NHS National Services Scotland

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Patient Access Scheme (PAS) Guidance

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Introduction

1. 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.

2. 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).

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

Patient Access Scheme Assessment Group (PASAG)

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

5. 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. A representative from the Association of the British Pharmaceutical Industry (ABPI) is also a member of the group.

6. 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).

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

Types of schemes

8. 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 (see paragraph 38).

9. 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; and a

confidential retrospective rebate to Health Boards for any supply in primary care (community pharmacies, dispensing doctors and prisons).

10. As part of simple discount schemes, the discount or rebate is applied to all purchases of the medicine within the lifetime of the PAS and there is no requirement 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.

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

    11.1. rebates (when medicine is supplied via secondary / tertiary care or homecare)

    11.2. stock supplied at zero cost

    11.3. dose / spend capping

    11.4. outcome-based schemes (based on patients' response to treatment).

12. 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.

Scheme setting

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

14. 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 dispensing settings. The PASAG Secretariat can be contacted for advice regarding supply chain arrangements to the NHS in Scotland if required.

Governance of pricing arrangement

15. The PAS Agreement is constituted and governed by the PAS Submission, PAS Approval Letter and the NHSScotland Standard Terms for Patient Access Schemes.

16. The PAS Submission is included in the relevant PAS application pack, hosted on the SMC website, and is completed by the pharmaceutical company.

17. The PAS Approval Letter is included in the relevant PAS application pack. It is issued by the NHS:

17.1. if the medicine is accepted for use (with or without a restriction) by the SMC on a routine or interim basis

17.2. if there is agreement to enter into a PAS agreement for the purpose of ensuring equitable commercial arrangements across the UK

17.3. as a condition for entry into the ultra-orphan pathway

17.4. if there is a novation of the agreement, such as change of ownership of the medicine between pharmaceutical companies

17.5. if the PAS is updated to amend the medicine formulations and packs covered by the PAS.

18. The NHSScotland Standard Terms for Patient Access Schemes can be accessed at the SMC website. These standard terms 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 Supplier and the Board or National Procurement in the normal manner. Any variation to the Standard Terms must be agreed in writing.

19. NSS has the authority to approve the establishment of the PAS agreement on behalf of all health boards.

Submission of proposed patient access scheme

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

20.1. to support a HTA conducted by SMC (see paragraph 27 for medicines which already have a PAS in effect).

20.2. to offer comparable commercial arrangements in Scotland, as per paragraphs 47 to 59 in this guidance

20.3. to revise an existing PAS to amend the formulations or pack sizes of the medicine included in the scheme

20.4. 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.

21. When proposed to support a HTA conducted by SMC, the general process, timescales and milestones for the submission and assessment of a PAS (and implementation) are outlined in Appendix 2.

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

23. 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.

24. When proposed to support a HTA conducted by SMC, the PAS application pack for a proposed scheme should be submitted to the SMC Secretariat along with the New Product Assessment Form (NPAF) and associated documents. The SMC Secretariat forwards the application pack to the PASAG Secretariat.

25. During the SMC assessment, pharmaceutical companies also have a second opportunity to submit a new or revised PAS to the SMC Secretariat within a two-week period following the issue of the New Drugs Committee (NDC) advice / report. A new application pack should be completed when revising the previous PAS application. It is important to note that a submission at this stage may extend timelines for the SMC review of the medicine. For this reason, pharmaceutical companies are strongly encouraged to submit any proposed PAS at the first opportunity with the initial SMC submission.

26. 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.

27. Where there is an existing PAS in effect for a particular medicine, unless the pharmaceutical company wishes the SMC to assess the medicine at NHS List Price, a new PAS application pack with updated “PAS Submission” is required for each new SMC submission for that medicine (for example new indications, or submission to SMC for reassessment under the interim acceptance arrangements).

PASAG assessment process

28. 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.

29. 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.

30. 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.

