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1 Introduction

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

1.2 Patient Access Schemes will be considered by NHS Scotland to enable patient access to medicines that are not, or might not, in the first instance be found to be cost-effective by the Scottish Medicines Consortium (SMC).

1.3 SMC will only consider the financial benefits of a proposed patient access scheme 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).

1.4 This document sets out the process for the submission, assessment and implementation of Patient Access Schemes in Scotland.

2 Patient Access Scheme Assessment Group (PASAG)

2.1 The role of the Patient Access Scheme Assessment Group (PASAG) is to deliver a national service conducting an objective and independent assessment, on behalf of NHS Scotland, of patient access schemes submitted by pharmaceutical companies and advise on their acceptability for implementation by NHS Boards in Scotland.

2.2 The group is co-chaired by a Director of Finance and a Director of Pharmacy and includes members from across NHS 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 a member of the group.

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

2.4 The PASAG Secretariat is hosted by National Procurement, NHS National Services Scotland (NSS).

3 Types of Schemes

3.1 Experience has enabled the development of a typology for Patient Access Schemes; schemes can be split into two categories, simple discount schemes and complex schemes.

3.2 A simple discount scheme involves a discount from the NHS list price applied at the point of invoice when supplied through secondary/tertiary care, homecare or a third party compounding and a confidential retrospective rebate to Health Boards for any supply in primary care (community pharmacies, dispensing doctors and prisons). 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 NHS Scotland and generally do not impose any significant additional burden to the NHS or pharmaceutical companies.
3.3 Complex schemes include all other types of PAS including:

- 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 introduce significant complexity and burden for the NHS and pharmaceutical companies and their perceived financial benefits are rarely fully realised in practice. They are only accepted in exceptional circumstances.

4 Scheme Setting

4.1 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.

4.2 Within the minimum 5 year lifetime of the PAS, models for the delivery of care may 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, for example, the expectation may be that supply of an infusion will be limited to the hospital setting but in the longer term, if alternative models for the dispensing of the medicine emerge, the PAS price should apply in these settings. The PASAG Secretariat can be contacted for advice regarding supply chain arrangements to NHS Scotland if required.

5 Governance of Pricing Arrangement

5.1 The PAS Agreement is constituted and governed by the:

- PAS Submission - which can be found in the relevant PAS application pack, hosted on the SMC website, and requires completion by the pharmaceutical company.
- PAS Approval Letter - which can be found in the relevant PAS application pack, hosted on the SMC website, and requires completion by the pharmaceutical company and the NHS (if the medicine is accepted for use). National Services Scotland has the authority to approve the establishment of the PAS agreement on behalf of all Scottish Health Boards.
- NHS Scotland Standard Terms for Patient Access Schemes - which can be accessed at the following link. These Standard Terms are an 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.

6 Submission of Proposed Patient Access Scheme

6.1 The general process, timescales and milestones for the submission and assessment of a PAS (and implementation, if the medicine is accepted for use) are outlined in Appendix 2.

6.2 Pharmaceutical companies wishing to submit a PAS proposal to PASAG should complete either the concise or full PAS application pack, as appropriate, which are available on the SMC website. Guidance on completing these application packs is contained in Appendix 3. Pharmaceutical companies can contact the PASAG Secretariat in advance of submission for general advice and guidance on the operational feasibility of proposed scheme types.
6.3 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.

6.4 For medicines considered under the SMC end of life/orphan process, pharmaceutical companies also have a second opportunity to submit a new or revised PAS following the issue of 'not recommended' advice from the New Drugs Committee (NDC). There is a two-week period following the issue of NDC advice for companies to submit a new or revised PAS to the SMC Secretariat. A new application pack should be completed when revising the previous PAS application and submitted to the SMC Secretariat. It is important to note that submission at this stage may extend timelines for SMC review of medicines. For this reason, pharmaceutical companies are strongly encouraged to submit any proposed PAS at the first opportunity with the initial SMC submission.

6.5 Where there is an existing PAS in effect within NHS Scotland for a particular medicine, a new PAS application pack with updated “PAS Submission” is required for each new SMC submission for that medicine (e.g. for a new indication).

7 PASAG Assessment Process

7.1 All proposed schemes are assessed by PASAG in the context of the agreed key principles (Appendix 1) and 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 realized.

