

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



Wales Patient Access Scheme: Process Guidance

July 2012

(Updated June 2019)

This guidance document has been prepared by the Patient Access Scheme Wales Group, with support from the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
AWDCC	All Wales Drug Contracting Committee
AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics and Toxicology Centre
FAR	Final Appraisal Report
HTA	Health Technology Assessment
NICE	National Institute for Health and Care Excellence
PAS	Patient Access Scheme
PASLU	Patient Access Scheme Liaison Unit
PASWG	Patient Access Scheme Wales Group
PPRS	Pharmaceutical Price Regulation Scheme
WPAS	Wales Patient Access Scheme

ACKNOWLEDGEMENTS

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1.0 INTRODUCTION

1.1 Background

A proposal to establish a Patient Access Scheme Wales Group (PASWG) was supported by the All Wales Medicines Strategy Group (AWMSG) at their meeting on 13 July 2011. The remit of PASWG is to consider the feasibility, workability and acceptability of Patient Access Schemes (PAS) within NHS Wales and to provide advice to Welsh Government. A pilot for considering PAS within NHS Wales was subsequently undertaken and completed in November 2011.

The All Wales Therapeutics and Toxicology Centre (AWTTC) worked with the Association of the British Pharmaceutical Industry (ABPI) Wales in developing a process for considering Wales Patient Access Schemes (WPAS) based on the key principles described in the 2009 Pharmaceutical Price Regulation Scheme (PPRS)¹ and updated in the 2014 PPRS².

It should be noted that the National Institute for Health and Care Excellence (NICE) Patient Access Scheme Liaison Unit (PASLU) also uses the principles outlined in the PPRS. AWTTC acknowledges the support of PASLU in developing the pilot within NHS Wales. Following consultation, the terminology for a PAS within Wales has been agreed as *Wales Patient Access Scheme* or *WPAS*.

1.2 Process

This document describes the process, including expected timescales, that PASWG follows when advising whether implementation of a proposed WPAS is feasible within NHS Wales. Manufacturers (or sponsors of the technology) need to complete the “WPAS submission form”, which requests specific information that PASWG needs in order to provide this advice. WPAS proposals are referred by the Welsh Government to PASWG, which provides advice on the feasibility of implementing the WPAS in NHS Wales.

The implementation of a WPAS aims to improve the cost-effectiveness of a certain medicine, which, subject to a positive Health Technology Assessment (HTA), allows AWMSG to recommend the use of a new medicine within NHS Wales that may not have been considered cost-effective without such a scheme.

Key principles for the implementation of a WPAS

The key principles considered by PASWG for the implementation of a WPAS are based on those used by PASLU at NICE, which are outlined in the PPRS. These provisions have been revised in line with the existing appraisal process in Wales and the PPRS² 2014 agreement:

- Arrangements must respect the role of AWMSG in providing Welsh Government and NHS Wales with an independent assessment and appraisal of the evidence on a technology.
- A WPAS should be submitted by manufacturers to AWTTC prior to submission of a Form B or C. AWTTC will record receipt and pass the details of the scheme to Welsh Government who will forward to PASWG.
- The full costs to NHS Wales of any such arrangement should be included in the costs submitted for consideration.
- 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.

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- It is important that any cumulative administrative burden of such schemes remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for the Welsh Government to take this issue into account when considering the viability of individual schemes.
- Schemes should be consistent with existing financial flows in NHS Wales.
- NHS Wales must be consulted on schemes by the applicant company, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines e.g. in relation to patient numbers, or the monitoring and recording of a patient's condition over and above that for the normal management of a patient.

2.0 MEMBERSHIP OF PASWG

Membership of PASWG will comprise experts from clinical, pharmacy, NHS finance, NHS contracting/procurement, lay and pharmaceutical industry backgrounds. All PASWG members:

- must agree to be bound by the terms and conditions of a signed confidentiality agreement;
- must agree to their name and affiliation appearing in PASWG advice;
- should have knowledge and/or experience relevant to the assessment of PAS;
- must be familiar with the AWMSG appraisal process;
- must declare any conflicts of interest.

PASWG will consist of:

- Chair/deputy
- Chief pharmacist/deputy
- Medical director/deputy
- Senior finance manager/deputy
- Representative of AWTTTC
- Representative of the All Wales Drug Contracting Committee (AWDCC)/deputy
- Representative of ABPI Wales/deputy
- Representative of PASLU
- Lay member

PASWG reserves the right to invite a clinical specialist or specialist pharmacist to attend each meeting in a non-voting capacity to set the clinical context.

3.0 PROCESS FOR CONSIDERATION OF A WPAS

The process outlined below has been developed following discussion with PASLU, the AWMSG Steering Committee, the Therapeutic Development Assessment Partnership Group and AWMSG, and was informed by the pilot conducted in 2011.

It should be noted that the time required for processing a WPAS may vary depending on the complexity of the submitted scheme (the estimated timelines for assessment of simple and complex schemes are shown in Figures 1 and 2).

A PAS that has been previously approved by the Department of Health will be accepted as part of the HTA process in Wales if the medicine is subsequently submitted to AWMSG for appraisal for another indication. This only includes simple discount schemes where the PAS is already included within a 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.

Submitting the WPAS

1. Appendix 1 provides a list of the information required from the manufacturer within their submission. The manufacturer must submit a WPAS proposal using the PASWG submission form (see Appendices 2 and 3), which is based on the PASLU template and PPRS criteria.
2. Manufacturers should indicate on Form A whether they wish to submit a simple or complex WPAS. If a medicine meets the criteria for a limited submission a simple WPAS should be submitted ahead of Form C. A complex WPAS would normally require a full HTA submission and should be made prior to the submission of Form B. A WPAS proposal should be submitted electronically by the manufacturer to AWTTTC (awttc@wales.nhs.uk).
3. In the event that the appraisal process is delayed longer than three months post marketing authorisation and pending consideration of a WPAS, a Delayed Appraisal Statement will be issued via the AWMSG website (see Appendix 4). This will confirm that the holder of the marketing authorisation has submitted a WPAS and notes that the process of appraisal for [generic name (Trade name)] for the treatment of [abbreviated indication] has been delayed until further notice pending consideration of the feasibility of the WPAS scheme in NHS Wales.
4. A simple WPAS proposal should apply to all licensed indications of the product under consideration. A proposed complex or outcome-based WPAS proposal may be specific to a single indication (see points 5 and 6 below).
5. It is NHS Wales policy to offer patients the opportunity to receive treatment closer to their homes. This includes the ability to collect medication from community pharmacies where it is considered safe and practical to do so. Therefore, all applicants should consider whether it is reasonable to include details as to how the WPAS may work in primary care.
6. Any WPAS that applies to primary care should be submitted as a complex scheme.
7. According to process timelines, all documentation should be received from the manufacturer eight weeks before the PASWG meeting (see Figures 1 and 2 for estimated timelines).
8. For time-limited WPAS proposals, with a fixed expiry date, arrangements post-termination will be taken into account.