31. The PASAG secretariat and the PASAG co-chairs have delegated authority to approve simple PAS on behalf of NHSScotland out with scheduled meetings. They reserve the right to refer schemes to the full PASAG membership, for example, if amendments are requested to the Standard “PAS Submission” for Simple Schemes. The full PASAG membership will consider any simple discount scheme referred by the secretariat or co-chair(s) and all complex schemes.

32. Pharmaceutical companies will be invited to attend (in person, on Microsoft Teams, or via teleconference) for part of the relevant PASAG meeting to respond to clarification questions raised by members.

33. 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 linked with a HTA conducted by SMC, PASAG will advise SMC of the outcome.

Assessment timelines

34. 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 NDC meeting or, for those PAS submitted at the second opportunity, the scheduled SMC meeting.

35. 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 HTA process.

Implementation process and communication

36. When linked to a HTA conducted by SMC, the general process, timescales and milestones for the implementation and communication of a PAS are outlined in Appendix 2.

    36.1. The PAS will only be available for implementation if approved by PASAG and accepted for use (with or without restriction) by the SMC

    36.2. 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.

36.3. 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.

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

38. 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 supplier confidential information and not disclose to any third-party as described in the NHSScotland Standard Terms for Patient Access Schemes.

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

39.1. The PAS Submission (as signed by the company) and submitted as part of the relevant PAS application form.
39.2. The PAS Approval Letter (as signed by an authorised representative of NHS National Services Scotland, eg the Associate Director – Medicines Pricing and Supply of National Procurement, NSS)
39.3. 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.

40. The possible communication channels for PAS information are:

40.1. restricted email distribution list - this involves an email to the chairs of the Area Drug and Therapeutic Committees (ADTCs), Directors of Finance and Directors of Pharmacy with an attached copy of the PAS Implementation pack. These individuals are then responsible for securely disseminating the information to relevant individuals within their health board. All PAS Implementation Packs are issued via this list.

40.2. PECOS Content Management System (PCM) - the standard communication route to securely share contract pricing information to appropriately authorised personnel within health boards which 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 PCM. There are two catalogues detailing information about medicines with a PAS; standard and restricted. 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.

41. With respect to communication of PAS within the PECOS Content Management System, there are three options available for companies to choose.

    41.1. Inclusion of PAS Purchase Price in the PCM Standard Catalogue

    41.2. Inclusion of PAS Purchase Price in the PCM Restricted Catalogue only.

    41.3. PAS Purchase Price not included in any catalogue in PCM

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

43. If a medicine with a proposed PAS is not recommended for routine use in NHSScotland, 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

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

45. A summary of the primary care rebate reconciliation process can be found in Appendix 4. 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.

46. 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

47. 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 and Access (VPAS) and the UK Statutory Pricing Scheme.

48. The 2019 VPAS 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. (VPAS 2019 paragraph 3.49).

49. 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.

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

51. 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.

52. 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.

53. 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.

54. 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.

55. 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).

56. If the medicine is used as a comparator in a subsequent SMC assessment, except for temporary discounted prices, 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.

57. 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.

58. 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 suppliers 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.

59. 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 CMU 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

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

61. 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

NHSScotland Standard Terms for Patient Access Schemes for early termination if the product is not recommended at reassessment.

Ultra-orphan pathway

62. 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:

    62.1. 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

    62.2. 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

63. 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.

64. 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 NHSScotland Standard Terms for Patient Access Schemes for early termination if the product is not recommended at reassessment.

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

Associated documented information

Document Ref	Document Title
PAS801-018.01	Concise Patient Access Scheme PAS Application
PAS801-018.02	Full Patient Access Scheme PAS Application
PAS801-018.03	NHSScotland PAS Standard Terms

Document revision history

For activation dates, refer to Q-Pulse.

