Public Services Delivery
Scotland

NHS SCOTLAND

Patient Access Scheme Guidance

PAS801-018

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Introduction

Patient Access Schemes (PAS) are proposed by pharmaceutical companies to improve the cost-effectiveness of a medicine. Agreed key principles for PAS can be found in Appendix 1.

A PAS can enable patient access to medicines that are not, or might not, be found to be cost-effective by the Scottish Medicines Consortium (SMC). The SMC will only consider the financial benefits of a proposed PAS in the Health Technology Assessment (HTA) process if the scheme has been accepted for use in Scotland by the Patient Access Scheme Assessment Group (PASAG).

This document sets out the process for the submission, assessment and implementation of PAS in Scotland.

Patient Access Scheme Assessment Group (PASAG)

The role of PASAG is to deliver a national service conducting an objective and independent assessment, on behalf of NHS Scotland, of PAS submitted by pharmaceutical companies and advise on their acceptability for implementation by health boards.

The group is co-chaired by a Director of Finance and a Director of Pharmacy and includes members from across the NHS in Scotland, with different specialist backgrounds including acute and primary care clinicians, pharmacy, finance, management, procurement, public health, formulary decision making, information services and information governance.

In addition, there are several PASAG observers or those who provide specialist input including representatives from the Scottish Government Health and Social Care Directorate, the SMC and the Central Legal Office (CLO).

The PASAG Secretariat is hosted by National Procurement, Public Services Delivery Scotland (PSD Scotland). The secretariat can be contacted via email: **nss.np-pasag@nhs.scot**

Types of schemes

There are two types of PAS; simple discount schemes and complex schemes. The NHS in Scotland commits to maintaining the confidentiality of the arrangements irrespective of scheme type.

A simple discount scheme is the simplest cost reduction mechanism. It involves a discount from the NHS list price which is applied at the point of invoice when supplied through secondary / tertiary care, homecare or a third-party compounder.

When the medicine is supplied via primary care or to NHS patients in prisons, then the simple discount is transacted through a rebate mechanism with the rebate applied to the volume reimbursed by the NHS. There is no requirement in a simple discount scheme to identify and track individual patients.

Simple discount schemes are the preferred scheme type within the NHS in Scotland as they do not impose any significant additional burden to the NHS or pharmaceutical companies.

Simple discount schemes are proposed using the Concise PAS Application Form. The Concise PAS Application Form includes standard terms and conditions supported by PASAG. If companies wish to propose a simple discount scheme with amendments to these terms, then a Full PAS Application Form should be used.

Complex schemes include all other types of cost reduction mechanism such as:

- indication-based pricing
- budget cap
- rebates (when medicine is supplied via secondary / tertiary care or homecare)
- stock supplied at zero cost
- dose / spend capping
- outcome-based schemes (based on patients' response to treatment).

Experience with complex schemes has been that they can introduce significant complexity and burden for the NHS and pharmaceutical companies, and their perceived financial benefits may not be fully realised in practice. They tend to be accepted only in exceptional circumstances. Companies will be asked to provide robust rationale and justification for a complex scheme as opposed to a simple discount PAS.

Assessment of complex PAS will involve engagement with key stakeholders in the health boards to understand the availability and feasibility of obtaining data to operationalise a proposed scheme

In NHS Scotland, all adult cancer centres use Chemotherapy Electronic Prescribing and Administration Systems (CEPAS) for systemic anticancer therapies (SACT). Data from the CEPAS in all territorial health boards in Scotland are fed into a National SACT Dataset administered by Public Health Scotland. Supported by the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG) investment fund, the NHS in Scotland is developing its data capability to support complex commercial arrangements such as indication-based pricing PAS. Subject to limitations on how CEPAS are configured and are able to differentiate and categorise

prescriptions to relevant indications, it is the vision that Public Health Scotland will provide PASAG with the data required to operate indication-based pricing PAS.

Scheme setting and duration

Proposed schemes should use existing models for the delivery of patient care within NHS Scotland and should not act as a barrier to the development of potential future models of care.

Within the minimum five-year lifetime of the PAS, care delivery models can change to meet the needs of patients and the NHS; given this, as a principle, the PAS pricing arrangements should be applicable in all settings that the medicine is dispensed. The PASAG Secretariat can be contacted for advice regarding supply chain arrangements to the NHS in Scotland if required.

Where SMC advice for a medicine has considered the benefits of a PAS for that medicine, the validity of the SMC advice is dependent upon the ongoing availability of a PAS, or NHS List Price, that delivers a net price for the medicine no more than the price used by SMC in that assessment. As such, the expectation is that an operational PAS will remain in place for the lifetime of the relevant SMC advice. Contractually, the PAS Agreement allows a company to provide notice to terminate a PAS after a minimum of five years since the most recent SMC advice was issued.

When changes to the PAS are made linked to new formulations, pack sizes or company changes, the original minimum duration of the PAS Agreement will be retained.

When changes to the PAS are made to harmonise pricing across the UK, if the change has been made linked to a temporary cost-reduction mechanism or temporary price reduction elsewhere, then the PAS will be clear on the duration of that temporary mechanism or price.

Governance of pricing arrangement

The PAS agreement is constituted and governed by the PAS Submission, PAS Approval Letter and the NHS Scotland Standard Terms for Patient Access Schemes.

The PAS application packs, hosted on the SMC **website**, include the PAS Submission, PAS Approval Letter and NHS Scotland Standard Terms for Patient Access Schemes.

The PAS Submission will be completed by the pharmaceutical company.

The PAS Approval Letter will be completed by the PASAG Secretariat.