Processing the WPAS

9. AWTTTC will review the WPAS proposal and provide a dossier including all relevant information (manufacturer's submission and clarification requests/responses) to the PASWG Chair. Following review by PASWG, AWTTTC will forward the submission dossier to Welsh Government for consideration.
10. A request for further clarification or evidence, if necessary, will be forwarded to the manufacturer within ten working days of receiving the proposal, and the manufacturer will have a maximum of five working days to respond (see Figures 1 and 2 for estimated timelines).
11. AWTTTC will be the main contact for the manufacturer submitting the WPAS.
12. All information will be handled in accordance with the principles and requirements of legal frameworks such as the Data Protection Act 1998 and the Freedom of

Information Act 2000. WPAS details will be treated as confidential in nature, and both AWMSG and AW TTC understand that manufacturers may suffer commercial and other harm if information relating to a WPAS were to be made publicly available. Therefore, if the information referred to herein is subject to a Freedom of Information Act Request (if the requestor is defined as a Public Authority in Part 1 Section 3(1) of the Freedom of Information Act 2000) or other request to share the data, then appropriate measures will be undertaken to engage and consult with such persons in order to determine whether or not an exemption applies to the information requested, or in order to reach a view on whether the obligations in Section 1 of the Act arise in relation to that information. All parties involved in the WPAS process will be subject to a confidentiality agreement.

13. Any documentation provided to PASWG in support of a scheme must be in line with copyright legislation. The manufacturer must ensure that they have copyright clearance if a submission contains full journal articles. Copyright-controlled material may not be provided via the internet. Journal articles in electronic format will only be accepted if they are submitted on a CD-ROM. Journal articles will be passed on to PASWG members in the format they are received. The manufacturer is required to sign a statement declaring that all relevant information in support of a proposed scheme has been submitted to PASWG.
14. The remit of PASWG will be to consider the WPAS dossier provided by AW TTC (as the PASWG secretariat) and to formulate advice for the Welsh Government regarding the feasibility and implementation of a proposed scheme.
15. The WPAS dossier will include the manufacturer's submission and, if relevant, clarification requests and responses.

PASWG meeting

16. A PASWG meeting may not be required if, in the opinion of the Chair, the proposal can be considered as a simple discount scheme. Under these circumstances, the scheme may be considered by the PASWG Chair.
17. The manufacturer will be given the opportunity to be available, in person or over the telephone, at the PASWG meeting.
18. The PASWG meeting is held in private and all information and discussions are considered "commercial in confidence". PASWG decisions will normally be made based on a majority vote, and voting details will be noted in the meeting minutes.
19. The decision of PASWG will be relayed by the Chair to Welsh Government.
20. Welsh Government will direct AW TTC on the use of a proposed WPAS after considering PASWG advice. AW TTC will inform the manufacturer of this decision.

Appraisal process subsequent to WPAS consideration

21. Depending on the outcome of the PASWG assessment, the manufacturer may subsequently:
 - incorporate the WPAS into their appraisal submission;
 - resubmit a revised WPAS to AWTTTC;
 - decide not to progress to appraisal, which is likely to mean that the medicine will not be funded for routine use within NHS Wales;
 - decide to progress to appraisal without incorporating the WPAS into their appraisal submission.
22. The recommendation of the New Medicines Group to AWMSG in relation to cost-effectiveness of the proposed WPAS will be captured in the Preliminary Appraisal Recommendation.
23. Appraisal by AWMSG will continue to be held in private in the short term until there is confidence that sensitive information relating to such schemes will not be disclosed at the public appraisal meeting.

