PATIENT ACCESS SCHEME
ASSESSMENT GROUP (PASAG)

Industry Guidance

Revised August 2013
Contents – Industry Guidance

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1. Introduction

The Patient Access Scheme Assessment Group (PASAG) was established in 2010 to assess proposed Patient Access Schemes (PAS) for acceptability in NHS Scotland against standard objective criteria.

This guidance has been produced for industry to provide background to the establishment of PASAG, to describe the process for submission and assessment of Patient Access Schemes (PAS) in NHS Scotland and communication of PASAG decisions. A company should complete the Patient Access Schemes in Scotland Industry Application Pack and ensure that they are familiar with NHS Scotland Standard Terms for Patient Access Schemes (Revised May 2013) when making an application for a Patient Access Scheme (PAS) to be used in NHS Scotland.

Applicants should note the following when making a submission to SMC with a PAS:

When a product is accepted for use or restricted use by SMC and includes an approved PAS, companies must be aware that if a future SMC submission refers to their product as a comparator and the SMC agrees that on account of the PAS there is not enough information on that product in the public domain to make the economic comparison, the original company will be required to provide the essential additional information to the second company, on a confidential basis after they have received the CHMP opinion and have agreed their list price with the Department of Health. In circumstances where the original company raises specific concerns with respect to providing this information, the matter will be referred to the SMC Executive Team for consideration. *(Scottish Medicines Consortium. Guidance to Manufacturers for completion of New Product Assessment Form (NPAF) available at: www.scottishmedicines.org.uk).*

If you require further information, please contact SMC at: gis.smsecrnetariat@nhs.net
2. Patient Access Schemes and the Patient Access Scheme Assessment Group

Patient Access Schemes (PAS) are schemes proposed by a pharmaceutical company and agreed between the Patient Access Scheme Assessment Group (PASAG) and the pharmaceutical company in order to improve the cost effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines using the usual existing models for delivery of patient care within NHS Scotland. PASAG was established in 2010 to assess proposed PAS for acceptability for implementation within NHS Boards in Scotland.

PASAG has a national focus, functioning under the auspices of NHS National Services Scotland (NSS). It is composed of members from across NHS Scotland, with different specialist backgrounds:

- Director of Pharmacy (Co-Chair)
- Director of Finance (Co-Chair)
- Senior Clinician Acute care (X2), Primary care (X1)
- NHS Board Pharmacy operational representative
- NHS Board Finance operational representative
- NHS Board Business Manager representative
- NSS National Procurement representative (X2)
- Area Drug and Therapeutics Committee (ADTC) representative (X2)
- Association of the British Pharmaceutical Industry (ABPI) representative
- NHS Board Caldicott Guardian representative
- NHS Board Public Health representative
- NHS Board Medical Director representative
- NSS Information Services Division (ISD) representative

In addition, there are several observers who attend PASAG meetings or who are approached to provide input on specialist areas as required. The key organisations represented by observers are:

- Scottish Government Health Directorates (SGHD) (X2)
- SMC (X2)
- Central Legal Office (CLO)

PASAG is supported by the PASAG Secretariat, which evaluates each PAS submitted, liaises with pharmaceutical companies and NHS Boards as required, and presents issues for PASAG’s consideration. The PASAG Secretariat is hosted by NSS National Procurement Division and comprises:

- Administration support
- Finance support
- Pharmaceutical support
- National Procurement support
3. Submission and Assessment of Patient Access Schemes in NHS Scotland

The submission and assessment process is outlined in Appendix 1.

In Scotland, pharmaceutical companies can propose a PAS:

a) As part of a Scottish Medicines Consortium (SMC) submission. PASAG assesses the PAS and SMC assesses the clinical effectiveness and cost-effectiveness of the product. If the PAS is accepted by PASAG then SMC considers the financial benefits of the proposed PAS as part of the appraisal process. SMC normal assessment process follows usual timelines with clear communication between SMC and PASAG.

b) In the context of a National Institute for Health and Care Excellence (NICE) Multiple Technology Appraisal (MTA). PASAG assesses the PAS and Healthcare Improvement Scotland (HIS) endorses the NICE recommendation as appropriate.