7.2 The PASAG Secretariat evaluates each submitted PAS, liaising with the pharmaceutical companies and NHS Boards as necessary, and presents any relevant issues for PASAG to consider. It can be an iterative process to deliver schemes that are efficient and minimize any administrative burden on NHS Boards.

7.3 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.

7.4 The PASAG Co-Chair(s) may approve a simple discount scheme outwith scheduled meetings; however, reserve the right to refer the scheme 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 Co-chair(s) and all complex schemes.

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

7.6 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 to make it acceptable for implementation. PASAG will also advise SMC of the outcome.
8 Assessment Timelines

8.1 Evaluation of simple discount schemes by PASAG takes approximately 4 weeks. PASAG review is scheduled to ensure that the decision is available prior to either the anticipated NDC meeting or SMC meeting (for those submitted at the second opportunity for end of life/orphan medicines).

8.2 Complex schemes require a longer period for evaluation (a minimum of 8 weeks) and may delay the anticipated SMC timeline for assessment. The PASAG Secretariat communicates timescales for review of the PAS scheme to the SMC Secretariat to support SMC scheduling of the HTA process.

9 Implementation Process and Communication

9.1 The general process, timescales and milestones for the implementation and communication of a PAS are outlined in Appendix 2.

9.2 The PAS will only be available for implementation if approved by PASAG and accepted for use by SMC.

9.3 Only brief information relating to the PAS and that considered not commercially sensitive will be included in the SMC DAD, which is publicly available. The Board is required to treat confidential all supplier confidential information and not disclose to any third party as described in the NHS Scotland Standard Terms for Patient Access Schemes.

9.4 In 2016, communication routes for secure sharing of PAS information were reviewed following concerns from companies that up to date pricing information was not always available to prescribing decision-makers within Boards. There was evidence of prescribing decisions being made without using up-to-date pricing information, potentially commercially disadvantaging individual companies. This is a particular issue for medicines that have been on the market for some time and medicines that face therapeutic competition. In addition to sharing information by email at the point of the SMC decision, appropriately authorized individuals within Boards can now also access PAS pricing information via a secure online repository known as CCM. More information is in the following sections.

9.5 The possible communication channels for PAS information are:

- Restricted email distribution list: via the SMC Secretariat this involves an email to the Chairs of the Area Drug and Therapeutic Committees (ADTCs), Directors of Finance and Directors of Pharmacy. These individuals are then responsible for securely disseminating the information to relevant individuals within their NHS Board.
- Standard e-mail distribution list for confidential commercial pricing information: in addition to above, an email is sent via National Procurement to NHS pharmacy purchasing leads. This is the email distribution list normally used to securely share information with Boards on secondary care contract pricing.
- CCM: The standard communication route to securely share contract pricing information to appropriately authorized personnel within Health Boards is the Catalogue Content Management System (CCM) 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 authorized personnel within NHS Scotland Health Boards via CCM. There are two access levels for Board pharmacy personnel, standard access rights for Framework pricing information and restricted access to PAS pricing (managed by PASAG Secretariat; access rights determined at Board level).
There are 3 options available for companies to choose:

- Standard (use the email distribution list used as standard by National Procurement for confidential contract pricing information and inclusion on CCM)
- Restricted communication (restricted e-mail distribution as outlined above and restricted access via CCM)
- Restricted e-mail email distribution only at the point of the SMC decision (product not included on CCM)

9.6 For simple schemes, the signed “PAS Submission” and signed PAS Approval Letter will be sent to NHS Boards as an implementation pack, along with a cover email detailing the ordering arrangements for the medicines and any further relevant information. The PAS Approval Letter will be signed on behalf of all NHS Scotland Health Boards by the Director of Procurement, Commissioning and Facilities, NHS National Services Scotland. The pharmaceutical company will also be sent a copy. Each Board should have a general standard operating procedure (SOP) for the implementation of simple PAS.

9.7 Further information regarding the established PAS in primary care process can be found in Appendix 4.

9.8 For complex schemes, bespoke guidance notes will be developed for that particular scheme (including an operational flow diagram). The signed “PAS Submission”, signed PAS Approval Letter, guidance notes and any supporting documents (e.g. rebate claim forms and verification record template) will be sent to NHS Boards as an implementation pack, along with a cover email. The PAS Approval Letter will be signed on behalf of NHS Scotland by the Director of Procurement, Commissioning and Facilities, NHS National Services Scotland. The pharmaceutical company will be sent a copy. Each Board should develop a standard operating procedure (SOP) for the implementation of that particular complex scheme. This should include, where necessary, maintaining the verification record included within the implementation pack with claims submitted and linked to a unique PAS patient number. Verification records may be requested by the relevant pharmaceutical company for audit purposes, where appropriate, and should be provided with any patient identifiable data excluded. Further information regarding the generation of a unique PAS patient number can be found in Appendix 5.

