

# Hints and tips for companies considering a Patient Access Scheme (PAS) proposal in England

# Why this guide?

- Chapter 6 of the [Pharmaceutical Price Regulation Scheme \(PPRS\) 2009](#) set out two new pricing flexibility measures aimed at linking more closely the value of medicines to what the NHS pays for them: flexible pricing and **Patient Access Schemes (PAS)**.
- Following a [review](#) of these measures in 2011, the Department of Health (DH) and the ABPI agreed that it would be useful to develop some additional guidance, based on learning and experiences of the Department of Health, NICE, PASLU and companies with experience of PAS. This document brings together these **hints and tips for manufacturers and sponsors considering making a PAS proposal**.
- This does not seek to revisit guidance that has already been published, but brings together factual information with hints and tips for companies. This should, therefore, be read in conjunction with Chapter 6 of the 2009 PPRS and the [PASLU Process Guide](#).
- **This document is intended to assist companies in considering whether they wish to make a PAS proposal and, if so, in developing their applications. It is not intended to be binding or comprehensive, and is without prejudice to the formal consideration process for PAS proposals.**

# Content of this Guidance

- What is a PAS?
- Planning
- Process map and commentary
- Making a submission
- Assessment
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- FAQs

# What is a Patient Access Scheme?

## Is a PAS proposal the right choice?

- A PAS is a scheme proposed by a pharmaceutical company and agreed between the company and the Department of Health (with input from NICE) in order to improve the cost-effectiveness of a drug. PAS proposals are made in the context of a NICE technology appraisal, with the aim of enabling a positive NICE recommendation. A full list of operational Patient Access Schemes with links to the relevant NICE guidance is available [here](#).
- To find out more about PAS, and help understand whether a PAS is likely to be the right choice for your company/medicine, please refer to **Chapter 6 of the PPRS** and the **PASLU process guide**. You can also contact DH for an informal discussion on a no-commitment basis, but it is important to be able to share some basic information on the medicine concerned, the prospective timescales for NICE consideration, and the type(s) of PAS you are thinking about.

### TIP

Companies often underestimate the amount of work required to put together a PAS proposal. Remember that a PAS is neither an 'easy fix', nor a panacea; and a PAS may not be appropriate or feasible in every case.

# I think I want to make a PAS proposal. Where should I start? Some basics.....

- Keep your PAS proposal as **simple as possible** – **simple** schemes are the preferred model because they add only minimal burden. Start by considering a simple discount and if you decide to propose something more complex, be prepared to justify your choice.
- It is often helpful to share draft proposals. DH can provide informal advice on them (on a 'no commitment' basis), but will not draft your proposal for you!
- Bear in mind that you may need to go through several iterations.
- Remember that, whilst pre-submission discussions can help avoid difficulties, they are not a substitute for the formal PAS consideration process – allow sufficient time.

## TIP

**Planning early is essential. Don't wait until the NICE appraisal process is well advanced to start thinking about a PAS proposal. Many companies leave it far too late!**

# Good planning is essential

- **Consult NHS customers widely** about the design of your PAS:
  - Commissioners and different provider types (secondary and tertiary care, private providers), as well as clinicians and pharmacists
  - Consider differences in practice across different geographical areas (and across the UK)
- Consider carefully what type of PAS to propose if your medicine has, or will have, **multiple indications**: simple discounts must apply to all current and future indications; other schemes may be indication-specific, but more than one PAS for a single medicine is unlikely to be agreed. So, if you need a PAS for more than one indication, design your proposal so that the same scheme could apply across all relevant indications.
- Think about the **settings** your medicine will be used in (hospitals, homecare?) and reflect this in your proposals. A PAS is unlikely to be suitable for a medicine widely used in primary care.
- Make sure you **recognise all administration requirements and costs**, even if they seem small compared to the medicine's costs – e.g. costs of processing and reconciling rebates.
- Remember that schemes requiring the **tracking of individual patients** (e.g. dose caps, single fixed payments, outcome-based schemes, etc.) are generally very burdensome for the NHS (and companies) to operate. The fact that clinicians will be monitoring patients is not the same as tracking for the purposes of operating a PAS.