Version	Description of Amendments
8	Last updated 29 May 2019
9	October 2020 Elaboration of guidance concerning submission, assessment and implementation of PAS when not linked with an SMC HTA. Opportunity to propose new or revised PAS following the SMC New Drugs Committee meeting no longer restricted to medicines assessed for rare conditions or end-of-life situations. Updated contact details of the PASAG secretariat. Re-formatted flow-chart in Appendix 2.
10	April 2023 Expanded guidance clarifying points in relation to: implementation process and communication achieving comparable commercial arrangements in each part of the UK Expanded guidance in Appendix 4 concerning the approach to managing rebates for primary care supplies in the event of generic competition entering the market. Minor update to Appendix 5: FAQs relating to governance arrangements for PAS updates.

Appendix 1: Key principles for PAS

1. PAS will be considered by NHSScotland 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.

2. It is recognised that while such schemes can facilitate access to new medicines there will be implications for NHSScotland in implementing them effectively. In order to ensure this is manageable, these 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 NHSScotland 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. Schemes must be clinically robust, plausible, practical and monitorable.

5. 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.

6. 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 NHSScotland.

7. 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.

8. 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.

9. Compliance must be assured with NHSScotland 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.

10. 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.

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

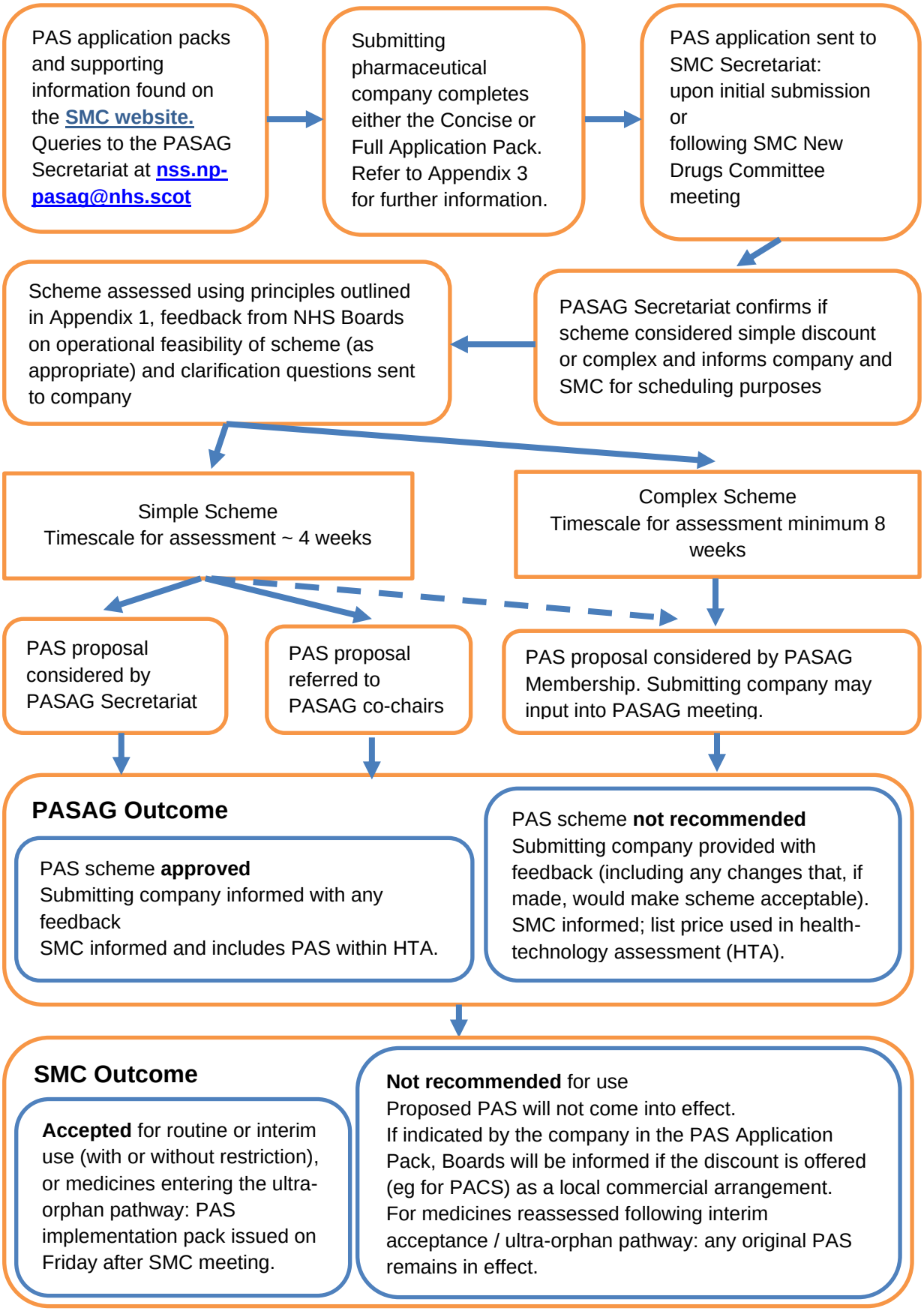
12. The duration of the scheme must be explicit and exit strategies for both parties must be clear. Continuity of care for patients must be explicitly addressed for both a scheduled completion of a scheme or should a scheme end prematurely. Any change to an accepted scheme must be submitted to the PASAG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