The NHSScotland Standard Terms for Patient Access Schemes are in addition to any conditions of contract for the supply of the medicine and do no not cover any issues relating to supply. The conditions of contract governing the sale and purchase of the

medicine are agreed between the company and the health board or National Procurement in the normal manner.

PSD Scotland has the authority to approve the establishment of the PAS agreement on behalf of all health boards.

Submission of proposed patient access scheme

There are several circumstances in which a company can propose a PAS for consideration by PASAG such as:

- to support an HTA conducted by SMC. Where there is an existing PAS in effect for a particular medicine, a new PAS Application Form should be completed and submitted to SMC for each new SMC submission for that medicine.
- to offer comparable commercial arrangements in Scotland that deliver an equivalent net price to those in effect elsewhere in the UK.
- to revise an existing PAS to update the company name, add new formulations or pack sizes of the medicine included in the scheme, or advise on an update to the NHS List Price.
- to amend the scope of the PAS, for instance to include new licensed indications that would otherwise not be considered within the remit of SMC. This includes situations when a medicine obtains an extension to its licence for paediatric populations.

When proposed to support an HTA conducted by SMC, the PAS Application Form should be submitted to the SMC at the same time as the SMC submission paperwork (for example New Product Assessment Form, references, health economic model etc) or as part of the company's response to the New Drugs Committee's draft advice. SMC staff will share the PAS Application Form with the PASAG Secretariat. The PASAG Secretariat will conduct an initial screen of the PAS proposal to determine if the scheme can be routed down an "optimised acceptance" pathway or if the scheme will require referral to the PASAG Committee. For schemes requiring referral to the PASAG Committee, the Secretariat will inform the company and SMC of the indicative timelines for PASAG decision-making. PASAG assessment timelines will inform the SMC's scheduling of its assessment of the medicine.

When a PAS is proposed for reasons other than to support a submission to SMC, the PAS application pack should be submitted directly to the PASAG Secretariat. The timescales, milestones, and implementation for the assessment of a PAS will be agreed between the PASAG Secretariat and the submitting company.

To submit a PAS proposal to PASAG, pharmaceutical companies should complete either the concise or full PAS application pack, as appropriate. Guidance on completing these application packs is contained in Appendix 3. General advice and guidance on the operational feasibility of proposed scheme types is available from the PASAG Secretariat in advance of submission.

PASAG assessment process

All proposed schemes are assessed by PASAG in the context of the agreed key principles (Appendix 1) which includes ensuring that the scheme is financially acceptable; robust ethically and legally; Caldicott compliant; and operationally practical now and within the lifetime of the PAS. PASAG will consider if the scheme can be fully implemented and the likelihood of benefits being realised.

The PASAG Secretariat evaluates each submitted PAS, liaising with the pharmaceutical company and health boards as necessary, and presents any relevant issues for PASAG to consider. It can be an iterative process which aims to deliver schemes that are efficient and minimise any administrative burden on NHS boards.

PASAG meetings are scheduled monthly to ensure decisions are timely. Assessment of individual PAS proposals will be scheduled based on the type of scheme and associated complexity.

The PASAG Committee has delegated authority to both the Secretariat and Co-Chairs to agree PAS proposals on its behalf. For example, for PAS proposals that are made using the Concise PAS Application Form, an “optimised acceptance” pathway may be used. In circumstances where a Concise PAS Application Form has been used and the proposal meets all the key principles for PAS, then PASAG has delegated authority to the PASAG Secretariat to issue advice that the PAS proposal is acceptable for implementation. Both the Secretariat and Co-Chairs reserve the right to refer proposed schemes to the full PASAG membership. All other schemes will be scheduled for and discussed at a meeting of the PASAG Committee.

For schemes referred to the full PASAG Committee, pharmaceutical company representatives may be invited to join the PASAG meeting should there be a need to respond to clarification questions raised by members.

PASAG has three decision options for PAS proposals:

- PAS acceptable for implementation in NHSScotland
- PAS not acceptable unless modification to the scheme are made*
- PAS not recommended*

*rationale and detail on modifications to be made will be clearly outlined to the company.

Following assessment, PASAG will advise the submitting company whether the PAS is acceptable for implementation. If the PAS is not recommended, the reasons will be transparent. Where appropriate, an opportunity will be provided to the pharmaceutical company at this stage to amend the scheme.

When PAS proposals are linked with a SMC assessment of the medicine, then PASAG's decision on the acceptability of the PAS will be communicated to the SMC at the same time as the company is informed.

