NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient Access Scheme Liaison Unit (PASLU)

FAST TRACK

Patient Access Scheme proposal template
(Simple Discount scheme)

# Introduction

In acknowledgment of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access ([VS2019](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf)) and the NHS Commercial Framework for Medicines ([NHSCF](https://www.england.nhs.uk/medicines-2/commercial-medicines/nhs-commercial-framework-for-new-medicines/)) simple confidential and complex published Patient Access Schemes will continue to operate and be available for new products using existing processes and in accordance with existing criteria and terms as set out originally in the 2014 Pharmaceutical Price Regulation Scheme ([PPRS](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf)), and guidance on the National Institute for Health and Care Excellence (NICE) website..

The [VS2019](https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access) is a non-contractual scheme between the Department of Health and Social Care, NHS England (NHSE) and the Association of the British Pharmaceutical Industry (ABPI). The purpose of the [VS2019](https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access) has two parts:

* first, it sets out a range of measures for England, unless otherwise stated, to support innovation and better patient outcomes through improved access to the most transformative and cost effective medicines; and
* second, it sets out a UK wide affordability mechanism under which Scheme Members make a financial contribution to the Department for sales of Branded Health Service Medicines above the agreed allowable growth rate.

The [VS2019](https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access) committed NHSE to publishing a commercial framework, setting out more operational detail on the commercial arrangements with industry. The [NHSCF](https://www.england.nhs.uk/medicines-2/commercial-medicines/nhs-commercial-framework-for-new-medicines/) clarifies the commercial flexibilities that may be available to companies where appropriate. It states that PASs are the starting point or default option for companies to consider when developing their value proposition for appraisal by NICE. Unless a treatment is to be considered by NICE at list price, companies should always include a PAS in their initial evidence submission to NICE to ensure sufficient time for full consideration in advance of the appraisal committee meeting

Patient Access Schemes are arrangements which may be used for the acquisition of medicines for the NHS in England and Wales. Patient Access Schemes propose a discount, rebate or other variation from the list price of a medicine that may be linked to the number of patients estimated to receive the medicine, the clinical response of patients to the medicine or the collection of new evidence (outcomes) relating to the medicine. Proposed schemes should aim to improve the cost effectiveness of a medicine and therefore allow NICE to recommend treatments which it would otherwise not have found to be cost effective. More information on the framework for Patient Access Schemes is provided in the [PPRS (2014)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf).

Patient Access Schemes are proposed by a pharmaceutical company and agreed with NHSE, with input from the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation at NICE.

The PPRS recognises the need to ensure that the cumulative burden on the NHS arising from Patient Access Schemes is manageable. Simple discount Patient Access Schemes are preferred to complex schemes because they create no significant implementation burden for the NHS. Where a more complex scheme is proposed, applicants should use the [complex scheme proposal template](http://www.nice.org.uk/About/What-we-do/Patient-access-schemes-liaison-unit) rather than this simple discount scheme template, and will need to explain and justify their choice of scheme.

# Instructions for applicants

This template should be read in conjunction with [procedure for advising on the feasibility of implementing a Patient Access Scheme](https://www.nice.org.uk/Media/Default/About/what-we-do/PASLU/PASLU-procedure-guide.pdf). Potential applicants may also find it helpful to read the informal guidance document [Hints and tips for companies considering a Patient Access Scheme (PAS) proposal in England](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217037/PAS-Good-Practice-Guidance.pdf). If applicants want NHSE to consider a simple discount Patient Access Scheme proposal, they should use this template to submit information (evidence). For all other Patient Access Scheme proposals, the complex scheme template should be completed in conjunction with ‘Process for advising on the feasibility of implementing a Patient Access Scheme’.

This simple discount scheme template is designed for applicants to provide the information PASLU requires to assess the feasibility of implementing the proposed Patient Access Scheme using the principles set out in the PPRS (2014) (see appendix A), and explains the way in which information should be presented. Applicants should include all relevant information, including evidence not directly related to the PPRS (2014) principles. If applicants cannot follow the template format, they must clearly state the reasons for this. Applicants should insert ‘N/A’ in the sections they do not consider relevant to the proposed scheme and provide reasons for this response. All responses should be as concise as possible, while providing all the necessary evidence to support the proposal.