Pharmaceutical companies wishing to submit a PAS to PASAG should complete the PASAG Industry Application pack, which can be found on the SMC website (www.scottishmedicines.org.uk).

When making a PAS submission to PASAG, the pharmaceutical company is required to confirm their acceptance of NHS Scotland Standard Terms for PAS, which were developed by the Central Legal Office (CLO). The Standard Terms outline the terms under which a PAS in NHS Scotland will operate and have been endorsed by ABPI and NHS Scotland. The Standard Terms are available on the SMC website and a User Guide to the Standard Terms is also available (Appendix 2).

The PAS submission completed by the company specifies: the drug and indication to which the PAS relates; the relevant dosages and formulations; how the PAS will operate in NHS Scotland; the rebate due to NHS Boards; and, data that the NHS Board will be required to maintain in order to confirm the validity of any claims (the ‘Verification Record’) (see section 4 (i)). Guidance points for completing the PAS submission form are provided in Appendix 3.

All proposed schemes are assessed by PASAG in the context of an agreed set of Key Principles (Appendix 4) and against standard objective criteria, which relate to whether or not the scheme is: financially acceptable; robust ethically and legally; Caldicott compliant; and operationally practical.

Patient Access Schemes fall into one of two categories:

- Performance based schemes where the rebate or supply of stock is based on patient response to treatment; or,
- Finance based schemes where the NHS receives a rebate or free supply based on usage. The rebate may take the form of a straight discount from list price. This is generally available for all purchases of a medicine for the indication under assessment although in some cases it may be restricted to a particular preparation.

The process by which a PAS provides a rebate may be either simple or complex.

- Simple schemes involve a straight discount on the list price of the product. The discount is applied at the point of invoice, to the full duration of treatment and to all clinical indications of the product (current and future). There is no requirement to identify and monitor the course of treatment of individual patients
- Simple schemes in primary care involve a retrospective discount on the product, paid directly to the NHS Board, based upon the quantity of prescribed medicine dispensed in primary care as
Complex schemes are varied. They include free stock/rebates at various stages of the patient treatment or are schemes which only apply to specified subgroups of patients. Complex schemes require Boards to monitor the course of treatment of individual patients whilst maintaining patient confidentiality in line with Caldicott principles. To monitor the course of treatment, each patient who is prescribed a product under the terms of the PAS is assigned a Unique PAS Patient Number by the NHS Board (Appendix 5). Any PAS which requires patient identifiable data to be collected and reported will not be accepted by PASAG.

Performance based schemes are always ‘complex’ while finance based schemes may be either ‘simple’ or ‘complex’. Some proposed PAS offer a combination of rebates including a straight discount on list price for some elements of the course of treatment. These should always be regarded as complex PAS due to the additional administrative burden of administering such PAS.

Assessment of PAS includes an iterative process with the pharmaceutical company and NHS Boards to deliver schemes that are efficient and to minimise any administrative burden associated with PAS for NHS Boards.

4. Communication of PASAG decisions and implementation of PAS by NHS Boards

Following assessment, PASAG advises SMC or Healthcare Improvement Scotland (HIS) and the submitting company whether the PAS is acceptable for implementation or not recommended. For schemes that are not recommended by PASAG, the reasons will be transparent.

If the PAS was proposed as part of a SMC submission, then the product may be: accepted for use or accepted for restricted use with or without the PAS; or, not recommended for use. If the PAS was proposed in the context of a NICE MTA, then HIS may endorse the NICE recommendation with or without the PAS as appropriate.

If a product is accepted for use or accepted for restricted use with a PAS by SMC, the SMC Detailed Advice Document (DAD) will include brief, non confidential information relating to the PAS. Similarly, if a product (reviewed as part of a NICE MTA) is endorsed with a PAS by HIS, the HIS advice will include brief, non confidential information relating to the PAS.