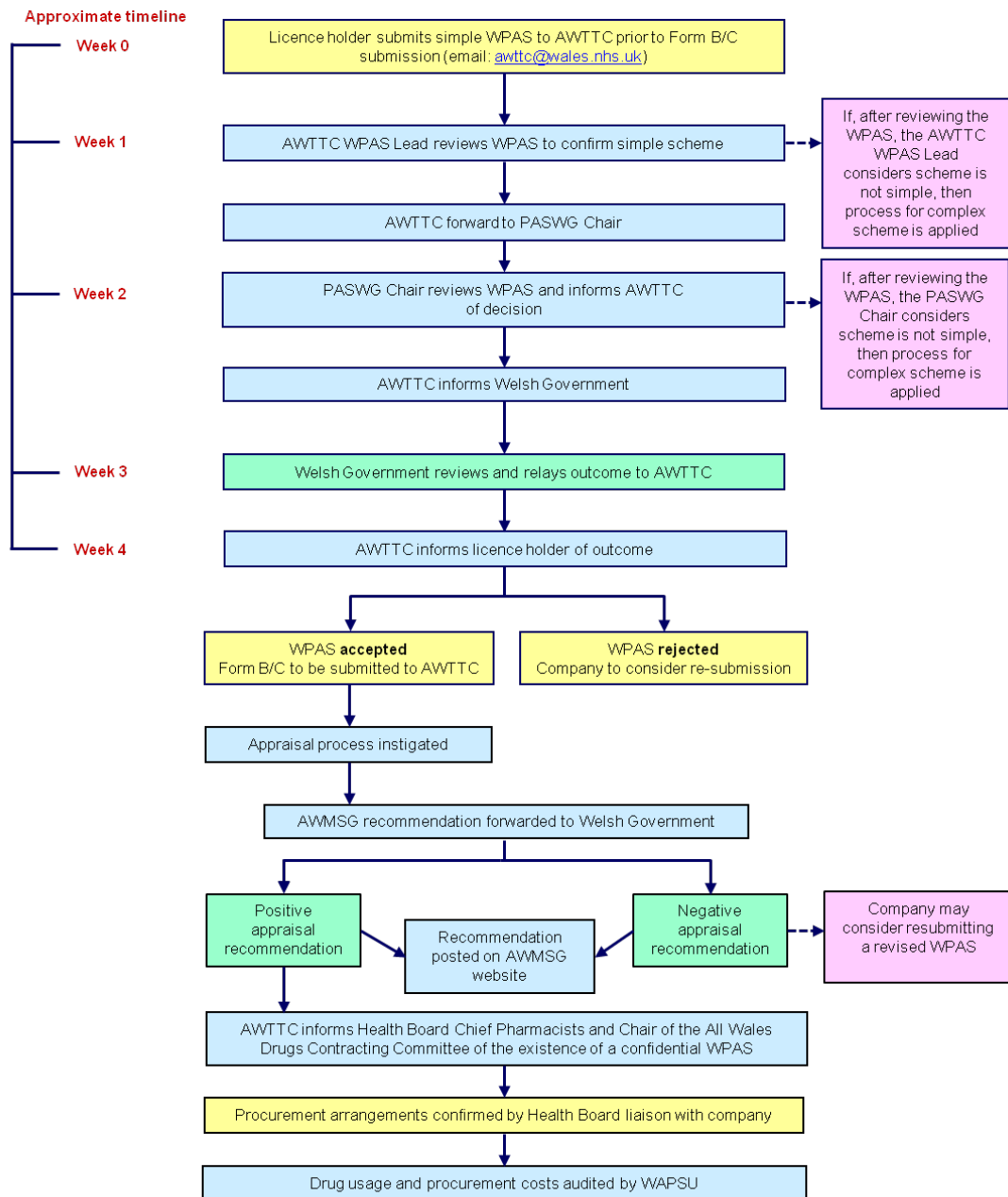
Post appraisal process

24. Where AWMSG has recommended that, based on the existence of an approved PAS, a medicine should be available within NHS Wales, the Final Appraisal Recommendation (FAR) will disclose the existence of a WPAS. The inclusion of WPAS details in any publicly available document will be subject to the extent of confidentiality requested by the manufacturer.
25. Health boards and the Chair of the AWDCC will be informed by AWTTTC 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.
26. For a simple WPAS, if a company wishes to amend the level of discount applicable to an operational WPAS, they must put a request in writing to the PASWG secretariat (awttc@wales.nhs.uk), which Welsh Government will consider.
27. AWMSG advice, with or without a WPAS, will be superseded by that of a NICE recommendation, should they subsequently issue final advice for the same technology.
28. AWMSG FARs will be reviewed three years after publication. At this stage, any WPAS associated with a recommendation will also be subject to review.

