical and pharmaceutical specialists, and NHS and patient experts will have complementary experience rather than similar backgrounds and experience. All selected specialists and experts are invited to attend the Expert Panel meeting provided they meet the following criteria:

- They agree to be bound by the terms and conditions of NICE’s confidentiality agreement.
- They agree to their name and affiliation appearing in the PASLU advice.
- They have knowledge and/or experience of the condition and/or technology under consideration.
• They are a confident public speaker, able to provide good descriptions of their experience and can act effectively as an advisor in the setting of an Expert Panel meeting.
• They are familiar with the purpose and processes of NICE.
• 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 participating in advice on whether the patient access scheme is feasible.

2.4.8 The following criteria are used to select clinical and pharmaceutical specialists.

• They are active in clinical practice and have specialist expertise in the area proposed by the patient access scheme.
• Their principal place of work is ideally within the NHS.
• They hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with the manufacturer or sponsor of the technology or any manufacturer or sponsor of a directly competing technology.

2.4.9 Usually, one of each of the expert categories is selected. Clinical and pharmaceutical specialists and NHS and patient experts attend the Expert Panel meeting as individuals and not as representatives of organisations.
Table 2 Expected timeline for the first two phases of the PASLU process: initiation and preparing the draft advice

<table>
<thead>
<tr>
<th>Step</th>
<th>What happens at this stage</th>
<th>Approximate time (weeks) from the start of the process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Evidence submissions received from manufacturer or sponsor</td>
<td>0</td>
</tr>
<tr>
<td>Step 2</td>
<td>Clarification sought on the evidence submission and response received</td>
<td>1 3</td>
</tr>
<tr>
<td>Step 3</td>
<td>Clinical and pharmaceutical specialists, and patient experts selected and invited to attend the Expert Panel meeting</td>
<td>2</td>
</tr>
<tr>
<td>Step 4</td>
<td>Review and drafting of the advice</td>
<td>3-6</td>
</tr>
<tr>
<td>Step 5</td>
<td>Draft advice sent to manufacturer or sponsor for check for factual errors</td>
<td>6</td>
</tr>
<tr>
<td>Step 6</td>
<td>Draft advice sent to Expert Panel</td>
<td>6</td>
</tr>
</tbody>
</table>

1 Timelines may change in response to individual appraisal requirements.

2.5 **Phase 3: Consideration of draft advice by the Expert Panel and submission of final advice to the Department of Health**

2.5.1 The Expert Panel’s remit is to consider the draft advice developed by the PASLU project team in the context of the evidence submitted by the manufacturer or sponsor of the technology and the review by the PASLU project team.

2.5.2 Consideration by the Expert Panel informs the final advice developed by the PASLU project team and issued by NICE to the Department of Health.

**Preparing for the Expert Panel meeting**

2.5.3 In preparation for the Expert Panel meeting, the draft advice is circulated to all attendees. The draft advice consists of:

- the manufacturer’s or sponsor’s evidence submission
- clarification requests and responses
• an overview of the review of the evidence submission by the PASLU project team
• an initial conclusion on the implementability of the PAS in the NHS in England and Wales.

2.5.4 The Expert Panel will also receive the manufacturer’s or sponsor’s identification of factual errors in the draft advice.

2.5.5 Meetings of the Expert Panel are not held in public; all information to be discussed is considered as ‘commercial in confidence’. NICE considers it essential that schemes can be received and considered in confidence. The manufacturer or sponsor of the technology is invited to attend the Expert panel meeting to clarify the information provided about the scheme in their evidence submission.

**Expert Panel meeting to consider the draft advice**

2.5.6 The Expert Panel considers and discusses the information provided for the patient access scheme. Decisions made by the Panel are normally based on consensus. When a vote is taken it is noted in the minutes of the meeting.

2.5.7 Written evidence supporting the patient access scheme is provided in the ‘draft advice’ (see 2.4.3). Oral evidence is drawn from discussions with Panel members (including co-optees), the PASLU project team and representatives of the manufacturer or sponsor of the technology.