When a product is accepted for use or restricted use in NHS Scotland and includes an accepted PAS, the PASAG Secretariat will produce an implementation pack to facilitate implementation of the PAS by NHS Boards. This pack contains confidential information and is issued to NHS Boards via SMC in strict confidence to Directors of Pharmacy, Directors of Finance and Chairs of Area Drug and Therapeutics Committees in each NHS Board as the main point(s) of contact for communication of PAS information. The contact person(s) is responsible for ensuring that relevant PAS are implemented within the NHS Board.

The Implementation Pack specifies the PAS Number assigned to the PAS by PASAG and consists of the PAS Submission Form, PAS Approval Letter, NHS Scotland Standard Terms for PAS, Guidance Notes and a Confidential PAS Register as follows:

(i) PAS Submission Form. This is completed by the company and includes:

- A description of the scheme, cost reduction mechanism and claims procedure where appropriate.
− Data that should be included in the Verification Record. Each NHS Board is responsible for locally developing and maintaining a Verification Record to confirm the validity of any claims, in line with NHS Scotland Standard Terms for PAS. Where appropriate, the Verification Record, excluding any patient identifiable information, may be requested by the relevant company to verify claims or by PASAG for audit purposes. If the company requests additional information held by the Board to confirm a claim, it will be at the company’s expense. To facilitate provision of this data, NHS Boards should maintain a PAS Monitoring Database for each accepted PAS implemented.
− Confidential Information. The PAS Submission Form details any information the disclosure of which could cause substantial commercial prejudice to either party. Guidance for the completion of the PAS Submission Form is provided (Appendix 3).

(ii) PAS Approval Letter
The format of the PAS Approval Letter depends on whether the PAS is simple or complex or whether the scheme will operate in Primary Care.
− Simple PAS for medicine prescribed in secondary/tertiary care - direct supply to hospital or via homecare: the PAS Approval Letter is completed by National Procurement, National Services Scotland, on behalf of NHS Scotland and sent to the company to confirm that the PAS is approved for use in NHS Scotland. A copy of the completed PAS Approval Letter is retained by the PASAG secretariat and is included in the Implementation Pack for information.
− Simple PAS for medicine prescribed in Primary Care and Complex PAS: the PAS Approval Letter is completed by the NHS Board. It must be printed on NHS Board notepaper and signed by the NHS Board Chief Executive, Director of Finance or authorised officer. If required, the NHS Board enters bank details to enable the company to make rebate payments to the appropriate account. The NHS Board also inserts the details of individuals authorised to sign the PAS claim forms (and/or other forms as appropriate) for complex PAS. The Board returns the completed PAS Approval Letter to the company to confirm that the PAS has been approved for use within that NHS Board and sends a copy to the PASAG Secretariat (NSS.NP-PASAG@nhs.net).

The Board of treatment rather than the Board of residence is responsible for implementing the PAS. If a patient transfers to another (receiving) Board to continue treatment, and the terms of the PAS are still applicable, then the receiving Board should also complete the PAS Approval Letter.

(iii) Guidance notes. The guidance notes outline the process for implementation of the PAS and include an operational flow chart and PAS Monitoring Template where required.

(iv) NHS Scotland Standard Terms. The Standard Terms outline the terms under which a PAS in NHS Scotland will operate and are endorsed by ABPI and NHS Scotland.

(v) Confidential PAS Register for NHS Boards. This document summarises the medicines accepted and not recommended for use with PAS in NHS Scotland.

The Implementation Pack (with the exception of the Confidential PAS register for NHS Boards) is shared with the company. Where a PAS is not accepted by PASAG or where a PAS is accepted by PASAG but the medicine is not recommended by SMC or not accepted as part of a NICE MTA submission, an Implementation Pack will not be available.
Appendix 1: Process for PAS submission and assessment

1. Any company intending to submit a SMC New Product Assessment Form with a PAS or a NICE MTA which involves a medicine with a PAS in Scotland can access the PAS documentation on the SMC website (www.scottishmedicines.org.uk).

2. All points of clarification with regards to PAS documents should be raised with the PASAG Secretariat by emailing NSS.NP-PASAG@nhs.net.

3. The company will complete the PAS documents and submit these to the PASAG Secretariat via the SMC Secretariat. For SMC submissions this will be at the same time as the SMC New Product Assessment Form is submitted.