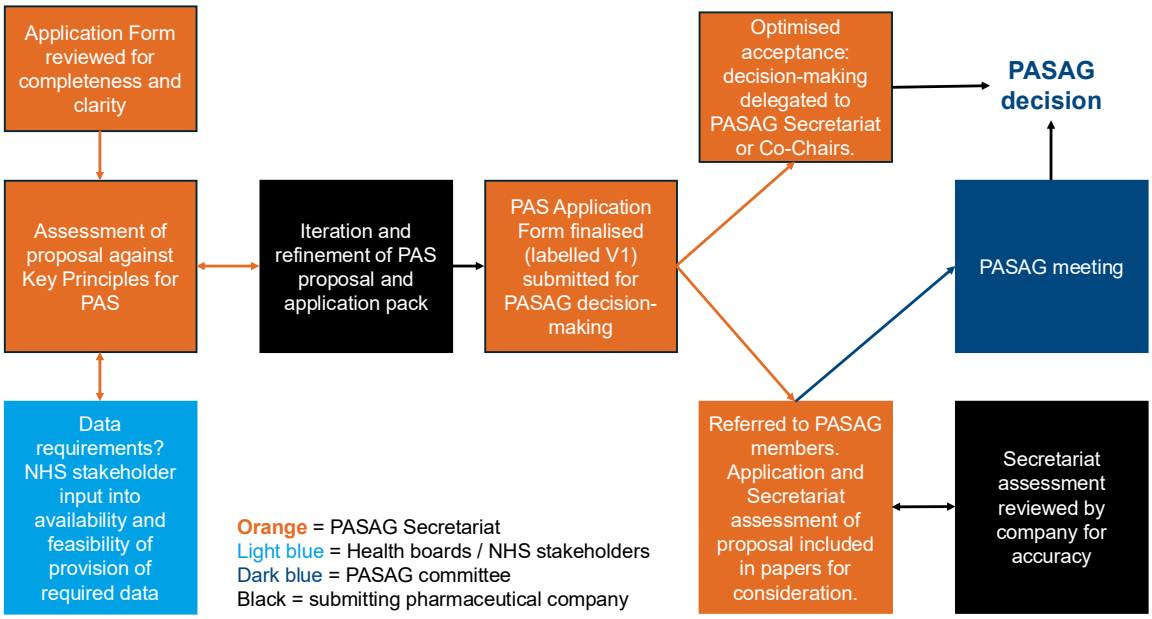
If PASAG opines that the PAS proposed for the current SMC submission is acceptable for implementation, then SMC will use the PAS in its health technology assessment. Otherwise, the SMC will use the medicine's NHS List Price in its assessment.

Assessment timelines

Evaluation of simple discount schemes by PASAG takes approximately four weeks. A PASAG review is scheduled to ensure that the decision is available prior to either: the anticipated New Drugs Committee meeting or, for those PAS submitted at the second opportunity, the scheduled SMC meeting.

Complex schemes require a longer period for evaluation (a minimum of eight weeks) and may delay the anticipated SMC timeline for assessment. The PASAG secretariat communicates timescales for review of the PAS to the SMC secretariat to support SMC scheduling of the health technology assessment process.

Figure: Indicative Assessment process



Implementation process and communication

When linked to a health technology assessment conducted by SMC:

- The PAS will only be available for implementation if approved by PASAG and accepted for use (with or without restriction) by the SMC
- In the case of medicines entering the ultra-orphan pathway, the PAS will only be available for implementation if approved by PASAG and following the initial assessment by the SMC.
- The effective date of the PAS will be the date in which the SMC issues its advice or assessment report, in confidence / under embargo, to health boards and the company. This is typically on the Friday following the scheduled SMC meeting.

The effective date of PAS proposed for reasons other than to support a SMC assessment, will be agreed between PASAG and the pharmaceutical company.

The pharmaceutical company can detail in the PAS agreement which elements of the scheme should be treated in confidence, for example the level of discount, purchase price and / or scheme cost reduction mechanism. Only brief information relating to the PAS and that considered not commercially sensitive will be included in the published SMC detailed advice document, or assessment report. The board is required to treat in confidence all company confidential information and not disclose to any third-party as described in the NHS Scotland Standard Terms for Patient Access Schemes.

A PAS Implementation Pack will be created by the PASAG Secretariat. The implementation pack will comprise:

- The PAS Approval Letter (as signed by an authorised representative of PSD Scotland, for example the Associate Director – Medicines Pricing and Supply of National Procurement)
- The PAS Submission (as signed by the company) and submitted as part of the relevant PAS application form.
- The NHS Scotland Standard Terms for Patient Access Schemes
- Implementation guidance notes prepared by the PASAG Secretariat. For more complex schemes this may include an operational flow-chart and specific actions / verification records required for successful operation of the PAS.

A copy of the PAS Implementation Pack is issued to health boards via a secure email distribution list managed by the PASAG Secretariat.

A confidential register of schemes in effect, as well as those that were proposed but not implemented, is distributed to health boards monthly.

National Procurement uses a content management system, known as ECM, to securely share contract pricing information to appropriately authorised personnel within health boards. This is part of the Scottish Government's eCommerce Shared Service. Information on all contracts and frameworks managed by National Procurement is shared with appropriately authorised personnel in health boards via this system. There are two catalogues detailing information about medicines with a PAS: standard access and restricted access. Health board pharmacy personnel have their access rights determined at health board level. Those with standard access rights for Framework pricing information can access the standard PAS catalogue. Those authorised at health board level to have restricted access rights are provided with separate access, by the PASAG Secretariat, to the restricted PAS catalogue.

Pharmaceutical companies are asked as part of the PAS Application Form to note what level of information to be included in the content management system:

- The PAS purchase price is listed in both the standard and restricted access catalogues
- The PAS purchase price is listed in the restricted access catalogue only
- The PAS purchase price is not included in any of the catalogues and the medicine entry will be recorded as £0.

If a medicine with a proposed PAS is not recommended for routine use in NHS Scotland, the PAS will not be implemented. A pharmaceutical company has the option of offering an equivalent commercial agreement to individual health boards to cover patient access via the Peer Approved Clinical System (PACS). Pharmaceutical companies are asked to indicate on the PAS application pack if the discount will remain available should this be the case. The PASAG secretariat will confirm the arrangements with the company prior to providing information on the pricing arrangements to health boards. A confidential register of available discounts will be distributed to boards monthly.

Rebate reconciliation

To improve financial governance and reduce the administrative burden to the NHS and pharmaceutical companies in managing payment of rebates, where feasible, PSD Scotland receives and reconciles rebates with pharmaceutical companies on behalf of NHS Scotland and then transfers consolidated funds to health boards.