2.5.8 Members of the Panel (including co-optees) and individuals having direct input into the Panel discussions (including NICE staff) declare their interests, which are recorded in the minutes. For further information on how NICE deals with conflicts of interest, please see ‘A code of practice for declaring and dealing with conflicts of interest’ ([www.nice.org.uk](http://www.nice.org.uk)). The PASLU project team usually introduces the topic to the Expert Panel members and other attendees (co-optees and representatives of the manufacturer or sponsor). This introduction does not pre-empt the Panel’s debate or the formulation of the final advice. The PASLU project team
answers questions from the Expert Panel and provides clarification on the
draft advice.

2.5.9 Clinical specialists and patient experts in attendance as co-optees
respond to questions from the other members of the Expert Panel and
provide clarification.

2.5.10 The manufacturer or sponsor of the technology provides clarification of the
information provided in its proposal and the information provided in
response to previous requests for clarification, and highlights any errors
identified in the draft advice.

2.5.11 The Expert Panel formulates its feedback to NICE in a private session.
Representatives of the manufacturer or sponsor are asked to leave before
this session starts.

Minutes

2.5.12 Unconfirmed minutes of the Expert Panel meeting are posted on NICE’s
website within 15 working days of the meeting. Confirmed minutes are
posted on the website when they have been approved by the Expert
Panel, normally within 6 weeks of the meeting. The minutes of an Expert
Panel meeting provide a record of the proceedings and a list of issues
discussed.

Final advice

2.5.13 After consideration of the feedback from the Expert Panel, the PASLU
project team develops the final advice. The final advice is circulated
among Expert Panel members for information.

2.5.14 The Director of the Centre for Health technology Evaluation or, in their
absence, the Technology Appraisals Programme Director reviews and
approves the final advice. The final advice, together with the Expert
Panel’s conclusions, are sent to the manufacturer or sponsor of the
technology for consideration of factual errors. Final advice is not subject to
public consultation. The PASLU contacts the manufacturer or sponsor of
the technology by email after the Expert Panel meeting to let them know when they can expect their copy of the final advice.

2.5.15 The PASLU usually circulates the final advice to the manufacturer or sponsor of the technology within 5 working days of the Expert Panel meeting. In exceptional circumstances, this may take longer. If the PASLU expects a delay, the manufacturer or sponsor of the technology is informed as soon as possible.

2.5.16 The final advice usually contains the following elements:

- the manufacturer’s or sponsor’s evidence submission
- clarification requests and responses
- an overview of the review of the evidence submission by the PASLU project team
- the Expert Panel’s conclusions
- final conclusions on the implementability of the PAS in the NHS in England and Wales.

Table 3 Expected timeline for the third phase of the PASLU process: Expert Panel meeting and drafting final advice

<table>
<thead>
<tr>
<th>Step</th>
<th>What happens at this stage</th>
<th>Approximate time (weeks) from the start of the process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 7</td>
<td>Expert Panel meeting</td>
<td>8</td>
</tr>
<tr>
<td>Step 8</td>
<td>Final advice produced</td>
<td>9</td>
</tr>
<tr>
<td>Step 9</td>
<td>Final advice sent to manufacturer or sponsor for consideration</td>
<td>10–11</td>
</tr>
<tr>
<td>Step 10</td>
<td>Final advice submitted to the Department of Health</td>
<td>12</td>
</tr>
</tbody>
</table>

¹ Timelines may change in response to individual requirements.
## Appendix A. PASLU process timeline

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Manufacturer/sponsor’s evidence submission received</td>
</tr>
<tr>
<td>1</td>
<td>Start of PASLU assessment and testing</td>
</tr>
<tr>
<td>2</td>
<td>Request for clarification sent to manufacturer/sponsor</td>
</tr>
<tr>
<td>3</td>
<td>Nominations of experts</td>
</tr>
<tr>
<td>4</td>
<td>Draft advice to manufacturer / sponsor for factual error check.</td>
</tr>
<tr>
<td>5</td>
<td>Committee papers compiled and sent to Expert Panel</td>
</tr>
<tr>
<td>6</td>
<td>Expert Panel meeting to consider draft advice</td>
</tr>
<tr>
<td>7</td>
<td>Final advice to manufacturer / sponsor for consideration</td>
</tr>
<tr>
<td>8</td>
<td>Final advice submitted to the Department of Health</td>
</tr>
</tbody>
</table>