# Key factors to consider in developing a PAS proposal

- Understand different **NHS IT systems** and different pharmacy systems – there is wide variation and what works for one may not work for all
- Understand **NHS financial flows** and the role of commissioners
- Understand the **supply chain** and its complexities
- Think about the **information needed to operate the scheme**, how this will be gathered, what documentation and/or electronic systems will be needed
- If your proposals require tracking, consider **patient confidentiality**: companies must not have access to information that allows the identification of individual patients
- Consider how your proposals fit with the **clinical pathway and NHS practice** including the feasibility of measurement of outcomes (e.g. clinical response) if required
- Remember that the NHS has to **audit PAS**. You should assess the feasibility of auditing a variety of pharmacy systems
- Consider what **support** you can provide to the NHS in implementing and operating the scheme
- Remember that your scheme needs to be **available for the duration of the relevant NICE guidance**

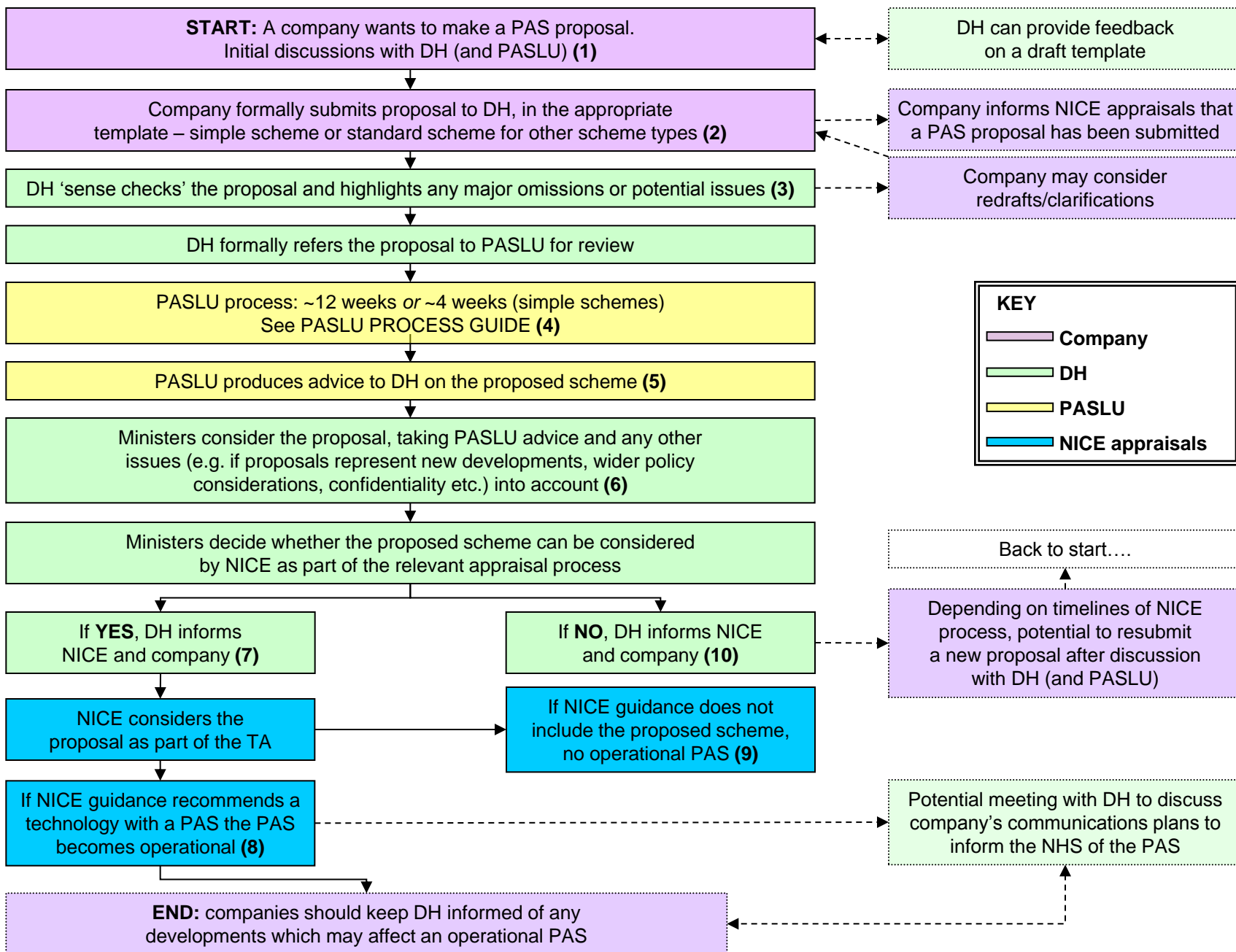
**TIP**

**Remember:  
Keep all aspects of proposals as simple as possible**

# Patient Access Scheme proposals: Process Map

[Click here to return to contents](#)

NOTE: this should be read in conjunction with the [explanatory notes](#) on the process





# Patient Access Scheme proposals: Process Map notes and commentary

[Click here for process map](#)

Note	Commentary
1	<p>PAS proposals can be made for medicines that will be assessed by NICE as part of a technology appraisal (STA or MTA). DH cannot accept proposals where no NICE appraisal is planned. DH can provide advice on potential issues with scheme designs and companies are strongly encouraged to contact DH for one or more pre-submission discussions before finalising PAS submissions. Three-way discussions involving PASLU can also be arranged. Pre-submission discussions about a potential proposal are treated in confidence, and are non-binding. Companies decide whether they wish to propose a PAS and, if so, the kind of scheme they wish to offer.</p> <p>In addition, companies are encouraged to engage at an early stage with:</p> <ul style="list-style-type: none"> <li>- NHS organisations (in order to test prospective PAS proposals)</li> <li>- Other UK Health Departments (Scotland, Wales and Northern Ireland)</li> <li>- NICE technology appraisals team (to alert them that a PAS proposal may form part of the appraisal submission)</li> </ul>
2	<p>PAS proposal templates can be obtained from DH or PASLU. There are two different templates:</p> <ul style="list-style-type: none"> <li>-Simple scheme template – for proposals made under the simple scheme criteria (set out in the template)</li> <li>-Standard scheme template – for all other types of scheme proposal; the standard template requires more detailed information due to the greater complexity and potential burdens of other types of PAS proposal</li> </ul> <p>Once a company has finalised its proposals, a completed template and any documentation associated with the proposed scheme should be submitted to DH. It is helpful to keep PASLU informed of when you plan to submit. Following submission to DH, the company should inform the NICE appraisals team, who can advise what information they require on the PAS proposal in the context of the appraisal process.</p>
3	<p>If there are no major omissions or issues, DH will normally refer the proposal to PASLU for their assessment. DH informs the company when this has happened. If clarification is required on any aspect of the template/proposal, DH may go back to the company and/or ask PASLU to consider the issue(s) as part of their review.</p>