Applicants should only provide evidence that relates to the NHS in England and Wales. (Different health technology assessment arrangements are in place in Scotland and Northern Ireland, and a separate application process applies for Patient Access Scheme proposals in Scotland).

The completed template should be submitted to NHSE. If NHSE is content that the template includes sufficient evidence to allow a review, it will normally refer the proposal to PASLU. Please note that a signed proposal template declaration is required.

PASLU will review the proposed scheme against the simple discount scheme criteria in relation to the NHS in England and Wales and, with input from representatives of an independent expert panel, produce final advice to NHSE. They will make the final decision about whether a proposed Patient Access Scheme can be considered as part of a NICE technology appraisal or highly specialised technology evaluation.

For details about how NICE handles information relating to this proposal, please see the document ‘[Procedure for advising on the feasibility of implementing a Patient Access Scheme’](https://www.nice.org.uk/Media/Default/About/what-we-do/PASLU/PASLU-procedure-guide.pdf)

# Qualification as a simple discount Patient Access Scheme

For a proposed scheme to qualify as a simple discount Patient Access Scheme, the applicant must provide evidence to show that the scheme meets the criteria set out below.

**Please note:** if the scheme is implemented, the discount must be applied to the UK list price given in the relevant technology appraisal or highly specialised technology guidance and to any subsequent UK list price reductions. Details of the PAS, e.g. the fact it is a simple discount, will be included in the relevant NICE guidance. The cost to the NHS of purchasing the product must not exceed that considered in the development of the relevant technology appraisal guidance.

When the simple discount scheme criteria below cannot be fully met, applicants should consider submitting a complex scheme proposal instead.

**Fast Track Proposal instructions**

The standard timeline for a simple discount proposal review is a minimum of four weeks. The review of this fast track proposal will be completed within a maximum of ten working days. In order to qualify for this faster process you must select the GREEN coloured response for all questions that have a colour coded response option. If you select the RED option then the review of this proposal will revert to the standard timeline for a simple discount proposal, which is a minimum of four weeks. These timelines are from formal referral from NHSE to the issuance of the final advice to NHSE. Timelines for NHSE’s review of that advice and issuing a final decision on the proposal are separate and in addition to the PASLU timelines stated above.
The included confidentiality agreement (Appendix C) must also be signed and returned.

This document must be returned in its locked word format. If you are unable to insert signatures electronically then the signed pages should be scanned and sent separately.

|  |  |
| --- | --- |
| Criteria **A simple discount scheme must:** | Evidence provided in response to questions: |
| 1 | Offer a price\* 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 Patient Access Scheme) and in all settings. | 1, 2, 3, 4, 10 11 |
| 2 | Offer a reduction from the list price through a discount applied to all original invoices for the product. | 4 |
| 3 | Require no additional administration; ‘additional’ means over and above the administration required to purchase the product without a Patient Access Scheme (a single simple letter to trusts\*\* is allowed). | 4, 6, 10, 11 |
| 4 | Remain in place until NICE next reviews the guidance\*\*\* on the product and a final decision has been published on the NICE website. | 6, 8, 9, 11 |
| \*The discounted price may be a fixed maximum price or a discount that tracks any changes to the UK list price.\*\* If required, a single letter outlining the terms of the pricing agreement should generally be no longer than 1 side of A4 at a font size of no smaller than 10 point. It should contain clear statements and expectations for the NHS and the applicant. It is expected that the content will not introduce additional administrative burden. The letter should detail scheme specific elements and must be separate from the standard terms and conditions of supply.  \*\*\*Please note, the review date specified in the technology appraisal or highly specialised technology guidance indicates the date that the guidance is eligible for review.  |

# Applicant and contact details

|  |
| --- |
| Applicant details |
| Company name: |   |
| Address line 1: |   |
| Address line 2: |   |
| Address line 3: |   |
| Address line 4: |   |
| Address line 5: |   |
| Postcode: |   |

Please provide contact details for the people responsible for the proposed Patient Access Scheme. Please note that only these contacts will receive correspondence from PASLU about the proposed scheme. If these contacts change during the PASLU review, PASLU must be informed in writing.