Figure 1. Simple PAS assessment process for Wales



PROCESS FOR SUBMITTING A SIMPLE WALES PATIENT ACCESS SCHEME

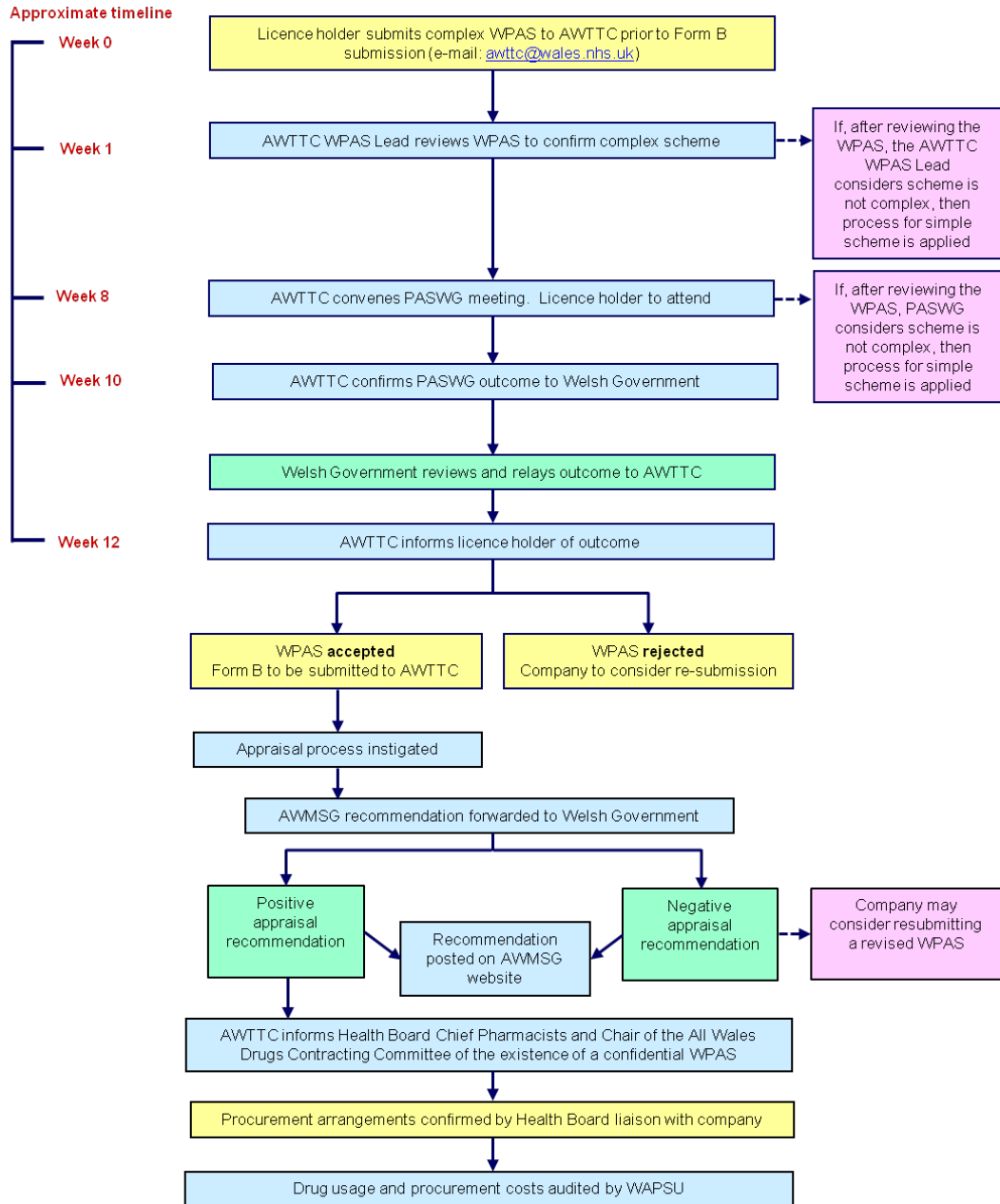


July 2016

Figure 2. Complex PAS assessment process for Wales



PROCESS FOR SUBMITTING A COMPLEX WALES PATIENT ACCESS SCHEME



REFERENCES

- 1 Department of Health, Association of the British Pharmaceutical Industry. The Pharmaceutical Price Regulation Scheme 2009. 2008. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf. Accessed Apr 2014.
- 2 Department of Health, Association of the British Pharmaceutical Industry. Pharmaceutical Price Regulation Scheme 2014. 2013. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf. Accessed Apr 2014.

APPENDIX 1. INFORMATION REQUIRED FOR A WALES PATIENT ACCESS SCHEME SUBMISSION

As part of a Wales Patient Access Scheme (WPAS) submission, the manufacturer will need to specify:

- the purpose and type of proposed scheme, based on Pharmaceutical Price Regulation Scheme classification;
- for simple schemes: whether the discount will be variable to maintain a constant purchase price over time (if the list price fluctuates; termed “fixed purchase price scheme”), or whether the discount will be fixed and the WPAS price will fluctuate with variations in list price. Details of the list price and level of discount should be included;
- for outcome-based schemes, the manufacturer will need to provide details regarding the collection of relevant outcome details;
- 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;
- if the technology has other indications not covered by the scheme;
- the proportion of patients expected to meet the scheme inclusion criteria and the anticipated number of patients that will be treated during years 1, 2 and 3 post-AWMSG appraisal (assuming a positive recommendation);
- the clinical benefits of the scheme;
- a financial and organisational flow diagram showing operation of the scheme;
- operational details of the scheme in different settings (e.g. homecare, primary care);
- if relevant to the scheme, the process of claiming rebates;
- whether the scheme has been previously assessed by the Patient Access Scheme Wales Group or the Patient Access Scheme Liaison Unit.

Manufacturers will need to supply all relevant documentation relating to the implementation of a scheme, e.g.:

- 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.

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Submission Form for a Simple Wales Patient Access Scheme

PATIENT ACCESS SCHEME WALES GROUP

Revised June 2019

1.0 INTRODUCTION

The 2009 Pharmaceutical Price Regulation Scheme (PPRS)¹ was a non-contractual scheme between the Department of Health and the Association of the British Pharmaceutical Industry. The purpose of the 2009 PPRS was to ensure that safe and cost-effective medicines are available on reasonable terms to the NHS in Wales and England. One of the features of the 2009 PPRS was the improvement of patient access to medicines at prices that better reflect their value, through Patient Access Schemes (PAS). The 2014 PPRS² became effective from January 2014, and included updated guidance on the use of PAS in the NHS.

A PAS is an arrangement that 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 Medicines Strategy Group (AWMSG) to recommend treatments that it might otherwise have found not to be cost-effective. More information on the framework for PAS is provided in the 2014 PPRS².

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.

2.0 INSTRUCTIONS FOR MANUFACTURERS AND SPONSORS

This document is the **simple WPAS** submission form for PASWG, which is based on the National Institute for Health and Care Excellence (NICE) Patient Access Scheme Liaison Unit (PASLU) proposal template. This form should be read in conjunction with the 'Wales Patient Access Scheme: Process Guidance' document. If manufacturers and sponsors wish PASWG to consider a scheme, they should use this form to submit information (evidence) for assessing the feasibility of implementing the scheme in Wales. All schemes involving primary care will be considered complex. WPAS proposals should be submitted to the All Wales Therapeutics and Toxicology Centre (AWTTC) at awttc@wales.nhs.uk. Receipt of your form will be acknowledged within one working day.

The submission form contains the information PASWG requires to assess the proposed WPAS using the principles set out in the 2014 PPRS (see Appendix A), and explains the way in which information should be presented. Manufacturers and sponsors are requested to include all information that is necessary to assess the feasibility of implementing a scheme, including evidence not directly related to the PPRS principles. If applicants are unable to follow this format, they must state the reasons clearly. Applicants should insert 'N/A' against sections that they do not consider relevant to the proposed scheme, and provide justification and/or reasons for this response.

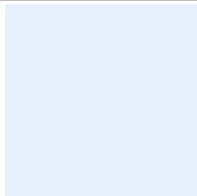
The evidence provided in a proposal should only focus on the NHS in Wales. PASWG will consider the proposed scheme and produce final advice to the Welsh Government on the feasibility of implementing the scheme in NHS Wales. The incorporation of each scheme in the AWMSG HTA process is subject to approval from the Welsh Government.

For information regarding confidentiality, and how AWMSG will handle information relating to a WPAS proposal, please see the document 'Wales Patient Access Scheme: Process Guidance'.

2.1 Instructions for completing the form

This document has been protected, which means that only designated fields can be edited. This can also affect some text formatting and reference management capabilities. For this reason, we recommend that you complete any sections requiring specific formatting or references in a separate Word document and paste the text into the fields when finalised. Reference lists can be attached as a separate document if necessary. If you experience any difficulties in filling in the form, please do not hesitate to contact awttc@wales.nhs.uk.

To qualify as a simple WPAS the applicant must answer YES to all of the following questions and sign below.

The proposed WPAS offers a discount or price reduction:		Insert YES here
1.	From the list price, applied for all supplies of the product applicable to all current and future indications (within the duration of the WPAS).	Please select.
2.	Which applies to the original invoice, or the indicated price for the product.	Please select.
3.	Which requires no additional administration to receive the price offered; 'additional' means over and above the administration required for procuring the drug without a PAS (a single simple letter is allowed).	Please select.
4.	Which will remain in place until or after AWMSG appraisal review (3 years).	Please select.
Signed*:		
		
Name:	Click here to enter text.	
Position:	Click here to enter text.	
On behalf of:	Click here to enter text.	
Date:	Click here to enter a date.	