A summary of the primary care rebate reconciliation process can be found in Appendix 3. The calculation of the value of rebates associated with medicines supply

through primary care does not include the VAT of the medicines purchased. This takes into consideration the VAT liability of the onward supply of the medicine by the community pharmacy which is typically zero-rated and the fact that the VAT incurred on the purchase of the medicine is recovered by the community pharmacy.

Where rebates relate to supplies made in the hospital setting for a complex PAS, the value of the rebate claim will include an element of non-recoverable VAT as incurred by the health board. Details will be shown on the backup file supporting the request for payment. HMRC has issued general guidance on the VAT treatment of refunds made by manufacturers; this guidance includes a section on companies making an adjustment against their VAT account for the VAT element of rebates (**HMRC VAT Information Sheet 03/014**).

Achieving comparable commercial arrangements in each part of the UK

Whilst responsibility for the arrangements to determine *access* to new medicines is devolved to the Scottish Government, responsibility for the arrangements for *pricing* of medicines is reserved to the UK Government. The Scottish Government is party to both the UK Voluntary scheme for branded medicines Pricing, Access and Growth (VPAG) and the UK Statutory Pricing Scheme.

The 2024 VPAG allows the details of national commercial arrangements agreed with the purchasing authority in one UK country to be made available on a confidential basis to the purchasing authorities in any part of the UK. Pharmaceutical companies will work with purchasing authorities to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK. (2024 VPAG paragraph 3.38).

For medicines that have been accepted for use by SMC in at least one indication, and where 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 for the medicine, then pharmaceutical companies will work with the PASAG Secretariat to achieve an equivalent commercial arrangement in Scotland as soon as practicable. This would include commercial arrangements offered in technology appraisals undertaken by the National Institute for Health and Care Excellence (NICE) (both Single Technology Appraisals, Multiple Technology Appraisals and Highly Specialised Treatment guidance [HST]), the All Wales Medicines Strategy Group Health Technology Appraisal (AWMSG) process, the NHS England Clinical Priorities Advisory Group (CPAG) and commercial arrangements linked to the NHS England budget impact threshold.

In the case of a simple discount mechanism this may involve changing the discount rate to deliver an equivalent commercial arrangement.

There are differences between each UK country in infrastructure and capacity to support complex confidential commercial agreements; a complex commercial agreement that is feasible in England may require adjustment to be feasible in the Scottish context. Where a complex confidential commercial agreement has been agreed in another part of the UK, the PASAG Secretariat will work with the company to agree an approach that will deliver an equivalent arrangement in Scotland.

Where a different commercial arrangement has been implemented in another part of the UK on an interim basis, for example offered as part of a Managed Access Agreement, the PASAG Secretariat will work with the company to agree an approach that will deliver an equivalent arrangement in Scotland through the Scottish PAS agreement for the duration that it is in effect in the other part of the UK.

The company should notify the PASAG Secretariat ideally as soon as practicable by completing the standard PAS submission form (concise or full, as appropriate) noting on the form that the PAS proposal is linked to ensuring comparable commercial arrangements with other parts of the UK.

A prospective change to an existing Scottish PAS to deliver comparable commercial arrangements should come into effect from the point that the lower price goes into effect in the other part of the UK, that is, if a PAS comes into effect on 1 July 2019 in Scotland and a commercial agreement with a lower price comes into effect on 1 January 2020 in England, a comparable arrangement should also come into effect in Scotland from 1 January 2020. An established and pragmatic approach that will enable this to happen is by proposing the change to PASAG at the same time as it is proposed in another part of the UK contingent on the revised arrangements coming into effect elsewhere.

Where there is an established PAS in place and a change in the commercial arrangement agreed, there would be no change to the length of the PAS agreement (ie the five-year minimum duration of the PAS in Scotland will remain linked to the timing of the associated / most recent SMC assessment).

If the medicine is used as a comparator in a subsequent SMC assessment, the PAS price that is current on the date the submission is received by the SMC would be used as the comparator price to ensure a fair and robust assessment process.

Agreement of a new PAS or revision of an established PAS, for the purpose of ensuring comparable commercial arrangements across the UK, will not result in an amendment to the SMC advice for the medicine.

As a principle, health boards should not be financially disadvantaged by delays in implementing updates to PAS. If necessary, the PASAG Secretariat will work with companies to agree and support the administration of a one-off retrospective rebate to health boards to compensate for any delays in implementation of pricing changes.

If a company has offered a lower price in another part of the UK but not as part of any national recommendations on use of the medicine, for example a regional Medicines Procurement and Supply Chain framework that has not been taken into consideration in a NICE assessment, then the company can choose to offer comparable pricing to the NHS in Scotland through alternative mechanisms such as a Framework Agreement. It is not possible to propose or amend a PAS in these circumstances.

Interim acceptance

Medicines which SMC has accepted for use in NHS Scotland on an interim basis subject to ongoing evaluation and future reassessment, may have a PAS.

At the point of reassessment, if the medicine is not recommended for use by SMC, the previously established PAS would remain in effect for at least the minimum period specified in the PAS Agreement. Once a PAS is in effect, there is no provision in the NHS Scotland Standard Terms for Patient Access Schemes for early termination if the product is not recommended at reassessment.

Ultra-orphan pathway

One of the conditions for entry into the ultra-orphan pathway[1] is that the company offers a PAS that complies with the standard terms and conditions considered acceptable by PASAG. This includes the company:

- notifying the PASAG Secretariat and sharing with it on a confidential basis, the details of any permanent or temporary national commercial arrangement agreed in England, Wales or Northern Ireland.
- working with the PASAG Secretariat to achieve comparable arrangements that provide an acceptable value proposition in Scotland as soon as practicable; for example, in the case of a simple discount mechanism, this would involve changing the discount rate to deliver an equivalent commercial arrangement. For complex confidential commercial arrangements, the PASAG Secretariat will work with the company to agree an approach that will deliver an equivalent arrangement in Scotland.