9.9 A confidential register of schemes in effect as well as those that were proposed but not implemented will be distributed to NHS Boards on a monthly basis.

9.10 If a medicine with a proposed PAS is not recommended for routine use in NHS Scotland then pharmaceutical companies have the option of offering an equivalent commercial agreement to individual NHS Boards (e.g. for IPTR/PACS Requests). Pharmaceutical companies are asked to indicate on the 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 to NHS Boards, in confidence regarding the proposed pricing arrangements including company contact details. A confidential register of available discounts will be distributed to NHS Boards on a monthly basis.
Appendix 1

Key Principles for Patient Access Schemes (PAS)

1. PAS will be considered by NHS Scotland to facilitate access by patients to medicines that are not, or might not in the first instance be found to be cost-effective by SMC. Any proposal must originate from the pharmaceutical company that holds the UK marketing authorization.

2. It is recognized that while such schemes can facilitate access to new medicines there will be implications for NHS Scotland 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 NHS Scotland to prioritize 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. 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 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 i.e. 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.

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 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.

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 the Data Protection Act 1998 and Caldicott principles.

11. 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.

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 NHS Scotland.

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

14. It is important that arrangements for proposing and agreeing such schemes do not in turn jeopardize the timeliness of SMC advice. The timing of discussions on schemes should not encourage ‘gaming’ of the appraisal system by any party (i.e. where either the company or health technology assessment organization attempts to exploit the system to ensure the most desirable outcome from their own perspective).

15. The experience with PAS in NHS Scotland will be reviewed on an ongoing basis.
Appendix 2

Overview of NHS Scotland Patient Access Scheme (PAS) Process

PAS application packs and supporting information found on the [SMC website](https://www.smct.org.uk)
Any queries can be directed to the PASAG Secretariat at [NSS.NP-PASAG@nhs.net](mailto:NSS.NP-PASAG@nhs.net)

Submitting pharmaceutical company complete either concise or full application pack
Refer to Appendix 3 for further information

PAS application sent to SMC Secretariat with NPAF

PASAG Secretariat confirms if scheme considered simple discount or complex and informs company and SMC for scheduling purposes

Timescale for **simple** scheme is approx. 4 weeks

Scheme assessed using principles outlined in Appendix 1, feedback from NHS Boards on operational feasibility of scheme (as appropriate) and clarification questions sent to company

Timescale for **complex** scheme is minimum 8 weeks

PAS proposal considered by PASAG Co-Chairs and may be referred to PASAG Membership

PAS proposal considered by PASAG Membership

NOTE: A new or revised PAS for medicines under review for end of life/orphan medicines may be submitted within two weeks after NDC, and scheduled accordingly.

PAS scheme **approved**
Submitting company informed including any feedback
SMC informed and includes PAS within HTA

PAS scheme **not recommended**
Submitting company provided with feedback (including any changes that would make scheme acceptable if made)
SMC informed

If medicine is **accepted** for use by SMC then PAS implementation pack sent to Boards/company within one week of advice issued

If medicine is **not recommended** for use by SMC then PAS will not come into effect. NHS Boards will be informed if the discount remains available (e.g. for IPTR/PACS) as a local commercial arrangement as indicated by company in PAS application pack.
Appendix 3
Guidance for Completion of the PAS Application Packs

- 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.net.

- 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 compounding and a confidential retrospective rebate for any supply in primary care (community pharmacy, dispensing doctor, prison) – see Appendix 5 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 recognized that certain supply routes may not be utilized by the NHS (e.g. due to the nature of the medicine) or only utilized after establishing appropriate governance and supply arrangements. For example, 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.

- The full 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 wish to propose an amendment to one or more of these clauses. The full 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.

- 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.