13. Schemes must be consistent with existing financial flows in NHSScotland.

14. 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).

15. The experience with PAS in NHSScotland will be reviewed on an ongoing basis.

Appendix 2: Process to propose a PAS for consideration by SMC



Appendix 3: 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 4 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 NHSScotland 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 NHSScotland 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** (page 1): 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 NHSScotland 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** (page 1): When the PAS is submitted linked to an SMC assessment, please detail the indication that is being reviewed within the HTA submission (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 paragraphs 40 to 42 within the main body of this guidance document.

10. **Supply chain and additional information** (page 1): 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:

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

    10.2 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

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

10.4 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)

11.1 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.

11.2 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.

11.3 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. **Supplier representative** (Section 12 of PAS submission): The supplier representative can be different from the signatory in Section 13. The signatory is typically a director, company secretary or authorised signatory of the supplier. The supplier 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)*

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

Appendix 4: PAS in Primary Care

1. There is an established process for PAS in the primary care setting developed through dialogue between NHSScotland and the ABPI.

2. To facilitate the reporting process for primary care rebates, pharmaceutical companies with newly approved simple PAS should ensure the medicine is added to the eVADIS database within four weeks of the effective date. The following information should be submitted to the DDI Medicines Team at Public Health Scotland (phs.DDIMedicines@phs.scot).

   2.1 A copy of the current Summary of Product Characteristics,

   2.2 A dated statement of the pack size(s) and published NHS price(s),

   2.3 The official date of product launch. For certain products, the company will be asked to confirm whether any discounts are offered to community pharmacies and dispensing doctors.

3. Community pharmacies and dispensing doctors obtain the medicine at list price less any distribution margins. On a quarterly basis, NHS NSS on behalf of boards provides the company with a request for payment and usage report, including the quantity of medicine **dispensed**, Gross Ingredient Cost (GIC) and rebate due to each board. This information is used by the company to pay a confidential PAS rebate to NSS as a BACS payment to their nominated bank account. NSS will then disburse funds to each board. Community pharmacies and dispensing doctors do not have access to PAS price information. Any supply chain discounts received by community pharmacy or dispensing doctors will not be included in estimations of the rebate due.

4. The rebate is applicable when the medicine is dispensed irrespective of whether it was prescribed generically, or by brand name.

5. If it is anticipated that there will be primary care supply from the outset of the PAS agreement, usage reports will be generated from the month that the scheme begins. In other cases, NSS will monitor primary care prescribing; reports will only be generated and sent to pharmaceutical companies if there is evidence of use of the medicine in primary care.