Where a different commercial arrangement has been implemented in another part of the UK on an interim basis, for example offered as part of a Managed Access Agreement, the PASAG Secretariat will work with the company to agree an approach that will deliver an equivalent arrangement in Scotland through the Scottish PAS agreement for the duration of the arrangement being in effect in the other part of the UK.

[1] Please see **https://www.gov.scot/publications/ultra-orphan-medicine-pathways-guidance/**

In the event that the medicine is not recommended at reassessment, the previously established PAS would remain in effect for at least the minimum period specified in the PAS Agreement. Once a PAS is in effect, there is no provision in the NHS Scotland Standard Terms for Patient Access Schemes for early termination if the product is not recommended at reassessment.

Associated Documented Information

Document Reference	Document Title
PAS801-018.01	Concise Patient Access Scheme PAS Application
PAS801-018.02	Full Patient Access Scheme PAS Application

Document Change History

For activation dates, refer to IQM

Version	Change Details
11	November 2025 Update to Key Principles for PAS New sections related to indication-based pricing, and clarifications on PASAG assessment and decision-making processes. Expanded guidance on primary care rebates.
12	May 2026 Update to reflect rebrand of NHS National Services Scotland to Public Services Delivery Scotland.

Appendix 1: Key principles for PAS

1. PAS will be considered by NHS Scotland to facilitate access by patients to medicines that are not or might not be found to be cost-effective by SMC. Any proposal must originate from the pharmaceutical company that holds the UK marketing authorisation. Only medicines which have at least one indication accepted for use by SMC (or in the ultra-orphan pathway) can have a PAS; commercial arrangements for medicines not meeting these criteria can't be made using the PAS framework described in this guidance.

2. It is recognised that while PAS can facilitate access to new medicines there will be implications for NHS Scotland in implementing them effectively. In order to ensure this is manageable, the commercial arrangements must be as simple as possible, minimising the burden on the NHS and frontline staff. Complex arrangements will only be considered once simple discounts alone have been fully demonstrated to be unsuitable. Complex schemes should be the exception rather than the rule. It is reasonable for the NHS to prioritise schemes that deliver most benefit to patients, for example, for medicines that address a previously unmet need. The full costs to NHS Scotland of operating must be taken into account in the assessment process.

3. Through partnership between the NHS and pharmaceutical industry, patients should benefit from any such scheme through improved access to new treatments on an equitable basis across Scotland.

4. The commercial arrangements should deliver an equivalent net price for the medicine as elsewhere in the UK during the lifetime of the agreement; refer to section titled "Equivalent pricing for equivalent access".

5. Schemes must be clinically robust, plausible, practical and monitorable.

6. PASAG recognises the challenges with differential benefits and incremental costs that apply to medicines licensed for multiple indications. Similarly to the criteria outlined in the NHS commercial framework for new medicines published by NHS England, PASAG considers the following when assessing the acceptability of PAS proposals with indication-based pricing:

    - The medicine for the indication under consideration addresses an unmet clinical need

    - The company demonstrates with a high degree of confidence that uniform pricing would reduce the total revenue for a medicine across all indications

    - Sufficient data are available within NHS systems to make such arrangements operationally feasible

- The cost-effective price is highly differentiated for all indications under consideration

7. The assessment of any proposed scheme must take place within a robust national framework, not on the basis of local negotiation, and must be consistent with the SMC assessment arrangements and timelines. Schemes submitted by pharmaceutical companies must be agreed with PASAG. SMC will assess the impact of any proposed scheme on the product's cost-effectiveness.

8. The integrity of the existing health technology assessment process must be maintained, that is, SMC will continue to assess the clinical and cost-effectiveness of medicines and PASAG will assess the acceptability of the PAS on behalf of NHS Scotland.

9. Any scheme should be operationally manageable for the NHS without unduly complex monitoring, disproportionate additional costs and bureaucracy. Any burden for the NHS should be proportionate to the benefits of the scheme for the NHS and patients.

10. There should be no risk of perverse incentives. For example, the ability to access a medicine through a PAS may have unintended adverse consequences on the pattern of patient care.

11. Compliance must be assured with NHS Scotland probity, governance and legislative requirements including formal agreements between the NHS and pharmaceutical company regarding respective responsibilities including burden of costs and protection of commercial-in-confidence information.

12. Patient information must be protected. No patient-identifiable data should be shared as part of these schemes. Schemes must not infringe the patient's right to confidentiality according to the requirements of Data Protection Legislation.

13. Data obtained through implementation of a PAS remains the property of NHS Scotland which retains the right to publish, subject to confidentiality outlined in NHS Scotland Standard Terms for PAS.

14. The duration of the scheme must be explicit and exit strategies for both parties must be clear. Continuity of care for patients must be explicitly addressed for both a scheduled completion of a scheme or should a scheme end prematurely. Any change to an accepted scheme must be submitted to the PASAG Secretariat and must not be to the financial detriment of the NHS.

15. Schemes must be consistent with existing financial flows in NHS Scotland.

16. It is important that arrangements for proposing and agreeing such schemes do not in turn jeopardise the timeliness of the SMC advice. The timing of

discussions on schemes should not encourage ‘gaming’ of the appraisal system by any party (for instance where either the company or health technology assessment organisation attempts to exploit the system to ensure the most desirable outcome from their own perspective).

