NHS Scotland

Patient Access Scheme (PAS) Guidance

Contents

Appendices

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 can 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). 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).

1.3 For medicines that have already been accepted by SMC, if a different effective price has been offered to secure a national recommendation on use of the medicine in another home country, pharmaceutical companies can offer a PAS or amend an established NHS Scotland PAS to ensure equitable pricing across the UK.

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 compounder 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 is issued by the NHS (if the medicine is accepted for use by SMC on a routine or interim basis or if there is agreement to enter into the PAS for the purpose of ensuring equitable pricing arrangements across the UK). 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 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.

6 Submission of Proposed Patient Access Scheme For Consideration by SMC

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 or where a medicine holds interim advice, submission to SMC for re-assessment under the interim acceptance arrangements).

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 realised.

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 minimise 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 secretariat and PASAG Co-Chairs have delegated authority to approve simple PAS on behalf of NHS Scotland out with scheduled meetings but 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.

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 authorised 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 authorised 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: e-mail distribution of PAS Pricing at the point of SMC decision via the distribution list used as standard by National Procurement for confidential contract pricing information and accessible via CCM for Board personnel with standard access rights to confidential contract pricing information.
- Restricted email and CCM communication: Restricted e-mail distribution of PAS pricing at the point of SMC decision and pricing information available via CCM to persons with access-rights to PAS pricing information).
- Restricted e-mail distribution only: Restricted e-mail distribution only of PAS Pricing 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 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. 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.

9.8 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.

9.9 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 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 on the pricing arrangements to NHS Boards. A confidential register of available discounts will be distributed to NHS Boards on a monthly basis.

10 Rebate Reconcilation

10.1 To improve financial governance and reduce the administrative burden to the NHS and pharmaceutical companies in managing payment of rebates, where feasible, National Services

Scotland (NSS) receive and reconcile rebates with pharmaceutical companies on behalf of NHS Scotland and then transfer consolidated funds to Health Boards.

10.2 A summary of the primary care rebate reconciliation process can be found in Appendix 4. Note, VAT is not applicable to primary care rebates.

10.3 Where rebates relate to supplies made in the hospital setting (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. The 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).

11 Interim Acceptance

11.1 In August 2018, SMC are introducing an interim acceptance advice option for medicines with European Medicines Agency (EMA) conditional marketing authorisation.

11.2 At the point of re-assessment, where there is an existing PAS in effect for the medicine, a new PAS application pack with updated "PAS Submission" is required. If the medicine is accepted at the point of re-assessment, the updated PAS will come into effect with a minimum term of 5 years from the point of re-assessment.

11.3 A key concern of Health Boards is the financial/budgetary impact if the price were to increase after re-assessment once patients, potentially a significant number of patients, have been initiated on the medicine. Given this, in general, it is unlikely that at the point of re-assessment a pricing proposal that increases the cost of treatment for patients established on the medicine would be accepted by PASAG. Companies can discuss exceptional product specific circumstances directly with the PASAG Secretariat.

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

12 Ensuring Equitable Arrangements across the UK

12.1 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. Scotland is within scope of both the PPRS Agreement and the statutory pricing scheme.

12.2 The 2014 PPRS allows for the confidential sharing of net price across the home countries between the respective Health Departments and their bodies responsible for the assessment of medicines (PPRS 2014 Section 5.44).

12.3 Differences in the pricing of new medicines between the home countries can arise for a number of reasons, for example, SMC decisions may be published before NICE has completed an appraisal of the technology or before a PAS agreement for the NICE-assessment has been finalised.

12.4 For medicines that have already been accepted by SMC, if a different effective price has been offered to secure a national recommendation on use of the medicine in another home country, a pharmaceutical company can choose to offer a new PAS or propose an amendment to an established NHS Scotland PAS with the aim of ensuring that there are equitable pricing arrangements for new medicines across the home countries.

12.5 The option to propose/amend a PAS to deliver price parity, is limited to:

- Where the medicine has a positive recommendation from SMC in at least one indication; **and**
- Where the company has agreed a lower effective price to secure a national recommendation on use of the medicine in England, Wales or Northern Ireland. This would include pricing agreements offered in technology appraisals undertaken by the National Institute for Health and Care Excellence (NICE) (both Single Technology Appraisals and Multiple Technology Appraisals), the All Wales Medicines Strategy Group Health Technology Appraisal (HTA) process, the NHS England Clinical Priorities Advisory Group (CPAG) and pricing agreements linked to the NHS England budget impact threshold.

12.6 There are differences between the home countries in infrastructure and capacity to support complex PAS schemes; a complex PAS that is feasible in England may require adjustment to be feasible in the Scottish context. Where a complex PAS has been agreed in another home country, the PASAG Secretariat will seek to work with the company with the aim of identifying and agreeing an approach that will deliver equivalent benefit in Scotland, for example identify appropriate alternative data sources.