*Please include a scanned signature.

3.0 DETAILS OF THE WPAS

3.1 Please give full contact details for the people responsible for the proposed scheme. Please state if the applicant is the manufacturer or sponsor. Where the applicant is the sponsor, please state the relationship with the manufacturer (e.g. UK distributor).

Applicant details:	
Organisation name:	Click here to enter text.
Address line 1:	Click here to enter text.
Address line 2:	Click here to enter text.
Address line 3:	Click here to enter text.
Address line 4:	Click here to enter text.
Address line 5:	Click here to enter text.
Postcode:	Click here to enter text.
Manufacturer or sponsor?	Please select.
Sponsor's relationship to manufacturer including details of the manufacturer:	Click here to enter text.
Primary contact – the individual responsible for the application	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

Operational contact – the individual who will be responsible for the operation of the WPAS	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

Other contact	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

3.2 Please give the name of the technology and the indication for which the proposed scheme applies.

Medicine name*	Click here to enter text.
Indication for which the proposed scheme applies:	Click here to enter text.
*Please detail all names that apply and include all trade names.	

3.3 Will the technology be used in any circumstances where the WPAS would not apply? If so, describe how the NHS and the company would identify the specific patient populations treated.

Click here to enter text.

3.4 Are any additional licensed indications anticipated in the next 3 years? If yes, what are the expected dates of the licence extensions?

Click here to enter text.

3.5 Does the scheme require any additional forms, registration or other administrative process to claim the discount? If so, a complex scheme submission form may be required.

Click here to enter text.

3.6 Is the technology with the proposed WPAS anticipated to be dispensed in primary, and/or secondary care? The NHS in Wales is keen to see care being delivered closer to patients' homes. Where possible, WPAS proposals should allow for medicines to be dispensed in primary care. A complex scheme submission will be required if primary care dispensing is anticipated.

Click here to enter text.

3.7 Will the technology be available through homecare arrangements? If yes, will the technology be available through homecare only? Will the health board or trust be able to select the homecare provider or will this be specified by the company? Who will fund the homecare delivery?

Click here to enter text.

3.8 What is the current list price of the technology excluding VAT?

Click here to enter text.

4.0 OPERATION OF THE SCHEME

Operational manageability: schemes should be clinically robust, clinically plausible, appropriate and auditable.

4.1 Please describe the type of scheme. State the proposed WPAS price or proposed discount. State whether the discount will be variable to maintain a constant purchase price over time (if the list price fluctuates), or whether the discount will be fixed, and the WPAS price will fluctuate with variations in the list price.

Click here to enter text.

4.2 Please provide a flow diagram that clearly shows how the scheme will operate. All processes from ordering to invoicing and payment must be clearly demonstrated.

Click here to enter text.

4.3 Patients from certain areas of Wales may receive treatment from hospitals in England. Please explain how the scheme will operate in these circumstances.

Click here to enter text.

4.4 Please provide details of the duration of the proposed scheme and confirm that the scheme will be in place until AWMSG appraisal review (three years after advice is published) and subject to Welsh Government agreement.

Click here to enter text.

4.5 Please outline the circumstances under which the scheme might be terminated by the company.

Click here to enter text.

4.6 Please confirm the notice period that will be provided to NHS Wales prior to termination of the scheme and/or the end of the period of operation (NB: this is usually six months).

Click here to enter text.

5.0 ADMINISTRATIVE BURDEN AND COST OF THE SCHEME

The full costs to the NHS of any WPAS should be clearly identified.

5.1 Please define the responsibilities of the following in implementing and monitoring the scheme:

- manufacturer or sponsor
- NHS trust or health board
- other relevant parties (e.g. homecare providers, wholesalers)

Click here to enter text.

5.2 Are other schemes currently available for patients with the disease for which this scheme applies? If so, please provide details.

Click here to enter text.

6.0 BENEFITS OF THE SCHEME

Proportionate burden: any burden for the NHS should be proportionate to the benefits of the scheme for the NHS and patients.

6.1 To what extent does the scheme enable NHS Wales to address a currently unmet clinical need? Please provide details of the current clinical care the population would otherwise receive. Please include clinical and non-clinical details if available.

Click here to enter text.

6.2 Please indicate the estimated number of patients who will be treated with the technology over years 1 to 3.

	Year 1	Year 2	Year 3
Number of patients covered by current indication (Incident + prevalent cases)	Click here to enter text.	Click here to enter text.	Click here to enter text.
Number eligible for treatment with this technology	Click here to enter text.	Click here to enter text.	Click here to enter text.
Expected uptake (%)	Click here to enter text.	Click here to enter text.	Click here to enter text.
Number of patients treated	Click here to enter text.	Click here to enter text.	Click here to enter text.

7.0 GOVERNANCE

7.1 Please provide information about expiry dates of relevant UK/EU patents and Supplementary Protection Certificates (SPCs) for this product.

Click here to enter text.

7.2 The NHS in Wales must be consulted on WPAS. Has any consultation with NHS Wales already been undertaken for the proposed scheme? If so, what was the response and was the scheme amended to reflect the response?

Click here to enter text.

7.3 Please state whether the technology will be made available to NHS England at a price that is at least equivalent to the WPAS price.

Click here to enter text.

7.4 Please explain how any missed savings would be reimbursed, should they be identified by the NHS in Wales (for example through audit or other monitoring).

Click here to enter text.

DECLARATION

I confirm that all relevant data pertinent to the scheme have been disclosed to AWMSG.

Signed*:	
Name:	Click here to enter text.
Position:	Click here to enter text.
Date:	Click here to enter a date.

*Please insert scanned signature and submit to AWTTTC at awttc@wales.nhs.uk. Receipt of your form will be acknowledged within one working day.