4. PASAG Secretariat initiates rapid review and assessment of the PAS in line with the assessment process (see diagram 1). This may require dialogue with the submitting company and/or NHS Service providers in order to obtain clarification of key points of the proposed PAS. If, for whatever reason, clarification cannot be secured within four days of receipt of the PAS application, the PAS will be scheduled as complex for the purposes of assessment timelines.

5. SMC or HIS as appropriate will send generic PAS questions to clinical experts and will forward the responses to the PASAG Secretariat. If the PASAG Secretariat has further additional questions, then the PASAG administrator will send the additional questions to clinical experts direct.

6. The PASAG Secretariat will send PAS questions to service providers in NHS Boards to obtain feedback on the operational feasibility of the PAS as appropriate.

7. A PAS Assessment Proforma will be completed by the PASAG Secretariat and submitted to PASAG for decision.

8. The company and SMC or HIS as appropriate will be notified of PASAG’s decision.

9. If the PAS is not recommended, the company may resubmit a revised PAS. For SMC assessed medicines this should be at the same time as the New Product Assessment Form is resubmitted.

10. For SMC submissions. SMC meetings will be held to review the SMC New Product Assessment Form with the accepted PAS.

11. When a product with a PAS is accepted for use in NHSScotland, SMC advice will be issued to NHS Boards. This will include brief, non confidential information relating to the PAS.

12. Where a product with an accepted PAS is accepted for use or restricted use in NHSScotland, the PASAG Secretariat will prepare an Implementation Pack to support implementation of the PAS by NHS Boards. The Implementation Pack will be issued to NHS Boards via SMC. Other than where the PAS is a simple discount scheme the Implementation Pack will include a PAS Monitoring Template to facilitate development of the PAS Monitoring Database by NHS Boards.
Diagram 1: Flowchart for the submission and assessment of Patient Access Schemes in NHS Scotland

1. SMC New Product Assessment Form and PAS Application Pack completed by company and submitted to SMC Secretariat

2. PAS Application Pack forwarded to PASAG Secretariat

3. PASAG Secretariat reviews PAS application and categorises as a Simple or Complex scheme. SMC advised of categorisation and scheduled accordingly.

4. Simple PAS
   - PAS Assessed for: Legal compliance, Caldicott compliance, Consistency with SMC submission, Clinical appropriateness
   - PAS Assessment proforma completed
   - PAS Assessment proforma Presented to PASAG for decision
   - Company and SMC notified of PASAG decision

5. Complex PAS
   - PAS Assessed for: Legal compliance, Caldicott compliance, Consistency with SMC submission, Clinical appropriateness
   - Financial evaluation completed
   - PAS Assessment proforma completed
   - PAS Assessment proforma Presented to PASAG for decision
   - Company and SMC notified of PASAG decision

6. Implementation Pack prepared for NHS Boards as appropriate

*PAS in NICE MTA will follow the process for Complex schemes.

The Standard Terms to be applied to Patient Access Schemes (PAS) introduced in Scotland have been developed by the Central Legal Office as part of an integrated package of documentation. This includes the Standard Terms, the PAS Approval Letter and the PAS Submission. The Standard Terms have been developed as an addition to the conditions of contract for the supply of the drug and do not cover any issues relating to the supply of that drug. The conditions of contract governing the sale and purchase of the drug are agreed between the Supplier and the Board or National Procurement in the normal manner. The key points covered by the Standard Terms are:

1. Any variation to the Standard Terms must be agreed in writing between the Board’s authorised representative and the Supplier’s authorised representative.

2. The PAS Approval Letter which is signed by or on behalf of the Board will state the drug and the indication to which the PAS applies. It will be printed on Health Board headed notepaper addressed to the company and will be authorised by the Health Board Chief Executive, Director of Finance or other authorised officer. It will list the names and job titles of the individuals authorised to sign PAS registration and claim forms where appropriate.

