



WALES PATIENT ACCESS SCHEME FREQUENTLY ASKED QUESTIONS

These questions and answers should be read in conjunction with the following documents:

- [AWMSG appraisal principles and process flowchart](#)
- [AWMSG appraisal process flow diagram and timeline](#)
- [AWMSG process for industry engagement](#)
- [Agreement between the Association of the British Pharmaceutical Industry \(ABPI\) and the All Wales Therapeutics and Toxicology Centre \(AWTTC\) on guidelines for the release of company data into the public domain during an appraisal](#)

This document aims to provide answers to the following frequently asked questions relating to Wales Patient Access Schemes (WPAS):

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Clarification of any aspect of the WPAS may be sought from:
Ruth Lang, Head of Liaison & Administration, All Wales Therapeutics and Toxicology Centre (AWTTC) at awttc@wales.nhs.uk Tel: 029 218 26900.

GENERAL INFORMATION

What is a Patient Access Scheme?

A Patient Access Scheme (PAS) is an arrangement which may be used on an exceptional basis for the acquisition of a medicine for the NHS in Wales and England. A PAS proposes a discount, rebate or other variation from the list price of a medicine that may be linked to the number, type or response of patients, and/or the collection of new evidence (outcomes). These schemes should aim to improve the cost effectiveness of a medicine and therefore allow the All Wales Medicine Strategy Group (AWMSG) to recommend treatments that it might otherwise have found not to be cost effective.

Wales Patient Access Schemes (WPAS) are proposed by a pharmaceutical company and agreed with the Welsh Government, with input from the Patient Access Scheme Wales Group (PASWG) within the AWMSG Health Technology Assessment (HTA) process.

A pilot for considering PAS within NHS Wales was undertaken and completed in November 2011.

How do simple WPAS and complex WPAS differ?

To qualify as a simple WPAS the applicant must offer a discount or price reduction:

- from the list price, applied for all supplies of the product applicable to all current and future indications (within the duration of the WPAS);
- which applies to the original invoice, or the indicated price for the product;
- which requires no additional administration to receive the price offered; 'additional' means over and above the administration required for procuring the medicine without a PAS (a single contract is allowed);
- which will remain in place until or after AWMSG review (3 years).

If any of the above criteria are not met, then the scheme would be considered complex.

Any proposed scheme that would operate in the primary care setting would be considered complex and should be submitted using the complex WPAS submission form. Schemes involving homecare may be considered complex or simple, depending upon the proposed operation of the scheme.

The details of a simple scheme would routinely remain commercial in confidence. The details of a complex scheme would not routinely remain commercial in confidence.

SUBMITTING A WPAS

What information is required for a WPAS submission?

As part of a WPAS submission, the manufacturer will need to specify:

- the purpose and type of proposed scheme, based on the Pharmaceutical Price Regulation Scheme classification. If the scheme is outcome-based, the manufacturer will need to provide details regarding the collection of relevant outcome measures;
- the patient population, and any subgroups, to which the scheme applies;
- selection criteria for subgroupings;
- additional tests and monitoring associated with the proposed scheme;
- how they have addressed any equity or equality issues related to the scheme;
- how they have addressed patient confidentiality and data protection;
- if commercial implications have been considered;
- the duration of the scheme and circumstances for termination;

- the impact of the scheme on the choice of other available treatments;
- the entire administrative process and expected net cost (including additional treatment-related costs) of the scheme to NHS Wales;
- the grounds for their proposed scheme format should other simpler schemes for a similar technology be available. Schemes need to be administratively simple;
- if the technology being evaluated has other indications not covered by the scheme;
- the proportion of patients expected to meet the scheme inclusion criteria;
- the clinical benefits of the scheme;
- a financial and organisational flow diagram showing how the scheme will operate;
- operational details of the scheme in different settings (e.g. homecare);
- if relevant to the scheme, the process of claiming rebates;
- whether the scheme has been previously assessed by PASWG or the Patient Access Scheme Liaison Unit.

Manufacturers will need to supply all relevant documentation relating to the implementation of a scheme, for example:

- Scheme agreement forms
- Patient registration forms
- Pharmacy claim forms/rebate forms
- Guides for pharmacists and physicians
- Patient information documents
- Declaration
- Other relevant information.

For outcome-based schemes, the manufacturer will need to provide details regarding the assessment, collection and costs of any new evidence that supports the scheme. These details may include:

- the design and patient population of the new study;
- outcomes to be collected and expected duration of data collection;
- an outline of the statistical analyses required and the expected results;
- planning of evidence synthesis or data pooling, and expected results from this type of analysis.

What other criteria should a WPAS meet in order to maximise its chances of being approved?