6. A standard usage report will be issued by NSS to the pharmaceutical company on a quarterly basis (see example below). The reports are drawn from reimbursement claims for supply against NHS prescriptions by community pharmacies or dispensing doctors. Reports detail usage in each health board area and cover NHS prescriptions originating either from primary care (for example, prescribing by GPs under ‘shared care’ arrangements) or directly from secondary / tertiary care. Reports contain the following information:

6.1 Quantity (for example number of tablets or capsules) of medicine which has been dispensed / supplied in each NHS board over a three-month period;

6.2 associated Gross Ingredient Cost (GIC) for each strength and formulation of the medicine, for instance, the basic NHS reimbursed cost (or the List Price) for the medicine that is charged to the prescriber's drug budget (excluding VAT and any pharmacy remuneration fees or allowances);

6.3 associated rebate that is due to each NHS board.

7. **Example Report Layout**

Health Board Name	Drug	Quantity (Dispensed)	GIC (Dispensed)	Rebate: 10%
NHS Ayrshire & Arran	PASAG_DRUG_1 TABS 5MG	2184	£780.00	
	PASAG_DRUG_1 TABS 10MG	4200	£3,000.00	
[Supplier] Prison Issues	PASAG_DRUG_1 TABS 5MG	112	£40.00	
	PASAG_DRUG_1 TABS 10MG	168	£120.00	
NHS Ayrshire & Arran		**Sum:**	**£3,940.00**	**£394.00**

8. Requests for payment and associated reports are issued quarterly to the named contact within the pharmaceutical company following the schedule below and with data three months in arrears. Note VAT is not applicable to primary care rebates.

Dispensing Quarter	Month that prescribing data available / NSS produces request for payment for company	Estimate for NSS quarterly reconciliation
1 January to 31 March	July	End August
1 April to 30 June	October	End November
1 July to 30 September	January	End February
1 October to 31 December	April	End May

9. The generation of reports is subject to the NSS 'Information Request Charging Policy'; currently there is no associated charge for the generation of reports associated with PAS primary care rebate reports.

10. The pharmaceutical company should rebate the requested amount(s) to the bank account of NSS by BACS (Banker's Automated Clearing Services) transfer within 30 days of receiving the report (unless alternative terms have been agreed with the PASAG secretariat in advance) and send a remittance advice note; NSS bank details can be obtained from the PASAG secretariat if required. If companies require completion of an account form, forward to the PASAG secretariat for completion. Upon receipt, NSS will disburse funds to each board.

11. A summary of rebate values by drug are issued quarterly to named individuals within each health board. NHS boards are required to have a process for reconciling primary care PAS rebates and attributing to the correct cost centre.

12. There is a similar arrangement in place for supplies to prisons and young offender institutions. There is a national NHS contract in place for the supply of pharmacy services to prisons and young offender institutions. Boards are responsible for medicine costs and are provided with a report of all supplies made to each prison / young offenders institution within their board area monthly. These reports are also provided to National Procurement and used to calculate rebates due.

13. Upon loss of market exclusivity, and at the point when generic or biosimilar competition enter the UK market, the PASAG Secretariat will:

    - conduct a feasibility analysis of ongoing administration of rebates for supplies of PAS medicines via Primary Care.

    - work with the originator product's company to agree how rebates from Primary Care supplies will be managed,

    - communicate to health boards any implications and recommended actions to be taken.

14. 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)

15. Any queries should be directed to the PASAG Secretariat (nss.np-pasag@nhs.scot).

Appendix 5: 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 the *"Scottish Medicines Consortium Guidance to Manufacturers for completion of New Product Assessment Form (NPAF). Supplement for medicines where the comparator medicine is available through a confidential PAS",* available 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)?

Paragraphs 47 to 59 outline the process for offering comparable commercial arrangements in Scotland. Companies can contact PASAG 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 with 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 supplier 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 NHSScotland 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 Supplier 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 Supplier 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 Supplier 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 NHSScotland 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.