3. The PAS Submission is completed by the company and will detail:
   - the drug
   - the indication to which the PAS applies
   - all relevant dosages and formulations
   - the commencement date of the PAS Agreement
   - review date (minimum period of PAS)
   - details of rebate or other method of reducing the cost of treatment
   - claims procedure

4. The Board is required to maintain a Verification Record for each PAS. The information to be included in the Verification record is detailed in the PAS Submission. The Board will record and check the rebate or other cost reduction mechanism prior to submitting a claim form. The Board will provide the Supplier with a copy of the Verification Record (excluding any patient identifiable data) on reasonable request. If the Supplier requests additional information and substantiating evidence held by the Board to confirm a claim it will be at the Supplier’s cost. The Board will use all reasonable endeavours to minimise the cost of providing such information. This is subject to the Boards’ obligations in respect of patient confidentiality.

5. Any additional stock provided following a claim will be subject to the conditions of contract that applied to the original supply of the drug.

6. Scottish Medicines Consortium (SMC) approval of the drug is dependent on the operation of the PAS Agreement.

7. The representatives of the Board and the Supplier for the purposes of administering the PAS will be notified in writing by one party to the other from time to time.

8. All queries and day to day communications regarding the operation of the PAS will be dealt with by these representatives in the first instance. They will directly liaise for the purposes of monitoring and reviewing the operation and performance of the PAS Agreement.
9. The PAS Agreement is subject to the **Freedom of Information (Scotland) Act 2002**. The PAS Submission must detail any information which the Supplier regards as Confidential Information, disclosure of which could cause substantial commercial damage to the company. The Board is unable to release such information under a Freedom of Information request without the prior written consent of the Supplier. This restriction does not apply where:
   - The information becomes available in the public domain through other channels.
   - The Board is legally required to release the information.
   - The Board is required to release specific information to a regulatory or government authority.
   - The Board discloses such information in confidence in connection with the operation of the PAS.

The Board and the recipients of the Confidential Information shall ensure that this information remains confidential.

10. The Board and the Supplier will take all necessary steps to maintain full compliance with the **Data Protection Act 1998**. No patient identifiable information will be provided to the Supplier.

11. The Board can agree to **assign the PAS Agreement** to a third party when requested to do so by the Supplier.

12. The PAS Agreement will automatically devolve to the **statutory successors** of the Board. The Board will give the Supplier reasonable notice of such changes.

13. Where either the Board or the Supplier is affected by a major disruption which impacts on the operation of the PAS (**Force Majeure**) they will promptly notify the other party in writing. In such circumstances neither party shall be deemed to be in breach of the terms of the Agreement.

14. Any **notice** required to be given under the Standard Terms or PAS Agreement will be made in writing and addressed to the registered office or principal place of business of the other party. This address may be changed provided that notice of the change has been given.

15. If either the Board or the Supplier agrees to waive a breach of the PAS Agreement this does not set a precedent for any subsequent breach.

16. If any part of the PAS Agreement is found to be invalid the remainder of the Agreement is unaffected.

17. Where the Board and the Supplier are unable to reach agreement on any matter it shall be referred to their respective Chief Executives. They will consider how best to resolve the dispute or difference by undertaking interviews and obtaining expert advice where appropriate. Independent experts can be invited to report on the dispute where agreed by both parties.

18. The Standard Terms and PAS Agreement are governed by the laws of Scotland.
Appendix 3: Guidance for completion of the Patient Access Scheme (PAS) Submission Form (Section D or E of the Industry Application pack)

The company should complete the correct version of the PAS Submission Form (according to whether the scheme is a simple discount scheme or a complex scheme) in addition to the PAS Synopsis and Template. This PAS Submission Form will be provided to NHS Boards if the medicine is accepted for use or restricted use by SMC with a PAS.

1. General information
   The company should insert the following: the name of the applicant company, the name of the medicine (generic and brand names), date of PAS submission, and the patient population covered by the PAS.

2. Defined Terms

3. Constitution of PAS Agreement

4. Duration
   4.1 Insert the date that the PAS Agreement is anticipated to commence. For SMC applications this will be the date that advice is posted on the SMC website. SMC product assessment timelines can be found on the SMC website (www.scottishmedicines.org.uk).