|  |
| --- |
| Primary contact  |
| Name: |   |
| Email: |   |
| Tel: |   |

|  |
| --- |
| Secondary contact  |
| Name: |   |
| Email: |   |
| Tel: |   |

 Please also provide contact details for any queries relating to the PAS if it becomes operational. This should be a generic email address or monitored email inbox and/or phone number. These contact details will be included in any positive NICE guidance and PASLU will pass these details on to anyone who requests them.

|  |
| --- |
| Contact details for operational PAS  |
| Email: |   |
| Tel: |   |

# Details of the Patient Access Scheme

1. Please provide the name of the product and the indications (current and future) to which the proposed Patient Access Scheme applies.

|  |  |
| --- | --- |
| Name of the product\* |   |
| Current indications with marketing authorisation details |   |
| Future indications with estimated marketing authorisation dates  |   |
| Please confirm that the proposed scheme will apply to all current and future indications (including those not explicitly named) for all preparations, in all settings\*\* | Yes [ ]  |  No [ ]  |
| If **NO**, please explain why and consider a complex scheme proposal instead of a simple discount scheme proposal.  |   |
| \*Please provide the generic (INN) name and all UK brand names. |
| \*\*‘All settings’ refers to homecare providers, secondary care, NHS patients in a private hospital, private patients in an NHS hospital, outsourced hospital pharmacies, via homecare and outsourced aseptic units.  |

1. Please tick the box for the proposed discounting approach.

|  |  |
| --- | --- |
| Percentage discount from the UK list price (the list price may vary)  | [ ]  |
| Fixed price (which will not vary with any change to the UK list price) | [ ]  |
| For fixed price proposals, if the UK list price was reduced to a level lower than the proposed fixed price, would the applicant implement the lowest price? |  Yes [ ]  | No [ ]  |
| If **NO**, please provide some additional information: |   |

1. Please indicate if the applicant would like the discount level offered as part of the proposed simple discount scheme to be considered confidential by NHSE\*.

|  |  |
| --- | --- |
| Yes [ ]  | No [ ]  |
| If **YES**, please briefly outline the rationale for this request |   |
| \*If NHSE agree that a discount level may remain confidential, such agreement is always subject to the condition that the NHS must have access to the discount price, so Trusts and commissioners are able to properly account for the PAS. In addition, NHS organisations must be able to share data on PAS discounts, including for the purposes of benchmarking, within appropriate arrangements to safeguard confidentiality. |

1. When a Patient Access Scheme is implemented there is an expectation that the details will be communicated to the NHS in England and Wales. Please provide a copy of the communication that will be sent if the proposed Patient Access Scheme is implemented. Only a single simple letter to trusts is allowed.

|  |  |  |
| --- | --- | --- |
| Please confirm that in the event of a positive recommendation in the NICE guidance that you will send the attached letter (on letter headed paper) without any changes to the wording. | Yes [ ]  | No [ ]  |
| Please confirm that you will sign up to the NHSE pricing portal. | Yes [ ]  | No [ ]  |

|  |  |  |
| --- | --- | --- |
| Please indicate if NHS organisations will be required to complete any additional documentation\* to receive the benefits of the proposed simple discount scheme. | Yes [ ]  | No [ ]  |
|  If **YES**, a complex scheme would be more suitable than a simple discount scheme. |
| \*Other than reading a simple letter. |

1. To the best of your knowledge, does the proposed Patient Access Scheme adhere to legislation related to competition in the market.

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |

1. A simple discount scheme should be in place from the date of guidance publication and until NICE next reviews the guidance\* on the product and a final decision has been published on the NICE website. Please confirm that the applicant is able to offer the proposed Patient Access Scheme under these terms.