12.7 The company should notify the PASAG Secretariat directly (NSS.NP-PASAG@nhs.net) of the requested change using the standard PAS submission form (concise or full as appropriate). Please note on the form that the PAS proposal is linked to ensuring equitable arrangements across the home countries.

12.8 The start date of the new or revised PAS will be agreed between PASAG and the company. To ensure Scottish Health Boards are not financially disadvantaged, the preference is for any price changes to come into effect in Scotland at the same time as other home countries. There are a number of ways this can be achieved:

12.8.1 Proposing the change to PASAG at the same time as it is proposed to another home country – but contingent on the revised pricing coming into effect elsewhere.

12.8.2 Agreeing a retrospective credit or rebate to compensate for sales in Scotland in the time period between the revised price coming into effect in another home country and the new price coming into effect for sales in Scotland.

12.9 Where there is an established NHS Scotland PAS in place and a change in the effective price is agreed, there would be no change to the length of the PAS agreement.

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

12.11 Agreement of a new PAS or revision of an established PAS for the purpose of ensuring equitable arrangements across the UK, will not result in an amendment to the SMC advice for the medicine, for example if the NICE decision is narrower in scope than the SMC advice.

12.12 It is not possible for a company to propose/amend a PAS for the purpose of ensuring price parity where:

- The lower price has been offered in another home country but not considered in any national recommendations on use of the medicine, for example, a CMU Framework price that has not been taken into consideration in a NICE or NHSE CPAG assessment.
- The lower price has been offered as part of a Managed Access Scheme under the NHS England Cancer Drug Fund arrangements, on the basis that this is a short-term pricing agreement.

In both cases, it is possible for the company to offer equivalent pricing to NHS Scotland through alternative mechanisms, for example a Framework Agreement rather than a Patient Access Scheme. NHS Scotland uses the 'Negotiated Procedure without Prior Publication' to agree Framework Agreements for in-patent medicines and companies can request that the restricted PAS communication routes are used for communication with Boards (see section 9.5).