APPENDIX A: KEY PRINCIPLES FOR THE IMPLEMENTATION OF WPAS

The key principles for the implementation of PAS in Wales are based on those used by PASLU, which are outlined in the PPRS. These provisions have been revised in line with the existing appraisal process in Wales and the PPRS 2014 agreement:

- Arrangements must respect the role of AWMSG in providing the Welsh Government and NHS Wales with an independent assessment and appraisal of the evidence on a technology.
- A WPAS should be submitted by manufacturers to AWTTTC prior to submission of a Form B/C. AWTTTC will record receipt and pass the details of the scheme to Welsh Government who will forward to PASWG.
- The full costs to NHS Wales of any such arrangement should be included in the costs submitted for consideration.
- Schemes should be clinically and financially robust and plausible, appropriate and auditable.
- Any scheme should be operationally manageable for NHS Wales without unduly complex monitoring, disproportionate additional costs and 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 at the outset.
- It is important that any cumulative administrative burden of such schemes remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for the Welsh Government to take this issue into account when considering the viability of individual schemes.
- Schemes should be consistent with existing financial flows in NHS Wales.
- NHS Wales must be consulted on schemes by the applicant company, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines e.g. in relation to patient numbers, or the monitoring and recording of a patient's condition over and above that for the normal management of a patient.

REFERENCES

- 1 Department of Health, Association of the British Pharmaceutical Industry. The Pharmaceutical Price Regulation Scheme 2009. 2008. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf. Accessed June 2019.
- 2 Department of Health, Association of the British Pharmaceutical Industry. Pharmaceutical Price Regulation Scheme 2014. 2013. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf. Accessed June 2019.

APPENDIX 3. SUBMISSION FORM FOR A COMPLEX WALES PATIENT ACCESS SCHEME

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



**Submission Form for a
Complex Wales Patient Access Scheme**

PATIENT ACCESS SCHEME WALES GROUP

September 2014

1.0 INTRODUCTION

The 2009 Pharmaceutical Price Regulation Scheme (PPRS)¹ is a non-contractual scheme between the Department of Health and the Association of the British Pharmaceutical Industry. The purpose of the 2009 PPRS is to ensure that safe and cost-effective medicines are available on reasonable terms to the NHS in Wales and England. One of the features of the 2009 PPRS was the improvement of patient access to medicines at prices that better reflect their value, through Patient Access Schemes (PAS). The 2014 PPRS² became effective from January 2014, and included updated guidance on the use of PAS in the NHS.

A PAS is an arrangement that may be used on an exceptional basis for the acquisition of medicines 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 Medicines Strategy Group (AWMSG) to recommend treatments that it might otherwise have found not to be cost-effective. More information on the framework for PAS is provided in the 2014 PPRS².

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.

2.0 INSTRUCTIONS FOR MANUFACTURERS AND SPONSORS

This document is the **complex WPAS** submission form for PASWG, which is based on the National Institute for Health and Care Excellence (NICE) Patient Access Scheme Liaison Unit (PASLU) proposal template. This form should be read in conjunction with the 'Wales Patient Access Scheme: Process Guidance' document. If manufacturers and sponsors wish PASWG to consider a scheme, they should use this form to submit information (evidence) for assessing the feasibility of implementing the scheme in Wales. It is likely that all schemes involving primary care and homecare will be considered complex. A simplified submission form is also available for simple discount schemes applicable to secondary care only. WPAS proposals should be submitted to the All Wales Therapeutics and Toxicology Centre (AWTTC) at awttc@wales.nhs.uk. Receipt of your form will be acknowledged within one working day.

The submission form contains the information PASWG requires to assess the proposed WPAS using the principles set out in the 2014 PPRS (see Appendix A), and explains the way in which information should be presented. Manufacturers and sponsors are requested to include all information that is necessary to assess the feasibility of implementing a scheme, including evidence not directly related to the PPRS principles. If applicants are unable to follow this format, they must state the reasons clearly. Applicants should insert 'N/A' against sections that they do not consider relevant to the proposed scheme, and provide justification and/or reasons for this response.

The evidence provided in a proposal should only focus on the NHS in Wales. PASWG will consider the proposed scheme and produce final advice to the Welsh Government on the feasibility of implementing the scheme in NHS Wales. The incorporation of each scheme in the AWMSG HTA process is subject to approval from Welsh Government.

For information regarding confidentiality, and how AWMSG will handle information relating to a WPAS proposal, please see the document 'Wales Patient Access Scheme: Process Guidance'.

2.1 Instructions for completing the form

This document has been protected, which means that only designated fields can be edited. This can also affect some text formatting and reference management capabilities. For this reason, we recommend that you complete any sections requiring specific formatting or references in a separate Word document and paste the text into the fields when finalised. Reference lists can be attached as a separate document if necessary. If you experience any difficulties in filling in the form, please do not hesitate to contact awttc@wales.nhs.uk.

3.0 DETAILS OF THE WPAS

3.1 Please give full contact details for the people responsible for the proposed scheme. Please state if the applicant is the manufacturer or sponsor. Where the applicant is the sponsor, please state the relationship with the manufacturer (e.g. UK distributor).

Applicant details:	
Organisation name:	Click here to enter text.
Address line 1:	Click here to enter text.
Address line 2:	Click here to enter text.
Address line 3:	Click here to enter text.
Address line 4:	Click here to enter text.
Address line 5:	Click here to enter text.
Postcode:	Click here to enter text.
Manufacturer or sponsor?	Please select.
Sponsor's relationship to manufacturer including details of the manufacturer:	Click here to enter text.

Primary contact – the individual responsible for the application	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

Secondary contact	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

Other contact	
Name:	Click here to enter text.
E-mail:	Click here to enter text.
Tel:	Click here to enter text.

3.2 Please give the name of the technology and the indication for which the proposed scheme applies.

Medicine name*	Click here to enter text.
Indication for which the proposed scheme applies:	Click here to enter text.
*Please detail all names that apply and include all trade names.	

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3.3 Does the technology have any licensed indications that are not covered by the proposed scheme? Where applicable, describe how the NHS and the company will identify the specific patient population treated for the different indications.

Click here to enter text.

3.4 Are any additional licensed indications anticipated in the next 3 years? If yes, what are the expected dates of the licence extensions?

Click here to enter text.

3.5 Is the technology with the proposed WPAS anticipated to be dispensed in primary, and/or secondary care?

Click here to enter text.

3.6 Will the technology be available through homecare arrangements? If yes, will the technology be available through homecare only? Will the health board or trust be able to select the homecare provider or will this be specified by the company?

