Patient Access Scheme (PAS) concise application insert approved name of medicine (Insert brand name of medicine)

**Document reference PAS801-018.01**

PAS Agreement comprising:

* PAS Approval Letter
* PAS Submission

and available from the [SMC website](https://www.scottishmedicines.org.uk/home):

the NHS Scotland Standard Terms for Patient Access Schemes (Revised January 2020)

# Instructions for completion

Companies should complete this concise application for proposed simple schemes that comply with the Standard “PAS Submission” for Simple Scheme; otherwise a Full PAS Application should be completed.

Refer to ‘NHSScotland Patient Access Scheme (PAS) Guidance’ document for further information and guidance on completion and submission.

Companies to complete sections titled:

* General Information
* Standard ‘PAS Submission’ for Simple Scheme

The PASAG Secretariat will complete sections titled:

* PAS Summary
* PAS Approval Letter
* For PASAG Secretariat Use Only

Completed applications should be saved as a Microsoft Word document using the following naming convention:

approved drug name (Brand Name) PAS Application Pack YYYYMMDD D0.1

# General information

1. Brand name

Insert brand name of medicine

1. Approved name

insert approved name of medicine

1. Company name

Insert company name

1. Submission date

Click or tap to enter a date.

1. Anticipated PAS start date

select anticipated effective date

For PAS proposals linked with an SMC assessment, the PASAG Secretariat shall select the date in which health boards and companies are advised, in confidence, of the assessment outcome. This date is typically the Friday following the scheduled SMC committee meeting. Until this date is known, the company should insert TBC into the date field.

For PAS proposals not linked with an SMC assessment, the company should select the date agreed with the PASAG Secretariat.

1. Context or circumstance in which PAS proposal is made

Choose an item.

1. If PAS proposal is linked to a SMC submission, please note the indication within the linked health technology appraisal (HTA) submission

Insert indication being reviewed within HTA submission or if not linked to an HTA submission, please state n/a.

1. When the HTA outcome is “not recommended” for routine use in NHSScotland, health boards can make the medicine available through individual patient request processes (eg PACS Tier 2). If the PAS proposal is linked to a SMC submission, please note if the stated discount will be available if the HTA outcome is “not recommended”.

Choose an option

1. Note any preparations of the medicine (SKUs, strengths, forms, pack sizes) which have a marketing authorisation, but are not included in the PAS proposal

Click or tap to enter text.

Enter details including pack sizes that are licensed but not marketed within the UK or enter N/A.

Note when completing the table in paragraph 8.1 of the PAS Submission, please use descriptors in alignment with the dictionary of medicines + devices (NHS dm+d).

1. Communication of PAS information to NHS boards (refer to PAS guidance – ‘Implementation process and communication’)

Select from drop-down list

1. Note the supply chain arrangements for the secondary care setting (hospital pharmacies)

Enter distribution arrangements for the medicine for hospital pharmacies

1. Note the supply chain arrangements for the primary care setting (for example community pharmacy and dispensing doctors)

Enter distribution arrangements for the medicine; will it be available for primary care supply? (refer to appendix 4 of the PAS guidance for operating a PAS discount in primary care)

1. Note if the company intends to, or has commissioned medicines homecare services for this medicine

Enter distribution arrangements for the medicine including if homecare is to be commissioned or not.

1. Information about expiry dates of relevant UK or EU patents, Supplementary Protection Certificates, and loss of data and or marketing exclusivity

Provide expected loss of exclusivity dates.

1. Commercial arrangements in effect elsewhere in the UK. Please confirm that the PAS proposal aims to deliver the same Net Price (effective price after all cost reduction mechanisms have been deployed) as those proposed, or in effect, for the medicine elsewhere in the UK.

Click or tap to add text.

1. Additional relevant information

Please provide any additional information relevant to the administration of the PAS, or the medicine in question.

1. Nominated Supplier Representative (to whom NHSScotland should work with during the operation of the PAS)

Insert Supplier’s Representative name or group email address or team name

Insert position or job title

Insert address

Insert contact no.

Insert email address

1. Contact details for any rebate requests made by NHSScotland

Please provide email addresses (preferably a centralised or team email address) to which NHS NSS should issue rebate claim requests to (as per the Claim Process) during the operation of the PAS.