4	<p>The standard PASLU review process normally takes a minimum of 12 weeks, including a meeting of the PASLU Expert Panel. There is an accelerated process for simple schemes which takes approximately 4 weeks.</p> <p>As part of the review process, PASLU may need to seek additional information from the company and this means that the process may take longer than the standard timescales, in particular for very complex proposals. Similarly, timescales are likely to increase if a company decides, based on feedback from PASLU/the Expert Panel, to alter or amend elements of their proposals.</p> <p>SEE THE PASLU PROCESS GUIDE FOR FURTHER INFORMATION</p>
5	<p>PASLU advice on the PAS proposal is sent to DH. This is not shared within NICE or with any other party.</p>
6	<p>DH Ministers consider the scheme proposal against the criteria set out in the 2009 PPRS, taking into account the advice received from PASLU. They decide whether the PAS proposal may be considered by NICE as part of the relevant appraisal(s).</p> <p>No indicative timeline is given for this stage as there are several variables that may affect timescales for consideration (e.g. Parliamentary recess periods). DH liaises with NICE appraisals colleagues regarding key dates in the appraisals process, but it is also useful for companies to make DH aware of upcoming deadlines (e.g. NICE appraisal meetings, evidence submission dates).</p>
7	<p>DH informs NICE and the company of the outcome of Ministerial consideration. The company is required to send details of the proposed PAS to the Technology Appraisals team as part of the evidence submission.</p>
8	<p><i>Where Ministers have agreed that a PAS proposal can be considered by NICE as part of the relevant appraisal:</i></p> <p>If final NICE guidance recommends the drug, with the proposed PAS, details of the PAS will be included in the relevant Technology Appraisal Guidance, and the PAS becomes operational. At this stage, DH may contact the company to confirm final details – e.g. where relevant, final paperwork and/or arrangements for informing the NHS of the PAS. Operational PAS are listed on the NICE website, along with a link to the relevant Technology Appraisal Guidance.</p> <p>It is expected that an operational PAS will remain in place for as long as it forms part of NICE Technology Appraisal Guidance. Any changes to an operational PAS, or developments which may affect the PAS, should be discussed and agreed with DH.</p>
9	<p><i>Where Ministers have agreed that a PAS proposal can be considered by NICE as part of the relevant appraisal:</i></p> <p>If final NICE guidance does not recommend the drug (or recommended the drug without the PAS), the proposal does <u>not</u> become an operational PAS. Companies may offer their scheme to the NHS at a local level (provided it does not contravene any aspect of the PPRS), but decisions on whether to participate in such schemes are a matter for the local NHS. To avoid confusion, such locally-based arrangements should <b>not</b> be referred to as a Patient Access Scheme or PAS.</p>
10	<p><i>Where Ministers do not agree that a PAS proposal can be considered by NICE as part of the relevant appraisal:</i></p> <p>Depending on the timeline and stage of the relevant NICE appraisal, there may be an opportunity for the company to submit a revised/new PAS proposal. There may also be the option of a 'rapid review' of final NICE guidance, to include consideration of a new PAS proposal. If a company is considering these options they should discuss their plans with both DH and NICE appraisals.</p>