Click here to enter text.

3.7 What is the current list price of the technology excluding VAT?

Click here to enter text.

3.8 Please outline the rationale for developing the scheme.

Click here to enter text.

3.9 If available, please provide a list of any forms, guides and other paperwork relevant to the scheme, including those addressing:

- formal agreements
- patient registration
- pharmacy claim/rebate
- guides for pharmacists and physicians
- patient information documents

Please include copies of all documents in an appendix to your application as outlined in Appendix B.

Click here to enter text.

3.10 Please describe the type of scheme, as defined by the [PPRS](#). If this is an outcome-based scheme, please provide relevant outcome collection details for the scheme, including those listed in Appendix C. Please include details of the proposed WPAS price and proposed level of discount or rebate etc. where applicable.

Click here to enter text.

4.0 OPERATION OF THE SCHEME

Operational manageability: schemes should be clinically robust, clinically plausible, appropriate and monitorable.

4.1 Please provide specific details of the patient population to which the scheme applies. Does the scheme apply to the whole population for which the technology is licensed or only to a specific subgroup (e.g., type of tumour, location of tumour)? If so:

- How is the subgroup defined?
- If certain criteria have been used to select patients, please explain why these criteria been chosen.
- How are the criteria measured and why have these measures been chosen?

Click here to enter text.

4.2 Please provide details of when the scheme will apply to the population specified in section 4.1. Is the scheme dependent on certain criteria, e.g., degree of response, response by a certain time point, number of injections? If so:

- Please explain why the criteria have been chosen.
- How are the criteria to be measured and why have these measures been chosen?

Click here to enter text.

4.3 Does the scheme require any additional tests, interventions or appointments with healthcare professionals compared with current treatment? If so, please provide details of all additional healthcare support that might be required.

Click here to enter text.

4.4 Are there any equity or equalities issues relating to the scheme, taking into account current legislation? If so, how have these been addressed?

Click here to enter text.

4.5 Have data protection laws been adhered to during the development of the scheme? Please take into account any patient information that is collected.

Click here to enter text.

4.6 Please describe the procedures that are in place to ensure that patient confidentiality and data protection requirements are met.

Click here to enter text.

4.7 Have all of the commercial implications been considered during the development of the proposed scheme e.g., have competition laws been adhered to?

Click here to enter text.

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4.8 Please provide details of the duration of the proposed scheme and confirm that the scheme will be in place until AWMSG review (three years after advice is published) and subject to Welsh Government agreement.

Click here to enter text.

4.9 Please outline the circumstances under which the scheme might be terminated by the company.

Click here to enter text.

4.10 Please confirm the notice period that will be provided to NHS Wales prior to termination of the scheme and/or the end of the period of operation (NB: this is usually six months).

Click here to enter text.

5.0 ADMINISTRATIVE COST OF THE SCHEME

The full costs to the NHS of any WPAS should be included in the costs considered by AWMSG.

5.1 Please provide details of how the scheme will need to be administered by clinicians. Please specify whether any additional information will need to be collected, explaining when this will be done and by whom. Please be specific about how the manufacturer or sponsor is involved in that process, to what extent and at what stages. This is to enable us to build a clear picture of the entire administrative process from start to finish.

Click here to enter text.

5.2 Please provide details of the expected cost of the scheme in NHS Wales. List any costs associated with the implementation and operation of the scheme (e.g., additional staff, time for stock management and/or rebate calculations). A suggested format is presented in Table 1. Please provide the reference source for all costs.

Table 1. Annual costs associated with the implementation and operation of the scheme

	Calculation of cost	Reference source
Stock management	Click here to enter text.	Click here to enter text.
Administration of claim forms	Click here to enter text.	Click here to enter text.
Staff training	Click here to enter text.	Click here to enter text.
Other costs	Click here to enter text.	Click here to enter text.
Total implementation/operation costs	Click here to enter text.	Click here to enter text.

5.3 Please provide details of any additional treatment-related costs incurred by implementing the scheme. A suggested format is presented in Table 2. Please provide the reference source for all costs.

Table 2. Additional treatment-related costs per patient incurred by implementing the scheme

	Calculation of cost	Reference source
Interventions	Click here to enter text.	Click here to enter text.
Monitoring tests	Click here to enter text.	Click here to enter text.
Diagnostic tests	Click here to enter text.	Click here to enter text.
Appointments	Click here to enter text.	Click here to enter text.
Other costs	Click here to enter text.	Click here to enter text.
Total treatment-related costs	Click here to enter text.	Click here to enter text.

5.4 Please explain in detail the financial aspects of the proposed scheme, e.g.:

- How will cost information be calculated?
- How will rebates be calculated and paid?

Click here to enter text.

5.5 Please describe the financial flow of the scheme, e.g., what is the procedure for issuing discounts and rebates under the scheme? Which organisation will be responsible for issuing any rebates?

Click here to enter text.

5.6 Please describe any mechanisms included in the scheme that will minimise the likelihood that NHS Wales might not request/claim a discount/rebate.

Click here to enter text.

Administratively simple: any scheme should be operationally manageable for NHS Wales without unduly complex monitoring, disproportionate additional costs and bureaucracy.

5.7 Are other simpler schemes for the technology available and if so were they considered for this technology? If so, why have you chosen to propose the scheme in this format?

Click here to enter text.

5.8 Is it necessary to gather patient data to implement the scheme? If so, how will this be gathered, collated and analysed, and by whom? For what purpose(s) will the data collection be used?

Click here to enter text.

All Wales Medicines Strategy Group

5.9 Is data collection for the scheme in line with the current methods of data collection for this patient population? If not, please explain how the data collection differs from usual practice, e.g., if the scheme applies after a certain number of injections have been given, and whether these data would be collected routinely if there were no scheme.

Click here to enter text.

5.10 Please define the responsibilities of the following in implementing and monitoring the scheme:

- manufacturer or sponsor
- NHS trust or health board
- other relevant parties

Click here to enter text.

Effect on the cumulative burden: it is important that the cumulative administrative burden of such schemes remains manageable for all parties involved in their operation, including front-line NHS staff.

5.11 Are other schemes currently available for the population for which this scheme applies? If so, please provide details.

Click here to enter text.