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |
|  If **NO**, a Patient Access Scheme proposal may not be appropriate. |
| \*Please note, the review date in the technology appraisal or highly specialised technology guidance indicates the date from which the guidance is eligible for review.  |

1. There may be specific circumstances in which the applicant might change or withdraw the proposed Patient Access Scheme, either nationally or for individual NHS organisations. Please tick the relevant boxes below:

|  |  |
| --- | --- |
| Nationally | [ ]  We do not envisage any circumstances in which the scheme would be withdrawn.  |
| [ ]  We do envisage a circumstance under which the PAS may be withdrawn but we agree that this would only be done following discussion and agreement with PASLU and NHSE.  |
| [ ]  Other; [ ]  |
| For individual NHS organisations | [ ]  We do not envisage any circumstances in which the scheme would be withdrawn.  |
| [ ]  We do envisage a circumstance under which the PAS may be withdrawn but we agree that this would only be done following discussion and agreement with PASLU and NHSE.  |
| [ ]  Other; [ ]  |

1. Please provide the current UK list price and details of the proposed discount.

|  |  |
| --- | --- |
| Date (DD/MM/YYYY) |   |
| Generic name |   |
| Brand name |   |
| PAS type |   |
| Discount (indicative if fixed price) |   |
| Preparation | UK list price\* | PAS price |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
| ID number | Indication |
|   |   |
| Conditions |   |
| \*If the list price has not been agreed with the Department of Health, please include proposed list price  |

1. How will the proposed discount appear on **all** the **original** invoices produced by the company to the purchasing organisations both **in England and Wales**. Please tick the most appropriate box

|  |
| --- |
| [ ]  The discount will appear on all original invoices, the first time the goods are transacted, to all purchasing organisations for NHS patients in England and Wales. |
| [ ]  The discount will appear on all original invoices, the first time the goods are transacted, to all NHS purchasing organisations in England and Wales. Where a third-party homecare provider or outsourced aseptics are used the original invoice will be at list price and a retrospective rebate will be applied for supplies to NHS patients. We will make it clear to the provider that we expect them to ensure that the NHS organisation is invoiced at the PAS price. |
| [ ]  Other; [ ]  |

1.
2. Please indicate whether the proposed Patient Access Scheme will operate under the following circumstances or settings. If so, give further details and any additional steps that would be required for the NHS to receive the product at the discounted price. **If it is anticipated that the product would not be delivered in any of the circumstances or settings listed, please briefly explain why and how you would ensure that there is no additional burden to the NHS**. **Please note that you should tick only one option.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Circumstance or setting** | **Has the NHS been consulted on this approach\*? (yes/no)** | **Scheme compatible? (yes/no)** | **Please select** ([x] ) **only one option in each category** |
| Homecare | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ] The discount will appear on all original invoices, the first time the goods are transacted, to all purchasing organisations for NHS patients in England and Wales. (no additional comment) |
| [ ]  The discount will appear on all original invoices, the first time the goods are transacted, to all NHS purchasing organisations in England and Wales. Where a third-party homecare provider is used the original invoice will be at list price and a retrospective rebate will be applied for supplies to NHS patients. We will make it clear to the provider that we expect them to ensure that the NHS organisation is invoiced at the PAS price. (no additional comment) |
| [ ]  This product is currently for hospital use only. Should there be a change to this in the future we confirm that option 1 or 2 will apply. (no additional comment) |
| [ ]  Other (additional comment required)  |
| NHS patients treated in non-NHS settings, e.g. private hospitals | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  In circumstances where the NHS Trust chooses to engage the services of a non-NHS provider to deliver a service we would seek evidence from the service provider that the product is to be used in the treatment of NHS patients and offer the PAS discount only for the treatment of these NHS patients. (no additional comment) |
| [ ]  Other (additional comment required)  |
| Private patients treated in an NHS hospital  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  All supplies to NHS hospitals will be at the PAS price. (no additional comment) |
| [ ]  Other (additional comment required)  |
| Contracted-out dispensing of NHS outpatient prescriptions by non-NHS organisations  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  An on-site outsourced non-NHS pharmacy will be supplied on the same terms as the hospital. They will be invoiced at the PAS price. (no additional comment)  |
| [ ]  Other (additional comment required)  |
| Outsourced aseptic units\*\*  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  The discount will appear on all original invoices, the first time the goods are transacted, to all purchasing organisations for NHS patients in England and Wales. (no additional comment) |
| [ ]  The discount will appear on all original invoices, the first time the goods are transacted, to all NHS purchasing organisations in England and Wales. Where an outsourced aseptic unit is used the original invoice will be at list price and a retrospective rebate will be applied for supplies to NHS patients. We will make it clear to the provider that we expect them to ensure that the NHS organisation is invoiced at the PAS price. (no additional comment) |
| [ ]  Other (additional comment required)  |
| FP10 prescription dispensed by a community pharmacist  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Not applicable. This product will not be FP10 prescribed. (no additional comment) |
| [ ]  Other (additional comment required)  |

\*It is expected that consultation will be carried out with the NHS in England and Wales. Please consider any operational variation between NHS organisations.
\*\* If appropriate for the treatment preparation.