# Making a submission

PAS proposals must be submitted to DH on the appropriate PAS proposal template

There are two different templates:

- [Simple scheme template](#) – for proposals made under the simple scheme criteria
- [Standard scheme template](#) – for all other types of PAS proposal

Things to remember in your submission:

- Submit as **early** as you can
  - In the case of simple schemes, you can submit without knowing the level of the discount
- Give **all the details** of your proposed PAS and explain everything – rationale, evidence, assumptions
- Demonstrate you **understand the issues** that the NHS will face in implementing your PAS and how you have addressed them
  - Include details of how you will reduce administrative burden
  - Have a clear rationale for your estimation of NHS time and staffing required to implement the PAS, including how you have consulted with experts to reach your conclusions
- Include **all the documents** to be used to implement the proposed PAS
- **Inform the NICE technology appraisals team** and they can advise you on the information required by NICE on the proposed PAS in the context of the appraisal process. If the proposed PAS is to be considered as part of the appraisal, you will need to include details in your submission to the TA team
- Companies are advised to discuss timing with DH and to highlight key upcoming deadlines (e.g. NICE appraisal meetings, evidence submission dates)

# PASLU assessment

- The standard PASLU process is normally planned to take a minimum of twelve weeks, including a meeting of the PASLU Expert Panel. Details of how PASLU assesses the viability of PAS are set out in *'Process for advising on the feasibility of implementing a patient access scheme'*.
- There is an accelerated process for simple schemes, which is normally planned to take a minimum of four weeks. Details of how simple schemes are assessed can also be found in the process guide.
- As part of the assessment process, PASLU may need to seek additional information from the company. Where this is necessary the 'clock is stopped' on the PASLU process. Similarly, timescales are likely to increase if a company decides, based on feedback from PASLU/the Expert Panel, to alter or amend elements of their proposals.
- In practice, this means that assessments can sometimes take longer than the standard timescales, in particular for very complex proposals.
- At the end of the assessment, PASLU sends its advice on the proposed PAS to DH. This is not shared with any other party.