Schemes should be clinically and financially robust, plausible, appropriate and auditable. Any scheme should be operationally manageable for NHS Wales without unduly complex monitoring, disproportionate additional costs or bureaucracy. Any burden to NHS Wales should be proportionate to the benefits of the scheme for the NHS and patients. The exact duration of any agreement and the circumstances in which it might be terminated should be clear to all parties from the outset. Schemes should be consistent with existing financial flows in NHS Wales.

What if the Form A meets the criteria for a limited submission and the manufacturer has indicated in Form A that they wish to submit a WPAS?

A simple scheme can be submitted prior to the Form C. A complex scheme may require a full submission i.e. Form B.

Where and when should a WPAS be submitted?

A WPAS proposal should be submitted electronically by the manufacturer to the All Wales Therapeutics and Toxicology Centre (AWTTC) at awttc@wales.nhs.uk and should be processed **prior** to the submission of Form B/C.

What if a PAS submission has already been made to Department of Health?

A PAS that has been previously approved by the Department of Health and is associated with a positive technology appraisal recommendation will be accepted as part of the HTA process in Wales if the medicine is subsequently submitted to AWMSG for appraisal for another indication. Normally this would only apply to simple discount schemes where the PAS is already included within a National Institute for Health and Care Excellence (NICE) Final Appraisal Determination. Verification of the details of the scheme would be required prior to the commencement of the appraisal by AWMSG and before production of the AWMSG Secretariat Assessment Report.

What should primary care applicable WPAS submissions take into account?

Any proposed scheme that may operate in the primary care setting would be considered complex and should be submitted using the complex WPAS submission form.

If a proposed WPAS is applicable to primary care, the mechanism by which the scheme operates may involve a rebate based on medicines usage. Consideration should be given to the data available to monitor medicines usage, particularly with respect to pack sizes and number of tablets issued. It may not always be possible to reconcile issues of complete packs of tablets; therefore, a WPAS that is based upon a fixed price for a pack of tablets may not be auditable. In this instance, a scheme which uses a fixed discount that can be applied to the total cost of the medicine issued may be more appropriate.

PROCESSING A WPAS

How long should the WPAS process take?

The time required for processing a WPAS may vary depending on the complexity of the submitted scheme. We anticipate this will take approximately 4 weeks for a simple scheme and 12 weeks for a complex scheme.

What is the process that PASWG follows when advising whether implementation of a proposed WPAS is feasible within NHS Wales?

WPAS proposals are referred by the Welsh Government to PASWG, who provide advice on the feasibility of implementing the WPAS in NHS Wales. PASWG will consider whether the potential benefits of the scheme (such as the extent to which the scheme enables NHS Wales to address a currently unmet clinical need) outweigh the potential burdens of the scheme.

What are the confidentiality arrangements for Ethical Medicines Industry Group companies?

The principles in the confidentiality agreement used by the Association of the British Pharmaceutical Industry Wales would also apply to the Ethical Medicines Industry Group.

Once the outcome of the submission has been decided, what is the next stage?

AWTTC will inform the manufacturer of the outcome, i.e. whether or not the WPAS is accepted for use within NHS Wales. Depending on the outcome of the PASWG assessment, the manufacturer may subsequently:

- incorporate the WPAS into their Form B/C submission;
- resubmit a revised WPAS to AWTTC;
- decide not to progress to appraisal, which is likely to mean that the medicine will not be funded for routine use within NHS Wales.

APPRAISAL PROCESS SUBSEQUENT TO WPAS CONSIDERATION

If a submission has an associated confidential PAS, will the appraisal be held in private?

Yes. Where a submission includes a confidential PAS the appraisal will be conducted in private. AWMSG's recommendation will be subsequently announced when the meeting recommences in the public domain. If the PAS is non-confidential the appraisal will be held in public.

What if the comparator medicine has an associated simple PAS?

In order to maintain confidentiality AWMSG will not share the details of a simple PAS for a comparator medicine with the company making an application to AWMSG for appraisal of a new medicine. To enable AWMSG to explore the impact of using the actual cost of the comparator in the analysis, the company applying for appraisal of a new medicine should model the cost-effectiveness of their medicine using a range of potential discounts for the comparator.

POST APPRAISAL PROCESS

How is NHS Wales notified of the existence of a WPAS?

Health boards and the Chair of the AWDCC will be informed by Welsh Government of the existence of the WPAS associated with a recommended medicine. Health boards will be advised to contact the manufacturer directly for procurement arrangements. To ensure consistency and to ensure that the WPAS is applied, health boards should contact the AWDCC Chair as a central point for confirmation of the agreed scheme, if required.

How is NHS Wales notified of the existence of a Department of Health-approved PAS?

Health boards and the Chair of the All Wales Drugs Contracting Committee will be informed by Welsh Government of the existence of a confidential PAS associated with a NICE-recommended medicine. Further information can be found at:

www.awmsg.org/awmsgonline/docs/awmsg/appraisaldocs/inforandforms/Department%20of%20Health%20Patient%20Access%20Scheme%20Notification%20within%20NHS%20Wales.pdf.