1. Person completing PAS application form (if different to Supplier Representative in question 17)

Insert name of person completing form

Job Title of person completing form

Email address of person completing the form

# PAS Summary

## Icon  Description automatically generated

## Context and pricing

| **Feature** |  |
| --- | --- |
| Type of Scheme | Choose an item |
| Context  | The PAS has been updated / implemented (delete as appropriate) Choose an item. |
| Is there an established PAS? | Yes / No (delete as appropriate) |
| Is there a change to the effective price? | To be completed by PASAG Secretariat |
| Is the purchase price available on PCM? | Select from drop-down list |

****

## Supply chain arrangements

| **Supply setting** | **Supply chain arrangements** |
| --- | --- |
| Primary care | Completed by PASAG Secretariat |
| Secondary care | Completed by PASAG Secretariat |
| Medicines homecare | Completed by PASAG Secretariat |

## Icon  Description automatically generatedConfidentiality obligations

The Patient Access Scheme submission was made on the basis that the level of discount and net purchase price would be treated as commercial in confidence and as such, in accordance with the Standard Terms for Patient Access Schemes, you are required to take all necessary steps to ensure the confidentiality of this information.

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nss.np-pasag@nhs.scot

# Standard ‘PAS Submission’ for simple scheme

1. **General information**

Drug: insert approved name of medicine (Insert brand name of medicine®)

Supplier name: Insert company name

PAS No: PASxxx (Secretariat to complete)

The Common Services Agency (NHS NSS) acts for and on behalf of NHS Scotland Boards (Boards) in the establishment of the Patient Access Scheme (PAS) Agreement.

1. **Defined terms**

Defined terms employed in this PAS Submission as indicated by the use of initial capital letters have the meanings ascribed to them in the NHS Scotland Standard Terms for Patient Access Schemes.

1. **Constitution of PAS Agreement**

The PAS Agreement between the Supplier and each Board for the above Drug will be established by the issue of the PAS Approval Letter by NHS NSS on behalf of and with the authority of each Board and such PAS Agreement will be constituted by and governed by the PAS Approval Letter, this PAS Submission and the NHS Scotland Standard Terms for Patient Access Schemes (Terms).

1. **Duration**
	1. The PAS Agreement will commence on select anticipated effective date and applies to Supply of the Drug by the Supplier after that date for the treatment of Patients in accordance with the following clauses of this PAS Submission.
	2. While it is anticipated that the PAS Agreement and Board approval as aforesaid will continue once established, it may be necessary to review the situation due to changing circumstances. Accordingly, without prejudice to paragraph 5 below, either Party may terminate the PAS Agreement at any time after a period of five years from select anticipated effective date providing not less than three months’ prior notice in Writing to the other, and the PAS Agreement will terminate on the expiry of the notice period. NSS should be informed in Writing of the date of termination (addressed to the Patient Access Scheme Assessment Group (PASAG) Secretariat).
	3. Notwithstanding the foregoing, the PAS Agreement shall automatically terminate on the effective date of any new PAS Agreement concluded between the Parties in respect of the Drug.
2. **Material breach**

The importance of maintaining the confidentiality of Supplier Confidential Information noted in paragraph 11 below is acknowledged. Accordingly, disclosure by a Board, NSS or HIS of Supplier Confidential Information will constitute a material breach entitling the Supplier to terminate the PAS Agreement to which this PAS Submission relates by notice in Writing to NSS as the Board’s Representative (addressed to the Patient Access Scheme Assessment Group (PASAG) Secretariat); And provided further that, in the event such a material breach negatively impacts, or is demonstrated by the Supplier to be substantially likely to negatively impact the price achieved for the Drug outwith Scotland as a result of Confidential Information being used as a reference price, the Supplier shall be entitled to terminate the PAS Agreement to which this PAS Submission relates with each and every Board; provided that no notice of termination shall be given unless and until the Supplier has submitted evidence of the alleged material breach and afforded NSS and the Board or Boards in question an opportunity to consider the evidence and respond thereto and the Supplier shall have regard to the process for dealing with matters arising in relation to the application of PAS described in section 9 (Unresolved Matters) of the NHS Scotland Standard Terms for Patient Access Schemes.

1. **Effect of early termination**

In the event of early termination, the Supplier will work with NSS and individual Boards to ensure continuity of care for those Patients already initiated on treatment.

