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

**Document reference PAS801-018.02**

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 the concise application for proposed simple schemes that comply with the Standard “PAS Submission” for Simple Scheme; otherwise this 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
* Details of proposed PAS
* PAS Submission

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 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 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.

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

# 

# Details of proposed PAS

##### Type of scheme

Please indicate the type of proposed PAS: Choose an item.

##### Proposed cost reduction mechanism

The cost reduction mechanism will be Choose an item

###### Purchase price

Table 1 should be completed to include all strengths, formulations and pack-sizes of the medicine within scope of the PAS and note the invoice price (PAS Price) applied when the medicine is purchased in the secondary care setting. Note the guidance for operation of PAS in primary care settings advises that the purchase price for primary care dispensing contractors will be the NHS List Price. Prices should be excluding VAT.

**Table 1: Purchase price of the medicine**

| **Strength** | **Form** | **Pack size** | **NHS List Price1** | **Discount** | **PAS Price2** |
| --- | --- | --- | --- | --- | --- |
| 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 |

1 – Primary care contractors will be reimbursed by health boards for dispensing the medicine at the NHS List Price; a rebate for the difference between NHS List Price and the PAS Price will allow the PAS discount to operate in this setting.

2 – The PAS Price will apply at the point of purchase when health boards supply the medicine via most settings (with exception of primary care or prisons).

###### Complex cost reduction mechanism

For complex cost reduction mechanisms, outline the details, associated processes and financial flows

Click or tap to enter text.

Supporting documents

List any additional supporting documents included with application such as PAS Claim Forms.

##### Clinical use of the medicine

###### Prescribing setting

Describe the anticipated setting in which the medicine will be prescribed. Please indicate if the scheme excludes any potential future prescribing settings that may occur within the lifetime of the PAS.

Click or tap to enter text.

###### Supply route

Describe the anticipated supply route for the medicine under the PAS (for instance hospital pharmacy, primary care, medicines homecare). Please indicate if the scheme excludes any potential future supply route that may occur within the lifetime of the PAS.

Click or tap to enter text.

###### Posology

Insert standard treatment dose, dosing schedule and duration of treatment

###### Posology adjustments

Insert any necessary posology adjustments (for example due to adverse effects or due to hepatic / renal impairment).

###### Treatment discontinuation

Provide information on the timing, reasons, and proportion of patients that discontinue treatment with the medicine

Click or tap to enter text.

##### Operation of the PAS (complex cost reduction mechanisms)

###### Identifying the patients or population for which the PAS is applicable

Describe how the information required to operate the complex cost reduction mechanism will be sourced and communicated to NHS and the company. Note any identified equity or equality issues and steps taken to address these issues.

Click or tap to enter text.

Does the PAS require additional patient monitoring over and above what would be required if the PAS was not in effect?

Outline any additional patient monitoring or reporting required to operate the complex cost reduction mechanism, that would otherwise not be required in routine practice.

Click or tap to enter text.

###### Uptake monitoring

Describe the plan to monitor the operation of the PAS to ensure it is delivering the intended benefits of the scheme

Click or tap to enter text.

###### Costs to the NHS to operate the PAS

The costs to the NHS in operating the scheme should be included in the assessment of the PAS proposal. Outline the estimated costs across NHSScotland to implement and operate the scheme, including

* initial set-up costs (such as developing local SOPs and verification record, staff training and awareness) across 14 NHS boards, and
* recurring costs (such as cost per patient to administer scheme including registration, initiating claims and reconciling payments).

Please provide as much details as possible, including basis of costs, such as time per activity, NHS staff grade and source of information.

Click or tap to enter text.

###### Burden minimisation

Outline what steps have been taken to minimise the operational burden of the complex cost reduction mechanism

Click or tap to enter text.

###### Prior engagement with NHS to inform the PAS proposal

Describe any engagement with NHSScotland in the PAS development

###### Operational flow diagram of the complex cost reduction mechanism

A flow diagram describing the exchange of information and financial flows between the company, health boards and NSS



##### Benefits of the proposed PAS

###### Patient numbers

Complete Table 2 to provide the number of patients expected to be managed with the medicine, for the indication under review, over the five‑year minimum duration of the PAS

**Table 2: Number of patients expected to receive the medicine**

| **Year** | **Number of new patients initiating treatment with the medicine** | **Total number of patients treated with the medicine (incident and existing patients)** |
| --- | --- | --- |
| 1 | xx | xx |
| 2 | xx | xx |
| 3 | xx | xx |
| 4 | xx | xx |
| 5 | xx | xx |

Please provide details for how the patient numbers have been estimated with sources cited (such as SMC budget impact template, epidemiological data, and market intelligence on uptake). In addition, for complex PAS, please provide an estimation of patient numbers where the PAS does not apply (for example, other licensed indications).

Click or tap to enter text.

###### Financial benefits

Complete Table 3 detailing for the medicine for the indication under review: utilisation, spend at the current price, spend at the net price delivered with the proposed PAS, and where applicable the expected value of rebates. Report financial values excluding VAT.