# Hints for the PASLU process

## Remember:

- **Sign the PASLU confidentiality statement as soon as you receive it**
- **Make sure you tell PASLU whom you have consulted within the NHS to help inform your PAS proposal**
- **When the clarification questions and draft advice are issued, read them carefully as they indicate a lot of the thinking about your submission and where it is believed there are areas of uncertainty**
- **If the process leads to a significant change in your PAS, it will need to be resubmitted to DH as well as to PASLU**
- **If in doubt, talk to PASLU – experience shows that good sustained dialogue is very helpful to all**

**TIP**

# Meeting of the PASLU Expert Panel

- The Expert Panel meets to discuss all standard PAS proposals. The company is invited to attend for the purpose of answering questions from the Panel
- It is essential you are well prepared to answer questions and provide clarification
- Please bring no more than three representatives (unless pre-agreed)

## Preparing for the meeting:

- **Ensure you know your submission in detail – scrutiny is strategic and detailed**
- **Examine the clarification questions and draft advice thoroughly so you are able to address the issues raised**
- **Anticipate likely questions and be prepared to give answers accordingly**
- **Agree who should answer questions on what**
- **Ensure you are represented by the people best equipped to answer the questions. For example:**
  - An expert in the submission who has intimate knowledge of the evidence included and assumptions used
  - A clinical expert able to give a clear clinical rationale for the design of your PAS
  - A supply chain expert who can discuss the details and complexities

**TIP**

# DH consideration

- DH Ministers consider the PAS proposal against the criteria set out in the 2009 PPRS, taking into account PASLU advice and other relevant considerations. They decide whether the proposal may be considered by NICE as part of the relevant appraisal(s).
- No indicative timeline is given for this stage as there are several variables that may affect the speed of consideration (e.g. Parliamentary recess periods), but DH always aims to deal with proposals in a timely manner, taking NICE processes into account.
- DH writes to NICE to confirm the outcome of Ministerial consideration, and informs the company when this has happened.
- Ministerial agreement results in a PAS proposal being referred to NICE for consideration. At this stage, it remains a proposal and **does not become an operational PAS unless and until the treatment is recommended in final NICE guidance.**
- If Ministers do not agree that a PAS proposal can be considered by NICE, depending on the timeline and stage of the relevant NICE appraisal, there may be an opportunity for companies to submit a revised/new PAS proposal. There may also be the option for 'rapid review' of final NICE guidance, to include consideration of a new PAS proposal. Companies considering either of these options should discuss their plans with both DH and NICE.

# Implementation of PAS

- If NICE recommends a medicine with a PAS, the PAS **must** be implemented and available to the NHS immediately on publication of final guidance.
- Share your draft communications materials with DH in the run up to implementation. DH will often provide feedback, so be prepared to revise drafts if required.
- Ensure DH has copies of all final documentation, highlighting any differences from earlier versions (if electronic systems are used, you can provide a pack of screen shots).
- Good communication about your PAS is essential – poor communication generally adds to negative perceptions of complexity.
- Keep your communications clear and simple, and provide an easily accessible point of contact for more information.
- Be proactive in informing the NHS about your PAS, what is involved in implementing it and what support the company will offer Trusts to help implement it.

## TIP

Only schemes included in final NICE appraisal guidance should be described as 'Patient Access Schemes'. A different term should be used for market access schemes available locally to NHS organisations.

# NICE review of the Guidance featuring your PAS

- It is expected that an operational PAS will remain in place (at least) until publication of a review of the relevant NICE guidance.
- Any changes to an operational PAS must be discussed and agreed with DH. Changes to simplify and improve the operation of a scheme (especially in response to NHS feedback) can often be relatively straightforward, but the expectation is that there should be no changes that fundamentally change the nature of a PAS once it is operational.
- NICE Technology Appraisal Guidance includes a date at which NICE will consider whether to review the guidance. As part of the review process, DH and NICE will ask for feedback as to how the PAS has worked in practice, for example:
  - Uptake (e.g. numbers of patients, numbers of centres)
  - Trusts' responses, perceptions and opinions
  - The proportion of sales of the medicine accessed under the scheme
- The NICE review process also provides an opportunity for the company to consider whether they wish to propose any changes to an operational PAS. All proposed changes **must** be discussed with DH and NICE, and may need to be submitted for consideration in the same way as a new PAS proposal.