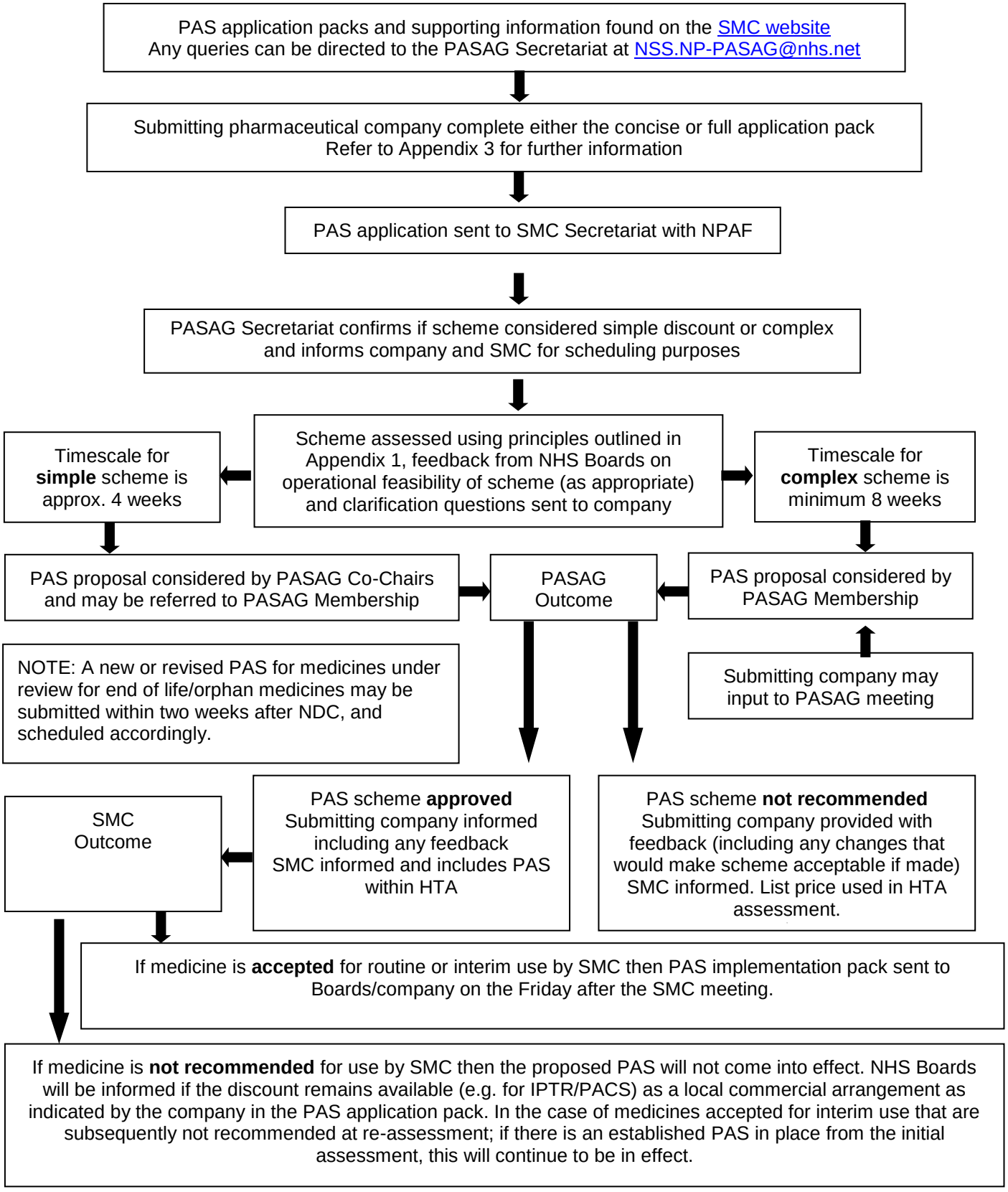
Appendix 1

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 authorisation.
2. It is recognised 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 prioritise schemes that deliver most benefit to patients, for example, for medicines that address a previously unmet need. The full costs to NHS Scotland of operating must be taken into account in the assessment process.
3. Through partnership between the NHS and pharmaceutical industry, patients should benefit from any such scheme through improved access to new treatments on an equitable basis across Scotland.
4. 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 Data Protection Legislation.
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 jeopardise 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 organisation 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 Process to Propose a PAS for consideration by SMC



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 compounder 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.

- **PAS start date** (page 1): The effective date for a new PAS submitted linked to an SMC assessment is the date that SMC issue its advice in confidence to the pharmaceutical company and NHS Scotland based on SMC assessment timelines – this is the Friday following the SMC meeting (one month prior to publication on the SMC website). There is advice on the SMC website on SMC's standard assessment timeline that can be used by companies to estimate the PAS start date. Should the assessment scheduling change (e.g. 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 (see section 11), the company and the PASAG Secretariat will agree the start date.

- 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 (e.g. arranging retrospective credits) and to ensure any delays are communicated to NHS Boards.

- **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 (i.e. as stated in the New Product Assessment Form). If the PAS is being proposed outside of an SMC submission, for example to ensure equitable pricing arrangements across the home countries (see section 11 of this guidance), please note here that the PAS is being proposed linked to ensuring equitable arrangements across the home countries.

- **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. Detailed to be provided include:
    - Where hospitals should order from e.g. direct or via third party distributor(s).
    - Whether a manufacturer-commissioned homecare service is being offered and whether there are any barriers to the NHS commissioning its own homecare service. If homecare is to be commissioned, there is a separate governance process to review proposals from companies for manufacturer-commissioned homecare via the 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.
    - Whether a supply route to primary care (community pharmacies and dispensing doctors) is available or planned.
    - Whether there are any barriers to the NHS commissioning a third party compounder to prepare patient ready products (where relevant).

- **Supplier representative** (Section 12 of PAS submission): The supplier representative can be different from the signatory. 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.

- **Version control:** 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 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. 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

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**

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

Dispensing Quarter	Month that Prescribing Data Available/NSS produce request for payment for company	Estimate for NSS quarterly reconciliation
1st January – 31st March	July	End August
1st April – 30th June	October	End November
1st July – 30th September	January	End February
1st October – 31st December	April	End May

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 offenders 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

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 hcis.smcsecretariat@nhs.net

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

   Changes were made to the NHS Scotland PAS arrangements in May 2018 to enable companies to propose a PAS or amend the level of discount for an implemented PAS outside of an SMC assessment in certain defined circumstances to ensure equitable pricing arrangements for new medicines across the UK. Detailed information can be found in section 11 of this guidance.

   Post initial market entry, a company may want to reduce the price of their product, for example, to compete for market share with therapeutic alternatives. Supplementary to an established PAS, companies can offer discounts to NHS Scotland through a Framework Agreement. Where a PAS is in place, this is sometimes referred to as a 'top-up' discount. NHS Scotland uses the 'Negotiated Procedure without Prior Publication' approach to agree Framework Agreements for in-patent medicines.

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

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

   To support Health Board Area Drug and Therapeutics Committees (ADTC), in considering the outputs of NICE MTAs, at the point NICE issues their 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.

   Section 11 of this guidance details the arrangements for offering equivalent pricing in Scotland. Companies can contact PASAG at the same time as proposing a scheme to PASLU to discuss the implementation of equivalent arrangements in Scotland. If PASAG is not already in contact with the company by the time NICE communicate their advice, PASAG will get in contact. 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 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 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.

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

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

If there is an unavoidable delay in updating pricing in the supply chain, companies should contact the PASAG secretariat to discuss how this is best managed (e.g. 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.