17. The experience with PAS in NHS Scotland will be reviewed on an ongoing basis.

Appendix 2: Guidance for Completion of the PAS Application Packs

1. Pharmaceutical companies should complete either the concise or full PAS application pack following the guidance outlined below. If unsure which application pack to complete or for any queries, please contact the PASAG Secretariat at **nss.np-pasag@nhs.scot**.

2. The Concise PAS Application Pack should be completed for proposed simple discount schemes that comply with all the pre-defined clauses of the Standard "PAS Submission" for Simple Scheme (contained within the concise application pack). The scheme should be a simple discount from the NHS list price applied at the point of invoice when the medicine is supplied through secondary / tertiary care, homecare or a third-party compounder and a confidential retrospective rebate for any supply in primary care (community pharmacy, dispensing doctor, prison) – see Appendix 3 for further information on the PAS in primary care process. The scope of the PAS agreement acknowledges the principle that the PAS price applies in any setting across NHS Scotland where patients may access supplies of the medicine. However, it is recognised that certain supply routes may not be utilised by the NHS (for example due to the nature of the medicine) or only utilised after establishing appropriate governance and supply arrangements. For illustration, a company would still complete the concise application pack when submitting a simple discount scheme proposal for a medicine that is administered by intravenous infusion, requires close medical supervision and anticipated to be secondary care only. The company therefore acknowledges the principle that the PAS price applies in all settings; however, due to the nature of the medicine, patients may only access via secondary care. The scope of the PAS agreement should not be a barrier to developing new models of pharmaceutical care within NHS Scotland and the settings in which the PAS price may be accessed within the lifetime of the agreement.

3. The Full PAS Application Pack should be completed for proposed simple discount schemes that do not comply with all the pre-defined clauses of the Standard "PAS Submission" for Simple Scheme and the submitting pharmaceutical company wishes to propose an amendment to one or more of these clauses.

4. The Full PAS Application Pack should also be completed for proposed complex schemes. Any patient registration form and / or claim forms should be included with the full application pack along with any other relevant supporting documentation. The PASAG Secretariat can be contacted to provide guidance on the creation of supporting documentation if required.

5. All required fields within the relevant application pack should be completed by the submitting company following any instructions provided, unless otherwise indicated. Types of fields to be completed include text entry, drop-down lists and date selectors (*highlight field and select drop down arrow for available options)*, and image insertion *(click field and select electronic signature or image to be inserted from file)*. Where appropriate, responses will auto-populate throughout the application pack. The application packs are protected; should additional modifications be required then the pharmaceutical company is advised to contact the PASAG Secretariat to facilitate these within the application pack.

6. **PAS effective date**: The effective date for a new PAS submitted linked to an SMC assessment is the date that the SMC issue its advice (or for medicines entering the ultra-orphan pathway, the SMC assessment report) in confidence to the pharmaceutical company and NHS Scotland based on SMC assessment timelines – this is the Friday following the SMC meeting (one month prior to publication on the SMC website). There is advice on the **SMC website** on the SMC's standard assessment timeline that can be used by companies to estimate the PAS start date. Should the assessment scheduling change (for example, if a PACE meeting is scheduled as part of the assessment process), the PASAG Secretariat will alter the effective date accordingly in the submission form. Where the PAS is proposed outside of an SMC assessment, the company and the PASAG Secretariat will agree the effective date.

7. Companies should aim to ensure the product is available to purchase under the PAS pricing arrangements at the point the PAS comes into effect. If there is an unavoidable delay in updating pricing in the supply chain, companies should contact the PASAG secretariat to discuss how this is best managed (for example arranging retrospective credits) and to ensure any delays are communicated to NHS boards.

8. **PAS Indication**: When the PAS is submitted linked to an SMC assessment, please detail the indication that is being reviewed within the health technology assessment (as stated in the New Product Assessment Form). If the PAS is being proposed outside of an SMC submission, detail the reasons for the PAS proposal (for example, to offer comparable arrangements across the UK, or to amend the packs included in the PAS).

9. **Communication of PAS information to NHS Boards**: refer to section titled Implementation process and communication within the main body of this guidance document.

10. **Supply chain and additional information**: Due to the number of different distribution routes for medicines in the UK and to prevent delays in obtaining medicines, the submission form requests a summary of supply chain arrangements for the medicine. If the medicine is recommended by SMC, this

information will be shared with Boards to support planning for use of the medicine. Details to be provided include:

- where hospitals should order from, eg direct or via third-party distributor(s)

- whether a manufacturer-commissioned homecare service is being offered and whether there are any barriers to the NHS commissioning its own homecare service. If homecare is to be commissioned, there is a separate governance process to review proposals from companies for manufacturer-commissioned homecare via the NHSScotland Medicines Homecare National Governance and Management Group. A copy of the guidance on the submission, review and implementation of proposals for manufacturer-commissioned homecare services is available by contacting nss.pchc@nhs.scot. Note: this process is separate from the PAS assessment process and will not impact on PAS assessment timelines

- whether a supply route to primary care (community pharmacies and dispensing doctors) is available or planned

- whether there are any barriers to the NHS commissioning a third-party compounder to prepare patient-ready products (where relevant)

11. **Duration** (paragraph 4 of the PAS Submission)

    - When a PAS proposal is linked with a submission to SMC, the minimum duration of the PAS will be five-years from the effective date of the scheme.

    - When a PAS is proposed to offer comparable arrangements with other UK countries, the minimum duration will be determined by the unique circumstances of that arrangement and agreed between PASAG and the pharmaceutical company.

    - When a PAS is proposed to novate the agreement following a change in pharmaceutical company ownership, or for other reasons such as a new formulation or pack-sizes, the minimum duration of the scheme will be linked to the previous effective date of the PAS.