   For NICE MTA applications, this will be the date that advice is posted on the Healthcare Improvement Scotland (HIS) website. If this date is not known at the time of submission, then state that the date is: ‘the date of publication of positive guidance by NICE with endorsement by Healthcare Improvement Scotland and applies to Drug Supplied by the Applicant after that date.’

   4.2 Insert when the PAS Agreement may be terminated. This will be at any time after a period of five years from the date that advice is posted on the SMC website. For NICE MTA applications this will be at any time after NICE completes any review of guidance. Also insert the number of months’ notice that will be provided by the company/Board to terminate the PAS Agreement. This should be based on the duration of treatment covered by the PAS to ensure that patients commencing treatment in accordance with the PAS Agreement will continue to receive the medicine under the terms of the PAS. For some schemes it may be necessary to describe any implications for patients who are receiving the medicine when the PAS is terminated. For example, the Applicant may agree to fulfil any outstanding rebate credits for any patient who has commenced treatment in accordance with the PAS Agreement prior to the date of termination.

5. Material Breach

6. Early Termination
   Insert an outline for the ongoing provision of medicine for patients already on treatment at the point of early termination following PAS withdrawal.

7. Scope of Agreement and Cost Reduction Mechanism
   Insert a description of the scheme to include the patient population covered and cost reduction mechanism in detail. Provide a comprehensive description of how the PAS will operate including how the product will be obtained (wholesaler or manufacturer) and how the NHS will be rebated. For complex schemes (financial or performance based) a flow chart should be attached separately
to illustrate the process, with funding flows clearly demonstrated. For performance based schemes, a reliable objective unambiguous clinical criterion for measurement of treatment benefits/outcomes should be specified. Consider: is the outcome routinely measured; how often is the outcome measured; cost of measurement; average duration of follow up; is training required. The company should identify equity or equality issues relating to the PAS, and how these have been addressed, bearing in mind current legislation and issues identified during the course of the appraisal.

8. **Claims Procedure**
   For Simple schemes a claims procedure is not applicable. For complex schemes, companies should provide a copy of claim forms, registration forms and other documentation that NHS staff should complete as part of the PAS, together with any guides for NHS staff and patients. If claims should be made by a Board within a specific timeframe, then this should be specified. Persons authorised to complete and sign the claim form will be specified in the PAS Approval Letter, which will be signed by the NHS Board and returned to the company.

9. **Verification Record**
   For Simple schemes verification data is not applicable. For complex schemes, companies should insert details of data that will need to be collected, explaining when this will be done and by whom (for example, the Board) and for how long (usually 6 years). Details of audit requirements or follow up should be included.

10. **Supplier Confidential Information**
    The company should detail any information the disclosure of which could cause substantial commercial prejudice to either party. No patient identifiable information should be requested from the Board.

11. **Supplier Representative and Signature**
    Provide details of the Applicant’s representative.

    The submission should be signed by director or company secretary or authorised signatory of applicant.
Appendix 4: Key Principles for Patient Access Schemes

All proposed schemes will be assessed in the context of an agreed set of key principles:

1. Patient Access Schemes (PAS) will be considered by NHS Scotland to facilitate access by patients in Scotland to medicines that are not, or might not in the first instance be, found to be cost-effective by the Scottish Medicines Consortium (SMC) or where a PAS has been accepted in the context of a National Institute for Health and Care Excellence (NICE) Multiple Technology Appraisal (MTA).

2. It is recognised that while such schemes can facilitate access to new medicines on cost-effective terms 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 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 such a scheme must be taken into account in the assessment process.

Any proposal for a patient access scheme must originate from the relevant pharmaceutical company that holds the UK marketing authorisation for the medicine under review and should reflect the following principles:

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

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

2.3 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 or NICE assessment arrangements and timelines as appropriate. Schemes submitted by pharmaceutical companies must be agreed with PASAG. SMC / NICE, as appropriate will assess the impact of any proposed scheme on the product’s cost-effectiveness.

2.4 The integrity of the existing health technology assessment process must be maintained i.e. SMC/NICE 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.

2.5 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.