1. **Event Drug is not recommended at reassessment**
	1. If the Drug is granted interim acceptance advice by SMC or is being considered under the Ultra‑Orphan pathway and is subsequently not recommended at reassessment, the Supplier will work with NSS and individual Boards to ensure continuity of care for those Patients already initiated on treatment.
	2. The Supplier acknowledges that if the Drug is granted interim acceptance advice by SMC or is being considered under the Ultra-Orphan pathway and is subsequently not recommended at reassessment, the provisions in Clause 4 (Duration) will continue to apply. There is no provision to terminate this Agreement on the basis that the Drug is subsequently not recommended at reassessment.
2. **Scope of PAS Agreement and cost reduction mechanism**
	1. The PAS Agreement is for Patients treated with insert approved name of medicine (Insert brand name of medicine®). The simple finance-based scheme provides a variable rate discount on the NHS List Price to maintain a fixed PAS Price as follows (excluding VAT):

| **Strength** | **Form** | **Pack size** | **NHS List Price** | **Discount** | **PAS Price** |
| --- | --- | --- | --- | --- | --- |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |
| strength | form | size | £x,xxx.xx | xx.x% | £x,xxx.xx |

To avoid the need for individual patient tracking, the discount will apply to all purchases of the Drug, including future licensed indications, without prejudice to paragraph 4 above.

* 1. The PAS Agreement is applicable when the Drug is Supplied to Patients through secondary and tertiary care. The PAS Price is available to the Board at the point of invoice when Supplied through secondary and tertiary care.
	2. The PAS Agreement is applicable when the Drug is Supplied to Patients via both Supplier and Board commissioned medicines homecare arrangements. The PAS Price is available to the Board at the point of invoice when Supplied through medicines homecare arrangements.
	3. The PAS Agreement is applicable when the Drug is Supplied to Patients via Board‑commissioned third‑party compounding arrangements. The PAS Price is available to the third-party compounder with additional costs for compounding met by the Board.
	4. The PAS Agreement is applicable when the Drug is Supplied to Patients through primary care. The PAS Price is available to the Board via a retrospective rebate. The Supplier will pay a retrospective rebate to the Board, calculated as the difference between the total amount of spend (Gross Ingredient Cost) on the Drug and the total cost of the Drug at the PAS Price.
	5. The PAS Agreement is applicable when the Drug is Supplied to Patients currently residing within His Majesty’s Prisons (HMP) or Young Offenders Institutions (YOI) in Scotland managed by or contracted to the Scottish Prison Service (SPS). The PAS Price is available to the Board via a retrospective rebate. The Supplier will pay a retrospective rebate to the Board, calculated as the difference between the total amount of spend (Gross Ingredient Cost) on the Drug and the total cost of the Drug at the PAS Price.

##### Review

* 1. The Supplier shall notify the Patient Access Scheme Assessment Group (PASAG) Secretariat as soon as practicable of any change to the NHS List Price.
	2. The Supplier shall notify the PASAG Secretariat as soon as practicable if a discount mechanism delivering a different effective price has been agreed in England, Wales or Northern Ireland.
	3. Where a discount mechanism delivering a different commercial arrangement has been implemented in another part of the UK, on a temporary or permanent basis, and that commercial arrangement results in a lower Net Price (hereafter defined) for the Drug, the Supplier will work with the PASAG Secretariat to agree a reduction in the purchase price or other cost reduction mechanisms that delivers an equivalent commercial arrangement for the Drug (“PAS Agreement Update”). Notwithstanding the date of signature of the PAS Agreement Update, it is intended that the PAS Agreement Update shall come into effect on the same date that the different commercial arrangement for the Drug is implemented elsewhere in the UK (“Effective Date of Applicability”). For the purposes of this paragraph 8.9, “Net Price” shall mean the actual price paid for the Drug after all cost reduction mechanisms have been deployed.
	4. Health Boards should not be financially disadvantaged by delays in agreeing a PAS Agreement Update. If there are sales of the Drug in Scotland after the Effective Date of Applicability and prior to implementation of the PAS Agreement Update, the Supplier shall work with the PASAG Secretariat to compensate the Boards through a retrospective rebate (the difference between the Net Price delivered by the PAS Agreement Update and the previous Net Price in Scotland) for supplies made between the Effective Date of Applicability and implementation of the PAS Agreement Update.
1. **Claims Procedures**
	1. No claims procedure is required by the Board when the Drug is Supplied through secondary and tertiary care, medicines homecare or via third party compounding arrangements as the PAS discount is provided at the point of invoice.