12. **Company representative**: The company representative can be different from the signatory. The signatory is typically a director, company secretary or authorised signatory of the company. The company representative is typically the company contact for any operational issues with the PAS.

13. **Version control:** Completed application packs should be saved as a Microsoft Word® document using the following naming convention and dated with submission date: **approved name (Brand Name) PAS Application Pack YYYYMMDD D0.1 (Initial)**

It may be necessary to revise the application throughout the assessment process and version control will also be applied to subsequent versions.

Appendix 3: PAS in Primary Care

There is an established process developed through dialogue between NHS Scotland and the ABPI, to operate PAS in the primary care (and prison supply) settings through use of rebate mechanisms. This is often referred to as a Primary Care Rebate Scheme (PCRS).

Figure 1 provides a high-level summary of the operational arrangements. Under a PCRS, primary care contractors purchase products at list price (less any supply chain margins). On a quarterly basis, the PASAG Secretariat, on behalf of boards, provides the company with a supply report and a request for payment. This information is used by the company to pay a confidential rebate to PSD Scotland via BACS payment. PSD Scotland then disburses funds to each board in proportion to usage of the product in each board area.

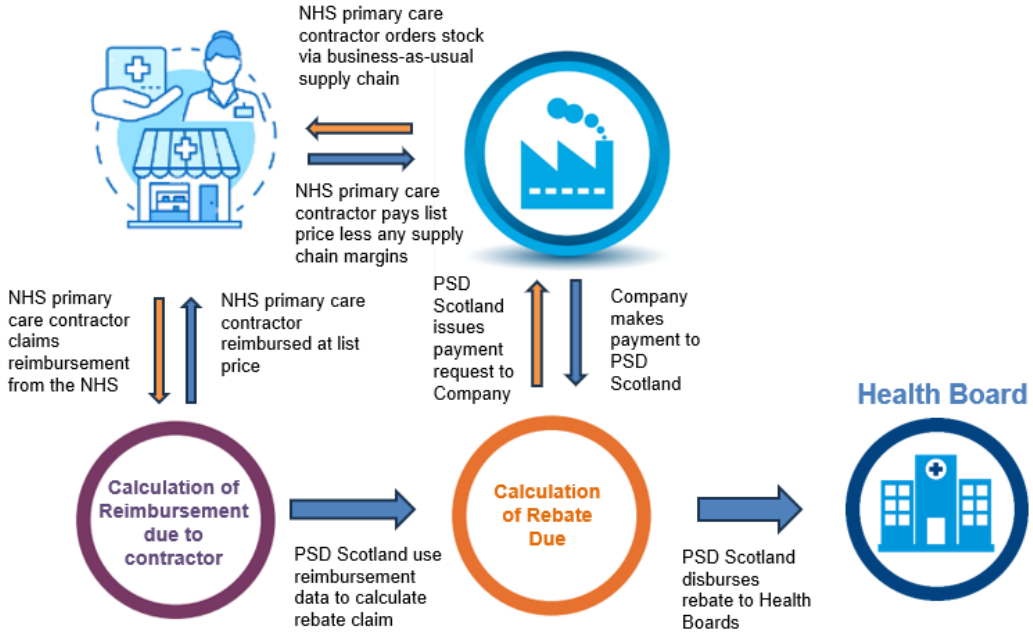
Primary care rebates cover supply of the medicines included in the PAS that are supplied to NHS Patients via primary care contractors. This includes:

- Supply via NHS Dispensing Contractors (that is a community pharmacy, or a dispensing doctor with a contract to provide an NHS dispensing service).
- Supply via a provider holding a contract with an entity within NHS Scotland to provide pharmaceutical goods and services to prisons and young offenders institutions that are directly managed or contracted by the Scottish Prison Service.

All presentations of products within scope of a PAS must be listed with an NHS List Price on the dictionary of medicines and devices (dm+d). This is essential to enable reconciliation of the scheme as pricing information held in dm+d is used to calculate reimbursement due to contractors for the supply of products to NHS patients. To add a product to dm+d or to notify the dm+d team of changes including new presentations, contact the NHSBSA at **pippa@nhsbsa.nhs.uk** or alternatively use the EMC **Market Access** facility.

Reimbursement data do not contain any information on the supply chain used by contractors to source a product, including whether a parallel import was used. PAS Agreements cover the total quantity of a product supplied by NHS dispensing contractors and prison pharmacy contractors to NHS patients, regardless of purchasing channel, including use of parallel imports.

Figure 1: Primary care rebates (PCRS) overview



Calculation of the rebate due

The total value of the rebate due to boards is calculated as the volume of product supplied to patients multiplied by the difference in the NHS List Price and the PAS Price.

For products dispensed by NHS dispensing contractors, the NHS Scotland Prescribing Information System is the reporting platform used as the basis of the volume of product supplied. For prison pharmacy contractors, it is reimbursement claims to boards from prison pharmacy contractors.

The volume used to calculate the value of the rebate due includes consideration of all instances that the product has been supplied by an NHS dispensing contractor or prison pharmacy contractor to an NHS Scotland patient, regardless of the supply chain used, including parallel imports and regardless of whether the prescription was written generically or using the product's brand name.

Financial reconciliation

On a quarterly basis, PSD Scotland will provide the company with a supply report which is drawn from reimbursement data and a request for payment for the total value of the rebate due to NHS Scotland (refer to Table 1 for an example report layout).