**Table 3: utilisation and costs for the medicine for the indication under review**

| **Year** | **Estimated utilisation1** | **Estimated spend at current price2** | **Estimated spend at net price proposed** | **Estimated value of rebates3** |
| --- | --- | --- | --- | --- |
| 1 | xx | £xx | £xx | £xx |
| 2 | xx | £xx | £xx | £xx |
| 3 | xx | £xx | £xx | £xx |
| 4 | xx | £xx | £xx | £xx |
| 5 | xx | £xx | £xx | £xx |

1 = please note units of measure such as vials, tablets, mL, mg and so forth

2 = If no PAS is in effect, then the current price will be NHS List Price. If there is a PAS in effect for the medicine, then the applicable PAS Price should be used.

3 = While PAS Prices for supplies via primary care are delivered by rebates; rebates for that purpose do not need to be estimated in Table 3. Only provide an estimate of rebates associated with the proposed complex cost reduction mechanism.

Please provide details on how utilisation in Table 3 has been estimated

Click or tap to enter text.

###### Estimated equivalent simple discount

For complex cost reduction mechanisms please provide an estimate of the equivalent simple discount that would deliver the same financial benefits to NHSScotland, with details on how this estimate was derived.

Click or tap to enter text.

##### Rationale and justification for proposal

###### Rationale for PAS

Outline the rationale for submitting a patient access scheme. If the aim of the PAS is to manage an area of uncertainty in the HTA, please detail what this is and how the PAS will address this.

Click or tap to enter text.

###### Justification for a complex cost reduction mechanism

If a complex cost reduction mechanism is proposed, please provide justification for complexity as opposed to a simple discount arrangement.

Click or tap to enter text.

##### Current and future health technology appraisals

###### Current SMC advice

Please detail the existing advice published by the SMC for the medicine for all indications

Click or tap to enter text.

###### Future indications or SMC submissions

Provide information on future licensed indications, timelines and SMC submissions for the medicine, within the next five years

Click or tap to enter text.

# PAS Summary

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## 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 |

*Bespoke guidance notes on the cost reduction mechanism, operational flowchart, and any actions for implementation or ongoing management to be written by PASAG Secretariat.*

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## 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** **(amend in line with clause 11 in PAS Submission)** 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](mailto:nss.np-pasag@nhs.scot)

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# PAS Submission

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 cost reduction mechanism will be Choose an item.
   2. A simple finance-based cost reduction mechanism 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.

**Clauses for complex cost reduction mechanisms**

* 1. Outline details of the complex cost reduction mechanism, relevant prices (excluding VAT), patient population, and any additional relevant information. The PASAG Secretariat will support with formatting these clauses as appropriate.

**Settings**

* 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 deliver 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 8.11, “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.
  5. The Supplier and the PASAG Secretariat will formally review the PAS arrangements on an annual basis. The review will include an assessment of the perceived and realised benefits to NHSScotland from the PAS, and with a view to simplifying the cost reduction mechanism.
  6. Include an exit strategy for complex cost reduction mechanisms which may become inoperable should certain anticipated events occur such as entry of generic, or biosimilar versions of the Drug. The exit strategy should include transition arrangements when simplifying from a complex cost reduction mechanism.

1. **Claims Procedures**

**Claims Procedure when the Drug is Supplied via primary care or 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 **8.7 and 8.8**) 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 the complex cost reduction mechanism**

* 1. Insert claims procedure for proposed complex schemes (including reference to any patient registration or claim forms, timeframe for claims). Include a clause noting that NSS will collate health board claims and submit a request for payment including individual board claims to the Supplier. The request for payment will include an element of non-recoverable VAT as incurred by health boards, for any Drugs supplied through secondary or tertiary care. The Supplier will pay the undisputed request for payment to the bank account of NSS by Banker’s Automated Clearing Services (BACS) within 30 days of receiving the applicable request and send a remittance advice note. NSS will then disburse funds to each Board.

**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 8.12**, 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 **9.2 to 9.4** 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**

Insert the following statement for proposed simple schemes: ‘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.’ OR insert the following statement for proposed complex scheme: ‘The Board shall maintain the following Verification Record for a period of six years’ and specify any required information to be maintained by the Board to validate claims, when this will be done and any audit requirements. 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**

Insert supplier confidential information are 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: Shape

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**Print name:** Insert name

**Position:** Insert position

**Date:** Insert date

# PAS Approval Letter

|  |  |  |
| --- | --- | --- |
|  | **National Procurement**  Gyle Square  1 South Gyle Crescent  Edinburgh EH12 9EB  [www.nss.nhs.scot](http://www.nss.nhs.scot) | N H S NATIONAL SERVICESLOG |
|  | Date PASAG Secretariat to add date  Our Ref: PASxxx (Secretariat to complete) | |
| Enquiries to  [nss.np-pasag@nhs.scot](mailto: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

**Shape

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**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.

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| --- | --- |
| **Version** | **Description of Amendments** |
| 10 | June 2021  Update to name of signatory on PAS Approval Letter and for National Procurement Approval  Inclusion of “Implementation” page for completion by Secretariat.  Revision of Clause 3 in PAS Submission to match wording with Concise Application Form  Reformatting of Clauses 8 in PAS Submission for ease of editing |
| 11 | April 2023  Update to PAS Submission (sections 8 and 9) to include more information on rebate payments for Primary Care and Prisons usage, including payment terms  Update to PAS Submission (sections 8 and 9) to include more detail on delivering comparable arrangements with the rest of the UK  Re-formatted document in line with NSS accessibility guidance  Revised “For PASAG Secretariat use only” section |