**Claims Procedure when the Drug is Supplied via primary care or to Patients residing in HMP / YOI**

* 1. When the Drug is Supplied in primary care or to Patients currently residing within His Majesty’s Prisons or Young Offenders Institutions in Scotland managed by or contracted to the SPS, then a rebate will be claimed as outlined in the following claims process.
	2. On a quarterly basis, NSS will provide the Supplier with a request for payment for the total value of the rebate due (as per paragraphs 8.5 and 8.6) to NHSS and a usage report. The usage report will include data from the Prescribing Information System for Scotland (PRISMS) and from prisons supplies. PRISMS is drawn from reimbursement claims for Supply against NHS prescriptions by NHS Dispensing Contractors. Reports detail usage in each Board area and will contain the following information:
		1. Quantity (for example number of packs, tablets or capsules) of Drug which has been dispensed in each Board over a three‑month period;
		2. Associated Gross Ingredient Cost (GIC) for each strength and formulation of the Drug, that is the total cost (quantity x NHS List Price) for the Drug charged to the prescribers’ drug budget (excluding VAT and any pharmacy remuneration fees or allowances);
		3. Calculation of the rebate that is due to each Board.
	3. PRISMS reports and the request for payment will be issued by NHS NSS quarterly to the Supplier’s named contact following the indicative schedule below in line with the availability of PRISMS data (which is three‑months in arrears).

| **Time period covered by the request for payment (months in which Drug was dispensed)** | **Month that reimbursement data are available / estimated month in which NSS issues request for payment to the Supplier** |
| --- | --- |
| 1 January to 31 March | July |
| 1 April to 30 June | October |
| 1 July to 30 September | January |
| 1 October to 31 December | April |

* 1. The Supplier will rebate the request for payment amount into the NSS bank account by BACS (Banker’s Automated Clearing Service) transfer within 30 days of receiving the request for payment. A remittance advice will be sent to the contact within NSS that is named on the request for payment. BACS transfers should include the request for payment number. NSS will reconcile and disburse payments to each Board. Boards will receive a consolidated report from NSS with product level details of all rebates due and confirmation that they have been received.

**Claims Procedure for delays in achieving comparable commercial arrangements with the rest of the UK**

* 1. When a PAS Agreement Update is agreed, as per paragraph 8.10, and the Supplier has agreed to pay a retrospective rebate, the following claims procedures will apply:
	2. Where the new cost reduction mechanism is a simple discount scheme:
		1. For supplies of the Drug through secondary care, tertiary care, medicines homecare and third‑party compounding arrangements, the Supplier shall promptly arrange a rebate to Boards for supplies made between the Effective Date of Applicability and the implementation date for the PAS Agreement Update (“Rebate Period”). The Supplier will agree with PASAG Secretariat whether the compensation to Boards is administered via credit note, bank transfer or adjustment of invoices.
		2. For supplies of the Drug made via primary care or for Patients residing in HMP / YOI; the Supplier and NSS shall work together to calculate and claim a rebate for supplies made during the Rebate Period on behalf of Boards following the procedure set out in 9.3 to 9.5 and taking into account any rebate claims already made by NSS and paid by the Supplier for the relevant time period.
	3. Where the cost reduction mechanism in the PAS Agreement Update is a complex financial or performance-based scheme, the Supplier and PASAG Secretariat will agree the appropriate procedure to rebate Boards for supplies made during the Rebate Period.
1. **Verification Record**

The Board is not required to maintain a Verification Record for PAS Agreements for simple schemes. No additional Patient monitoring is required over and above what would be required if the PAS Agreement was not in use. The Supplier will provide PAS monitoring data to the Patient Access Scheme Assessment Group (PASAG) Secretariat on request, which may be shared with the relevant Board subject to the obligation of confidence contained in NHS Scotland Standard Terms for Patient Access Schemes.

1. **Supplier Confidential Information**

The level of discount and purchase price is subject to the obligation of confidence contained in NHS Scotland Standard Terms for Patient Access Schemes.

1. **Supplier Representative**

The Supplier’s Representative for the purposes of the PAS Agreement is Insert Supplier’s Representative name or group email address or team name or such other person as may be notified to the Board in accordance with the Standard Terms.

1. **Authorised signatory**

To be signed by director or company secretary or authorised signatory of Supplier. In case of execution by authorised signatory, Board minute or other document confirming authority should be exhibited and a copy retained with the PAS Submission.

**Signature: **

**Print name:** Insert name

**Position:** Insert position

**Date:** Insert date

# PAS Approval Letter

|  |  |  |
| --- | --- | --- |
|  | **National Procurement**Gyle Square1 South Gyle CrescentEdinburgh EH12 9EB[www.nss.nhs.scot](http://www.nss.nhs.scot) | N H S NATIONAL SERVICESLOG |
|  | Date PASAG Secretariat to add dateOur Ref: PASxxx (Secretariat to complete)  |
| Enquiries to nss.np-pasag@nhs.scot  |

Insert Supplier’s Representative name or group email address or team name

Insert position or job title

Insert company name

Insert address

Insert email address

DearInsert Supplier’s Representative name or group email address or team name

The Patient Access Scheme (PAS) proposed by Insert company name (the “Supplier”) for insert approved name of medicine (Insert brand name of medicine®) (the “Drug”) has been approved by PASAG.