- The anticipated effective date for PAS submitted is the date that SMC will issue its advice in confidence to the pharmaceutical company and NHS Scotland based on SMC assessment timelines (generally the Friday following the SMC meeting and one month prior to publication on the SMC website). This date may be subsequently altered by the PASAG Secretariat should the assessment scheduling change. It is acknowledged some companies will require an additional short period of time to ensure the supply chain is available / pricing updated as appropriate; if required, companies are requested to liaise with the PASAG secretariat to ensure any delays are communicated to NHS Boards.

- 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. Detailed to be provided include:
o Where hospitals should order from e.g. direct or via third party distributor(s).

o 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 NHS Scotland 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.net. Note: this process is separate from the PAS assessment process and will not impact on PAS assessment timelines.

o Whether a supply route to primary care (community pharmacies and dispensing doctors) is available or planned.

o Whether there are any barriers to the NHS commissioning a third party compounding service to prepare patient ready products (where relevant).

- Completed application packs should be saved as a Microsoft Word® document using the following naming convention and dated with SMC submission deadline:

  Generic Drug Name (Brand Name) PAS Application Pack YYYYMMDD V0.1 (Initial)

  It may be necessary to revise the application throughout the assessment process and version control will also be applied to subsequent versions.
Appendix 4

PAS in Primary Care Process

1. There is an established process for Patient Access Schemes in the primary care setting; developed through dialogue between NHS Scotland and the ABPI.

2. In order 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 4 weeks of the start date. The following information should be submitted to the eVADIS team (NSS.evadis@nhs.net): (i) a copy of the current Summary of Product Characteristics, (ii) a dated statement of the pack size(s) and published NHS price(s), and (iii) 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 National Services Scotland (NSS) on behalf of Boards provides the company with an invoice 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. 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 and prison/young offender institution supply data for any usage; reports will only be generated and sent to pharmaceutical companies if there is evidence of use of the medicine in primary care.

5. 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:

- quantity (e.g. number of tablets or capsules) of medicine which has been dispensed/supplied in each NHS Board over a 3 month period
- associated Gross Ingredient Cost (GIC) for each strength and formulation of the medicine i.e. the basic NHS reimbursed cost (or the List Price) for the medicine that is charged to the prescribers drug budget (excluding VAT and any pharmacy remuneration fees or allowances).
- associated rebate that is due to each NHS Board (calculated as a percentage of the GIC of each unit dispensed e.g. tablet, capsule, etc)
Example Report Layout

<table>
<thead>
<tr>
<th>Health Board Name</th>
<th>Drug</th>
<th>Quantity (Dispensed)</th>
<th>GIC (Dispensed)</th>
<th>Rebate: 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Ayrshire &amp; Arran</td>
<td>PASAG_DRUG_1 TABS 5MG</td>
<td>2184</td>
<td>£780.00</td>
<td></td>
</tr>
<tr>
<td>[Supplier] Prison Issues</td>
<td>PASAG_DRUG_1 TABS 10MG</td>
<td>4200</td>
<td>£3,000.00</td>
<td></td>
</tr>
<tr>
<td>NHS Ayrshire &amp; Arran</td>
<td>PASAG_DRUG_1 TABS 5MG</td>
<td>112</td>
<td>£40.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PASAG_DRUG_1 TABS 10MG</td>
<td>168</td>
<td>£120.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sum:</td>
<td></td>
<td>£3,940.00</td>
<td>£394.00</td>
</tr>
</tbody>
</table>

6. Invoices 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. Copies of reports will also be sent to a named contact within each NHS Board. Note VAT is not applicable to primary care rebates.

<table>
<thead>
<tr>
<th>Dispensing Quarter</th>
<th>Month that Prescribing Data Available/NSS produce invoice for company</th>
<th>Estimate for NSS quarterly reconciliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st January – 31st March</td>
<td>July</td>
<td>End August</td>
</tr>
<tr>
<td>1st April – 30th June</td>
<td>October</td>
<td>End November</td>
</tr>
<tr>
<td>1st July – 30th September</td>
<td>January</td>
<td>End February</td>
</tr>
<tr>
<td>1st October – 31st December</td>
<td>April</td>
<td>End May</td>
</tr>
</tbody>
</table>

7. The generation of reports is subject to the National Services Scotland (NSS) ‘Information Request Charging Policy’; currently there is no associated charge for the generation of reports associated with PAS primary care rebate reports.

8. 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.

9. NHS Boards are required to have a process for reconciling primary care PAS rebates and attributing to the correct cost centre.