1. Please confirm that cost and volume data will be collected and will be shared with PASLU and NHSE to enable the review of the PAS 12 months after becoming operational. Data required will include number of units sold to the NHS for each fiscal quarter of the year.

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |

1. Please confirm you will set up an exception reporting system to monitor the PAS. This system should highlight anomalies, explain the reason for these and detail the action taken to correct the situation.

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |

1. Please give the estimated number of patients who will be treated with the product over 3 years (including known future indications). Please provide references for the data source.

|  |  |
| --- | --- |
| Indication | Estimated number of patients |
| Year 1 | Year 2 | Year 3 |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
| Source:  |

1. Please provide details of any clinical uses outside the marketing authorisation (that the applicant is aware of) for which the technology could be used\*.

|  |
| --- |
|   |
| \*Please be as concise as possible. |

1. Is this product within, or intended to be included in, the Payment by Results tariff (National Tariff Payment System)?

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |
| If **YES**, please provide details here |   |

1. Is this product commissioned as part of specialised services (commissioned by NHSE) or as part of services commissioned by Clinical Commissioning Groups (CCGs)?

|  |  |
| --- | --- |
|  Yes [ ]  | No [ ]  |

1. Please provide information about expiry dates of relevant UK / EU patents and Supplementary Protection Certificates (SPCs) for this product.

|  |
| --- |
|   |

1. Is there any additional information that PASLU should take into consideration when reviewing the scheme? If so, please provide details.

|  |
| --- |
|   |

# Declaration

I confirm that all data relevant to the proposed Patient Access Scheme have been disclosed to NICE.

I confirm that the proposed Patient Access Scheme will:

* offer a price\* for the product that is lower than the list price, applies for all supplies and preparations of the product and is valid for all current and future indications (for the duration of the Patient Access Scheme) 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 Patient Access Scheme (a single letter is allowed)
* remain in place until NICE next reviews the product under the technology appraisals programme and a final decision has been published on the NICE website.

\*Note: the price offered may be a maximum fixed price or a discount that tracks any changes to the UK list price.

|  |  |
| --- | --- |
| Signed |   |
| Name |   |
| Position |   |
| Date |   |

Please insert a scanned signature or send a copy of this completed page as an attachment. (Note that a Word version of the completed template is required for PASLU review).

# Appendix A: Key principles of implementing a Patient Access Scheme in England and Wales from the PPRS (2014)

* 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 NHSE 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 PAS.
* The full costs to the NHS of any such arrangements should be included in the costs considered by the Appraisal Committee.
* 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 NHSE to take this issue into account when considering the viability of individual PAS. Priority is likely to be given to PAS 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 local commissioning (for example, 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 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 numbers, or the monitoring and recording of a patient’s condition over and above that for the normal management of a patient. PASLU has been established to advise NHSE on the feasibility of Patient Access Scheme proposals, and the PASLU process includes arrangements for consultation with the NHS.

# Appendix B: Letter template for sending to Chief Pharmacists at PAS implementation. At implementation this must be issued on company letterhead.

<<Chief Pharmacist>>

<<NHS Trust>>

<<Address >>

<<Date>>

**Notification of Patient Access Scheme**

**TA XXXX: [drug name] for the treatment of [indication]**

Dear Chief Pharmacist

This is to notify you that NICE has approved [brand name] ([drug name]) for use in the above indication.

[company name] has agreed a Simple Patient Access Scheme which has been approved by NICE and NHSE.

**The discount is confidential and commercially sensitive** and therefore should only be disclosed to those personnel who you believe need to know the discounted price in order to effectively manage the purchasing and commissioning of this product including internal NHS benchmarking.

If you receive any requests from non-NHS third-parties to disclose this confidential price please inform [company name].