I am pleased to confirm that the Common Services Agency (commonly known as NHS National Services Scotland) has approved the establishment of the PAS Agreement on behalf of and with the authority of each Board. As such the individual Boards’ Representatives need not be listed. The PAS shall be governed by the following terms and conditions:

1. The NHS Scotland Standard Terms for Patient Access Schemes;
2. The Supplier’s PAS Submission; and
3. This PAS Approval Letter.

The date on which the PAS shall come into effect isselect anticipated effective date.

Yours sincerely

****

**Lindsay McClure**

**Associate Director – Medicines Pricing and Supply**Secretariat to add signature

# For PASAG Secretariat use only

|  |  |
| --- | --- |
| **PASAG Secretariat Assessment** | **Date** |
| **Assessed by:** | **Insert name**  | **Insert date** |
| **Peer-reviewed by:** | **Insert name**  | **Insert date** |
| **Date of scheduled PASAG Meeting:** | **Insert date** |

|  |  |  |
| --- | --- | --- |
| **PASAG Decision Making** | **Check** | **Date** |
| **Proposal appropriate for delegated approval by the PASAG Secretariat** |[ ]  **Insert date** |
| **PAS referred to Co-Chairs** | Approved by Co-Chairs  | [ ]  | **Insert date** |
|  | Referred to full PASAG committee | [ ]  |  |
| **PAS proposal considered by PASAG committee**  | **Check** | **Date** |
| PAS acceptable for implementation in NHSScotland |[ ]  **Insert date** |
| PAS not acceptable unless modifications to the scheme are made\* |[ ]   |
| PAS not recommended\* |[ ]   |
| \* modifications requested and / or rationale for not recommended decision |
| Click or tap here to enter text. |

|  |
| --- |
| **PASAG Decision - Declaration** |
| I/We (delete as appropriate) confirm the decision above and that I/we (delete as appropriate) have no declarations of interest relevant to this patient access scheme.  |
|  | **Shape  Description automatically generated with low confidence** |
| **PASAG Co-Chair / Secretariat** **(delete as appropriate)** | **PASAG Co-Chair / Secretariat** **(delete as appropriate)** |
| **Date** | **Insert date** | **Date** | **Insert date** |

|  |
| --- |
| **Additional information for consideration or inclusion in implementation pack** |
| Enter other additional information or issues for consideration, including items of relevance for an implementation pack. |

|  |
| --- |
| **National Procurement - Governance** |
| Approval given for the PASAG Secretariat to add the signature to the ‘**PAS Approval Letter’** of the Associate Director – Medicines Pricing and Supply, of National Procurement. |
| **Digital signature and date stamp** |  |

|  |
| --- |
| **PAS Context and Implementation Outcome**  |
| **SMC Advice on medicine****(**SMC ID [Secretariat to complete]**)** | Choose an item. | **PASxxx (Secretariat to complete)** **or****PAS No. NRXX (Secretariat to complete)** |
| **SMC initial Ultra-Orphan assessment report (SMC ID [Secretariat to complete])** | **PASxxx (Secretariat to complete)** |
| **PAS for other reason (eg paediatric licence extension, technical change, or alignment with Home Countries)** | **PASxxx (Secretariat to complete)** |

## Associated documented information

Document Ref Document Title

|  |  |  |
| --- | --- | --- |
| PAS801-018 |  | Patient Access Scheme (PAS) Guidance |
| PAS801-018.03 |  | NHSScotland PAS Standard Terms |

## Document revision history

For activation dates, refer to Q-Pulse.

|  |  |
| --- | --- |
| **Version** | **Description of Amendments** |
| 10 | June 2021Update to name of signatory on PAS Approval Letter and for National Procurement Approval |
| 11 | April 2023Update to PAS Submission (sections 8 and 9) to include more information on rebate payments for Primary Care and Prisons usage, including payment termsUpdate to PAS Submission (sections 8 and 9) to include more detail on delivering comparable arrangements with the rest of the UKRe-formatted document in line with NSS accessibility guidanceRevised “For PASAG Secretariat use only” section |