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

2.7 Compliance must be assured with NHS Scotland probity, governance and legislative requirements including formal agreements between the NHS and the pharmaceutical company regarding respective responsibilities including burden of costs and protection of commercial-in-confidence information.
2.8 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.

2.9 Data obtained through the implementation of a PAS remains the property of NHS Scotland which retains the right to publish, subject to 2.7 and 2.8 above.

2.10 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.

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

3. Whilst Patient Access Schemes are intended to help secure access for NHS patients to medicines that might otherwise not have been deemed cost effective, it is important that arrangements for proposing and agreeing such schemes do not in turn jeopardise the timeliness of SMC or NICE advice (in the case of MTA’s endorsed by Healthcare Improvement Scotland). It is also important that the timing of discussions on schemes does not encourage ‘gaming’ of the appraisal system by any party (i.e. where either the company or health technology assessment organisation attempts to exploit the system to ensure the most desirable outcome from their own perspective).

4. Where a company wishes to propose a PAS for a new medicine, this may be done

   • with a submission for a medicine which has been assessed by SMC and ‘not recommended’ or ‘restricted’ advice has been issued for the product
   • for a product that has not yet been assessed by SMC, at the same time as the submission is made to SMC

   OR

   • In the context of a NICE MTA submission

5. There will be a requirement to review the experience with PAS in NHS Scotland. This will be undertaken on an ongoing basis.
Appendix 5: Unique Patient Access Scheme (PAS) Patient Number

Purpose

To advise NHS Boards in Scotland and pharmaceutical companies on the format and use of the Unique Patient Access Scheme (PAS) Patient Number.

Background

A Patient Access Scheme (PAS) is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. To receive a rebate, pharmaceutical companies may require NHS Boards to complete a registration form and/or claim form for eligible patients receiving treatment under the terms of a Complex PAS. In order to comply with Caldicott Guardian requirements, any PAS which requires patient identifiable data will not be accepted by PASAG.

Use of the Unique PAS Patient Number

Patients who receive treatment under the terms of a PAS where individual patient tracking is required to obtain a rebate are assigned a Unique PAS Patient Number by the Board to maintain patient confidentiality. 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. This may happen when a patient is initially treated in a tertiary centre but is then transferred to their Board of residence for continuing treatment.

Each NHS Board is responsible for maintaining a Verification Record for each PAS, to record and check the rebate or other cost reduction mechanism prior to submitting a claim form, and to confirm the validity of any claims. The information to be included in the Verification Record is detailed in the PAS Submission, and may consist of, for example, Unique PAS Patient Number and date of treatment. The Board will provide the pharmaceutical company with a copy of the Verification Record (excluding any patient identifiable data) on reasonable request, subject to the Boards’ obligations in respect of patient confidentiality.

The Unique PAS Patient Number should be used by Finance to track receipt of the rebate and ensure this is allocated to the correct budget where necessary.

Format of the Unique PAS Patient Number

To facilitate collection of data for audit purposes in the future, the Patient Access Scheme Assessment Group (PASAG) advise that a standardised format of the Unique PAS Patient Number should be used, which takes the form: PAS Number/Location code/Patient Number (Figure 1). The ‘location code’ is obtained from the Location Code Directory, maintained by Information Services Division (ISD) and General Register Office (Scotland) (GROS). This directory provides a code for each NHS Scotland location including hospitals. The code consists of five characters: an alpha-prefix for the NHS board; a three-digit serial number; an alpha-suffix for the type of location. For example, 3/N101H/1 would be the Unique PAS Patient Number for the first patient (number 1) treated with a medicine under the terms of a PAS (PAS Number 3) at Aberdeen Royal Infirmary, Grampian (N101H).

A list of location codes is available from the PASAG administrator on request (email: NSS.NP-PASAG@nhs.net).
Figure 1: Format of the Unique PAS Patient Number

The PAS Number is allocated to an accepted scheme by PASAG after SMC has reviewed the PAS medicine. The PAS Number is included in guidance notes sent to NHS Boards.

The location code relates to the NHS Board of treatment. It is taken from the Location Code Directory maintained by ISD and GROS.

The Patient Number is assigned by Boards to eligible patients receiving a medicine under the terms of a PAS.