# FAQs: who does what?

As the [process map](#) shows, a number of different bodies are involved in the development of PAS. The notes below give a brief overview of respective roles and responsibilities.

**Companies** decide if they want to offer a PAS and develop proposals. They submit these to DH (often following pre-submission discussions), answer clarification questions and/or provide further information required during the PASLU process, including, where relevant, at the PASLU Expert Panel meeting. Where Ministers agree a proposal can be considered by NICE, the company includes it in their submission to the NICE STA or MTA process. If a PAS ultimately forms part of final NICE guidance, the company informs the NHS of the details and implements the PAS.

**The Department of Health (DH)** acts as the 'gateway' for PAS proposals. DH can offer informal pre-submission advice on draft PAS proposals. When ready, PAS proposals must be submitted to DH on the appropriate 'Patient Access Scheme proposal template'. DH checks submissions for completeness, and refers them to PASLU for review. DH receives advice from PASLU, which informs a Ministerial decision as to whether a PAS proposal can be considered by NICE.

**Patient Access Scheme Liaison Unit (PASLU)** reviews PAS proposals against the PAS criteria. In assessing proposals and preparing advice to Ministers, PASLU engages the expertise of an [Expert Panel](#). PASLU provides advice to DH Ministers, to aid them in determining whether the proposal can be considered by NICE.

**NICE** assesses the clinical and cost-effectiveness of a medicine through either the Single Technology Appraisal (STA) or Multiple Technology Appraisal (MTA) process. A PAS proposal may only be considered as part of a relevant appraisal with Ministerial agreement. Where Ministers have agreed that a PAS proposal can be considered by NICE, the costs and benefits of the scheme are considered as part of the appraisal.

# FAQs: transparency of PAS and handling of information about PAS proposals

PAS can be associated with sensitive commercial information and **handling of information about PAS proposals** is often a key issue for companies.

All PAS proposals (and discussions about possible proposals) are **treated in confidence** whilst they are under consideration by DH (this includes the PASLU process). Proposals that do not proceed to consideration by NICE would normally remain confidential.

Where a PAS proposal is considered by NICE as part of an appraisal, NICE may need to disclose details about the proposed scheme as part of the appraisal process.

DH's general position is that all operational PAS should be transparent. The only exception to this principle is in the context of simple scheme PAS proposals, where Ministers have agreed that the discount rate can, under some circumstances, be treated as commercial-in-confidence. However, this is not automatic and companies wishing to propose that a discount remains confidential must specifically request this as part of their simple scheme PAS application.

NICE must be satisfied that sufficient information about a PAS can be published in appraisal guidance to explain an appraisal decision. You will also need to provide a contact point for NHS staff to find out more about the proposed PAS, should it come into operation.

**It is important to remember that, as public bodies, neither NICE nor DH can ever give absolute guarantees about confidentiality as there are legal circumstances, e.g. in the context of the Freedom of Information Act, in which they may be legally required to disclose information. Similarly, NHS organisations are independent bodies and the DH cannot guarantee the use that they may make of information.**

## FAQs: PAS in Scotland, Wales and Northern Ireland

The Devolved Administrations (DAs) determine many aspects of health policies, including those affecting the use and availability of medicines within their health systems.

Whilst the DAs make their own decisions about whether to take up a PAS, it is usually simpler for all parties if the same scheme can be offered across the UK.

It is helpful if companies can notify the DAs when they are submitting a PAS proposal in England. This is especially important if a company is proposing a PAS in England for a medicine that is being considered by Scottish Medicines Consortium (SMC) and/or the All Wales Medicines Strategy Group (AWMSG), or as part of a NICE multiple technology appraisal.

Where a medicine is due to be considered by the SMC and/or AWMSG, but no NICE appraisal is planned, a company may be able to propose a PAS, or similar arrangement, within the relevant process. Companies considering this should contact the SMC or AWMSG (and/or the Scottish or Welsh Governments), as appropriate. DH and PASLU are not able to advise in this situation.