6.0 BENEFITS OF THE SCHEME

Proportionate burden: any burden for the NHS should be proportionate to the benefits of the scheme for the NHS and patients.

6.1 What proportion of the patient population (specified in 4.1) is expected to meet the scheme criteria (specified in 4.2)? Please include evidence to support this view.

Click here to enter text.

6.2 To what extent does the scheme enable NHS Wales to address a currently unmet clinical need? Please provide details of the current clinical care the population would otherwise receive.

Click here to enter text.

6.3 Please indicate the estimated number of patients who will be treated with the technology over years 1 to 3.

	Year 1	Year 2	Year 3
Number of patients covered by current indication (Incident + prevalent cases)	Click to enter text	Click to enter text	Click to enter text
Number eligible for treatment with this technology	Click to enter text	Click to enter text	Click to enter text
Expected uptake (%)	Click to enter text	Click to enter text	Click to enter text
Number of patients treated	Click to enter text	Click to enter text	Click to enter text

7.0 GOVERNANCE

NHS financial flows: schemes should be consistent with existing financial flows in NHS Wales.

7.1 Please provide a flow diagram that clearly shows how the scheme will operate. All planned flows of funds must be clearly demonstrated (please ensure consistency with responses to 5.2 to 5.4).

Click here to enter text.

7.2 Please state who the scheme agreement is between (e.g. between the manufacturer and the hospital trust or health board). Please provide copies of any relevant documents.

Click here to enter text.

7.3 If the scheme offers rebates, can the payer claim these in the form of cash payments, credit or free stock? Please provide full details.

Click here to enter text.

7.4 Please describe any impact that the scheme may have on the choice of treatment available in NHS Wales and/or the delivery of treatment for an individual patient. Schemes should not incentivise the use of treatments that may not be the safest or most suitable for an individual patient.

Click here to enter text.

7.5 If patient care is likely to be given in more than one setting, please detail how the scheme will operate in each situation e.g. include details of any homecare or other similar arrangements.

Click here to enter text.

7.6 Has any consultation with NHS Wales already been undertaken for the proposed scheme? (The NHS in Wales must be consulted on WPAS.) If so, what was the response and was the scheme amended to reflect the response?

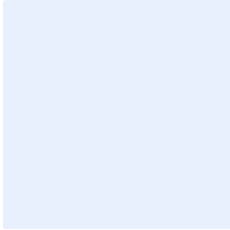
Click here to enter text.

7.7 Please state whether the Department of Health has received the same scheme outlined within this document.

Click here to enter text.

DECLARATION

I confirm that all relevant data pertinent to the scheme have been disclosed to AWMSG.

Signed*:	
Name:	Click here to enter text.
Position:	Click here to enter text.
Date:	Click here to enter a date.

*Please insert scanned signature and submit to AWTTTC at awttc@wales.nhs.uk. Receipt of your form will be acknowledged within one working day.

APPENDIX A: KEY PRINCIPLES FOR THE IMPLEMENTATION OF WPAS

The key principles for the implementation of WPAS are based on those used by PASLU, which are outlined in the PPRS. These provisions have been revised in line with the existing appraisal process in Wales and the PPRS 2014 agreement:

- Arrangements must respect the role of AWMSG in providing the Welsh Government and NHS Wales with an independent assessment and appraisal of the evidence on a technology.
- A WPAS should be submitted by manufacturers to AWTTTC prior to submission of a Form B/C. AWTTTC will record receipt and pass the details of the scheme to Welsh Government who will forward to PASWG.
- The full costs to NHS Wales of any such arrangement should be included in the costs submitted for consideration.
- Schemes should be clinically and financially robust and plausible, appropriate and auditable.
- Any scheme should be operationally manageable for NHS Wales without unduly complex monitoring, disproportionate additional costs and 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 at the outset.
- It is important that any cumulative administrative burden of such schemes remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for the Welsh Government to take this issue into account when considering the viability of individual schemes.
- Schemes should be consistent with existing financial flows in NHS Wales.
- NHS Wales must be consulted on schemes by the applicant company, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines e.g. in relation to patient numbers, or the monitoring and recording of a patient's condition over and above that for the normal management of a patient.

APPENDIX B: RELEVANT DOCUMENTS AND FORMS

If available please provide appropriate information supporting the scheme. This should include:

- scheme agreement forms
- patient registration forms
- pharmacy claim forms/rebate forms
- guides for pharmacists and physicians
- patient information documents
- declaration
- other relevant information.

Please list any other included documents and state their relevance:

Click here to enter text.

APPENDIX C: DETAILS OF OUTCOME-BASED SCHEMES

For outcome-based schemes as defined by the PPRS, please provide full details of the new information (evidence) planned to be collected, who will collect it and who will carry the cost associated with this planned data collection. Details of the new information (evidence) may include:

- design of the new study
- patient population of the new study
- outcomes to be collected in the new study
- expected duration of data collection
- planned statistical analysis and definition of study groups (including uncertainty)
- expected results of the new study
- planned evidence synthesis/pooling of data (if applicable)
- expected results of the evidence synthesis/pooling of data (if applicable).

Click here to enter text.

REFERENCES

- 1 Department of Health, Association of the British Pharmaceutical Industry. The Pharmaceutical Price Regulation Scheme 2009. 2008. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/pod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf. Accessed Apr 2014.
- 2 Department of Health, Association of the British Pharmaceutical Industry. Pharmaceutical Price Regulation Scheme 2014. 2013. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf. Accessed Apr 2014.

APPENDIX 4. AWMSG DELAYED APPRAISAL STATEMENT DUE TO A WALES PATIENT ACCESS SCHEME SUBMISSION



Generic name (Trade name[®]) formulation

Name of applicant company

Month Year

Statement to NHS Wales – Delayed Appraisal

The holder of the marketing authorisation has submitted a Wales Patient Access Scheme. The process of appraisal for [generic name (Trade name[®])] for the treatment of [abbreviated indication] has been delayed until further notice pending consideration of the feasibility of the scheme in NHS Wales.

Advice context:

The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Care Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intend to publish final advice for the same product within twelve months of the projected Form B/C submission date. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot currently be endorsed for use within NHS Wales as an appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement serves to inform NHS Wales and will be removed when the appraisal process is underway.