10. 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. Lloyds Pharmacy is the current contractor and provides the service from 5 closed dispensaries across Scotland. Boards are responsible for medicine costs and are provided with a report of all supplies made to each prison/young offender’s institution within their Board area on a monthly basis. These reports are also provided to National Procurement and used to calculate rebates due.

11. Any queries should be directed to the PASAG Secretariat (nss.np-pasag@nhs.net).
Appendix 5

Unique PAS Patient Number (Complex Schemes)

1. Pharmaceutical companies may require that for proposed complex schemes NHS Boards track individual patients and medicine supplies purchased for the treatment of those patients e.g. to claim rebates. To ensure patient confidentiality and comply with Caldicott principles, patients receiving treatment under the terms of the scheme are therefore allocated with a unique PAS patient number to facilitate this tracking. This would be specified on the patient registration form and any subsequent claim forms, where appropriate.

2. The NHS Board is responsible for assigning the unique PAS number following the standard format:

PAS Number / Location Code / Patient Number

XXX / LLLLL / PPPP

The PAS Number is allocated by PASAG Secretariat when scheme comes into effect e.g. PAS No. 006

The Location Code is a 5 character code consisting of alpha-prefix for NHS board; 3-digit serial number; and alpha-suffix for location type e.g. N101H. A list of codes is maintained by Information Services Division and General Register Office (Scotland) and can be obtained from PASAG Secretariat.

The Patient Number is allocated sequentially by Boards for new patients enrolled in scheme at that location

3. The PAS Verification Record should also include the unique PAS patient number and attributed to any claims submitted. This verification record may be requested by the relevant pharmaceutical company for audit purposes, where appropriate. No patient identifiable data should be provided to the pharmaceutical company.

4. The unique PAS number(s) should be included on any remittance advice detailing the rebate amount(s) relevant to that patient to enable financial reconciliation by the Board and allocation to relevant budget code (if necessary). For BACS transfers, the BACS payment reference should have the following standard format:

PASXXXMEDICINENAME

5. Where a patient is registered for a PAS and transfers to a different location, the patient should retain the original Unique PAS Patient Number including the location code.
Appendix 6

Frequently Asked Questions (FAQs)

1. What happens when a future SMC submission refers to a medicine 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 hcis.smcsecretariat@nhs.net

2. What happens if a PAS is submitted in relation to a NICE Multiple Technology Appraisal (MTA)?

NICE MTAs are not assessed on a national basis for applicability to Scotland however to support consideration at Board level, at the point NICE issues their final MTA advice, National Procurement shares up-to-date pricing information for products within the scope of the MTA with Board Area Drug and Therapeutics Committees (ADTC) and provides confirmation to Boards on whether pricing used in the NICE assessment is in line with pricing in Scotland.

If companies offer a PAS in England linked to a NICE MTA or enhance the discount on an established PAS, they are encouraged to contact National Procurement at the same time so that arrangements can be made to implement equivalent pricing arrangements in Scotland. If National Procurement is not already in contact with the company by the time NICE communicate their advice, National Procurement will get in contact. If you require further information, please contact the PASAG Secretariat at nss.np-pasag@nhs.net.

3. Once the PAS has been implemented, can the level of discount be increased?

It is not possible to amend the level of discount for an implemented PAS outside of an SMC assessment; however companies can offer an additional ‘top up’ discount, arranged via National Procurement, NSS.

If you require further information, please contact the PASAG Secretariat at nss.np-pasag@nhs.net.

4. 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 NHS Scotland Standard Terms for Patient Access Schemes - which can be accessed at the following link.

5. What happens if there is a change of ownership of the medicines (e.g. 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 5 year term of the agreement will be retained. The PASAG Co-Chairs and Director of Procurement, Commissioning and Facilities, NHS National Services Scotland will be requested to
confirm the change for internal governance purposes. An updated PAS implementation pack will be cascaded 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 a NHS list price that is equivalent or lower.

6. **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 5 year term of the agreement will be retained. The PASAG Co-Chairs and Director of Procurement, Commissioning and Facilities, NHS National Services Scotland will be requested to confirm the change for internal governance purposes. An updated PAS implementation pack will be cascaded to Boards and the company provided with a copy.

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

Given the duration of PAS agreements, schemes may eventually become redundant e.g. 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 at nss.np-pasag@nhs.net to discuss and agree if the PAS should be temporarily suspended or terminated.