Product: [brand name] ([drug name])

Strength: [xxxx]

Product Code:

NHS List Price: £xxxx\*

For information on the discount price of [drug name], in England Trusts should access the NHSE Commercial Access and Pricing (CAP) Portal and in Wales, Health Boards / Trust should access the Vault. Your chief pharmacist or pharmacy procurement specialist should have access and will therefore be able to view this information directly.

<<Insert pack code>>

If you have any questions regarding this Patient Access Scheme please do not hesitate to contact me

Yours XXXXXX

[signature line]

# Appendix C: Company or Sponsor Confidentiality Acknowledgement and Undertaking

Confidentiality form – Manufacturer or Sponsor



Patient Access Scheme Liaison Unit (PASLU)

Company or Sponsor

Confidentiality Acknowledgment and Undertaking

1. We, [insert name of organisation] ("**We**", "**Our**", "**Us**" orthe "**Organisation**"), acknowledge that We may receive Confidential Information in relation to our participation in NICE’s consultation process.

"**Confidential Information**" means all confidential information (however recorded or preserved) disclosed or made available, directly or indirectly, by NICE or its employees, officers, representatives or advisers to Us and/or Our employees, officers, representatives or advisers. Often this material will be commercially sensitive, or will have been provided to the Institute on an academic-in-confidence basis (for example research that has not yet been published). Confidential Information may include, but is not limited to:

* 1. points for clarification;
	2. draft advice;
	3. final advice;
1. Subject to paragraph 3 below, We undertake to NICE that We shall:
	1. keep all Confidential Information strictly confidential and, except as expressly permitted under this agreement shall not disclose, use, copy in whole or in part or modify or adapt any Confidential Information in any way without NICE’s prior written consent which may be given or withheld in its absolute discretion;
	2. not use any Confidential Information for any purpose other than participating in the consultation process and any appeal that We may lodge;
	3. limit access to any Confidential Information to such individuals within the Organisation as require access for the purpose set out in paragraph 2)(b) above;
	4. procure that any individual within the Organisation with access to any Confidential Information complies with this agreement;
	5. apply the same security measures and degree of care to the Confidential Information as We apply to Our own confidential information, which We warrant as providing adequate protection from unauthorised disclosure, copying or use;
	6. securely destroy or return all Confidential Information to NICE on written demand; and;
	7. not disclose any Confidential Information to any third party without the prior written consent of NICE, and in the event that such disclosure is permitted, We shall procure that such third party is fully aware of and complies with this agreement as if he were a party to it.
2. The undertakings set out in paragraph 2 above (the "**Undertakings**") shall not apply to information which:
	1. is in the public domain otherwise than through a breach of any of the Undertakings or a breach of any other confidentiality obligation owed by any person to NICE;
	2. was lawfully within Our possession before it was disclosed to Us by NICE, and neither the Organisation nor our alternative source of the information owed any confidentiality obligation to NICE in respect of it;
	3. is required to be disclosed by any court of competent jurisdiction or any government agency lawfully requesting the same provided that We use Our best endeavours to notify the Institute in advance of such disclosure; or
	4. is approved for release by prior written authorisation of NICE.
3. We acknowledge that:
	1. breach of any of the Undertakings could cause NICE harm that is irreparable and that cannot be compensated by damages, and that in the event of any actual or threatened breach of any Undertaking NICE shall be entitled to apply for and obtain (regardless of any rights NICE may have to claim damages) an injunction or other equitable relief against the Organisation;
	2. We acknowledge the fundamental importance of maintaining confidentiality to the Institute's consultation processes.  We acknowledge that if We breach any of the Undertakings, NICE shall be entitled to refuse to provide Us with Confidential Information in the future, whether relating to this or any other matter.
4. We acknowledge that:
	1. this agreement constitutes the entire agreement between the Organisation and NICE relating to the Confidential Information;
	2. any amendments to or waiver of any of the terms of this agreement must be set out in writing and signed on behalf of the Organisation and NICE;
	3. this agreement is governed by English law and subject to the exclusive jurisdiction of the English courts.

Signed by .…………………………………….…

Print name ...………………………………………

a duly authorised officer for and on behalf of………………..………..…………….

Date ………………………………..

C005\_PASLU\_MS\_Confidentiality\_Agreement\_V1-2