Table 1: Example supply report layout

Health Board	Paid Financial Year / Quarter	Paid Calendar Month and Year	Paid VMP Name	Paid Product Name	Paid Pack Size	Form Type Code	Quantity	Cost	Rebate

VMP = virtual medicinal product (descriptor as per dm+d). Paid Product Name = actual medicinal product (descriptor as per dm+d)

Where a company has multiple PAS in place, a separate usage report and request for payment will be provided for each PAS.

There is a time lag in the availability of data. This is due to the timescales for contractor reimbursement to be calculated and constraints around the sharing of data that will form the basis of an official Publication (official statistics). Requests for payment are usually issued quarterly to the named contact within the company following the schedule summarised in Table 2.

Table 2: Indicative timelines for data availability and financial reconciliation

Dispensing quarter	Month that reimbursement data are available	Estimate for PSD Scotland reconciliation and issue of request for payment
1 January to 31 March	July	End of August
1 April to 30 June	October	End of November
1 July to 30 September	January	End of February
1 October to 31 December	April	End of May

The company must raise any queries relating to the value of the rebate claim with PSD Scotland within 15 days of receiving the request for payment.

The company then rebates the requested amounts to the bank account of PSD Scotland by BACS transfer within 30 days of receiving the report and sends a remittance advice note; if companies require completion of an account form, forward to **nss.np-pharmfin@nhs.scot** for completion.

Upon receipt, PSD Scotland will disburse funds to each board. Boards will receive a consolidated report with product level details of all rebates due and confirmation they have been received.

Public Health Scotland publishes Open Data for prescriptions dispensed in primary care: **Prescriptions in the Community - Datasets - Scottish Health and Social Care Open Data (nhs.scot)**

Appendix 4: Frequently Asked Questions (FAQs)

1. What happens when a future SMC submission refers to a medicine with a PAS as a comparator?

Please refer to **Comparator medicines with a PAS** on the SMC website. If you require further information, please contact SMC at **his.smcsecretariat@nhs.scot**

2. Can I propose a PAS linked to a NICE Multiple Technology Appraisal (MTA)?

Refer to section titled Achieving comparable commercial arrangements in each part of the UK in the main body of this document.

Companies can contact the PASAG Secretariat at the same time as proposing a scheme to PASLU / NHS England, to discuss the implementation of equivalent arrangements in Scotland. If PASAG is not already in contact with the company by the time NICE communicates its advice, PASAG will get in contact. If you require further information, please contact the PASAG Secretariat.

To support health board Area Drug and Therapeutics Committees (ADTC) in considering the outputs of NICE MTAs, at the point NICE issues its final MTA advice, PASAG shares up-to-date pricing information for products within the scope of the MTA along with confirmation of whether pricing used in the NICE assessment is in line with pricing in Scotland.

3. What happens if there is a dispute regarding the PAS agreement?

The board and company should attempt to resolve any dispute or difference between them by mutual dialogue consistent with the overall aims and objectives of the PAS agreement. Further information about dealing with unresolved matters can be found in the NHS Scotland Standard Terms for Patient Access Schemes.

4. What happens if there is a change of ownership of the medicines (for example following company merger)?

The PASAG Secretariat should be informed by both companies prior to the change of ownership of the medicine. A new PAS agreement will need to be established with the new Company however, the original minimum five-year term of the agreement will be retained. For governance purposes this change to the PAS Agreement will be approved by PASAG and the Associate Director for Medicines Pricing and Supply for National Procurement. An updated PAS implementation pack will be issued to Boards and the new Company provided with a copy. It is important to note that the associated SMC advice is contingent upon the continuing availability of the PAS or an NHS list price that is equivalent or lower.

5. What happens if a pharmaceutical company wishes to add / remove a new strength / formulation / pack size to the PAS?

The PAS agreement will need to be updated accordingly. However, the original minimum five-year term of the agreement will be retained. For governance purposes this change to the PAS Agreement will be approved by PASAG and the Associate Director for Medicines Pricing and Supply for National Procurement. An updated PAS implementation pack will be issued to Boards and the Company provided with a copy.

6. What happens if a pharmaceutical company wishes to terminate a PAS?

Given the duration of PAS agreements, schemes may eventually become redundant, for example a permanent reduction to NHS List Price equal to or lower than the PAS discounted price; launch of alternative product (strength, formulation etc.) negating the PAS agreement. Companies should contact the PASAG secretariat to discuss and agree if the PAS should be suspended or terminated.

7. A PAS has come into effect, but the distributor has indicated that there will be a delay in updating their systems to reflect the new price, what should the company do?

The effective date for a new PAS is the date that SMC issue its advice in confidence to the pharmaceutical company and NHS Scotland based on SMC assessment timelines – this is the Friday following the SMC meeting (one month prior to publication on the SMC website).

If there is an unavoidable delay in updating pricing in the supply chain, companies should contact the PASAG secretariat to discuss how this is best managed (eg arranging retrospective credits for any sales from the date that the revised PAS price comes into effect to the date that the new price is implemented in the supply chain) and to ensure any delays are communicated to NHS Boards.

8. Can I propose a further discount on the medicine if there is a PAS in operation?

Yes, National Procurement will work with companies to consider and agree further discounts on medicines which have a PAS in operation. Depending upon the context of the proposed price reduction, methods to enact this include update to the PAS, or the award of a Framework Agreement. The circumstances in which a PAS price can be reduced include: a new submission to the SMC, or to achieve comparable commercial arrangements in each part of the UK, as described above. Commercial offerings outside of these circumstances, such as response to market dynamics, or to unbundle the costs associated with medicines homecare, would require alternative approaches such as the award of a Framework Agreement as opposed to updating of the PAS. Companies should contact the PASAG secretariat to discuss on a case-by-case basis.

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