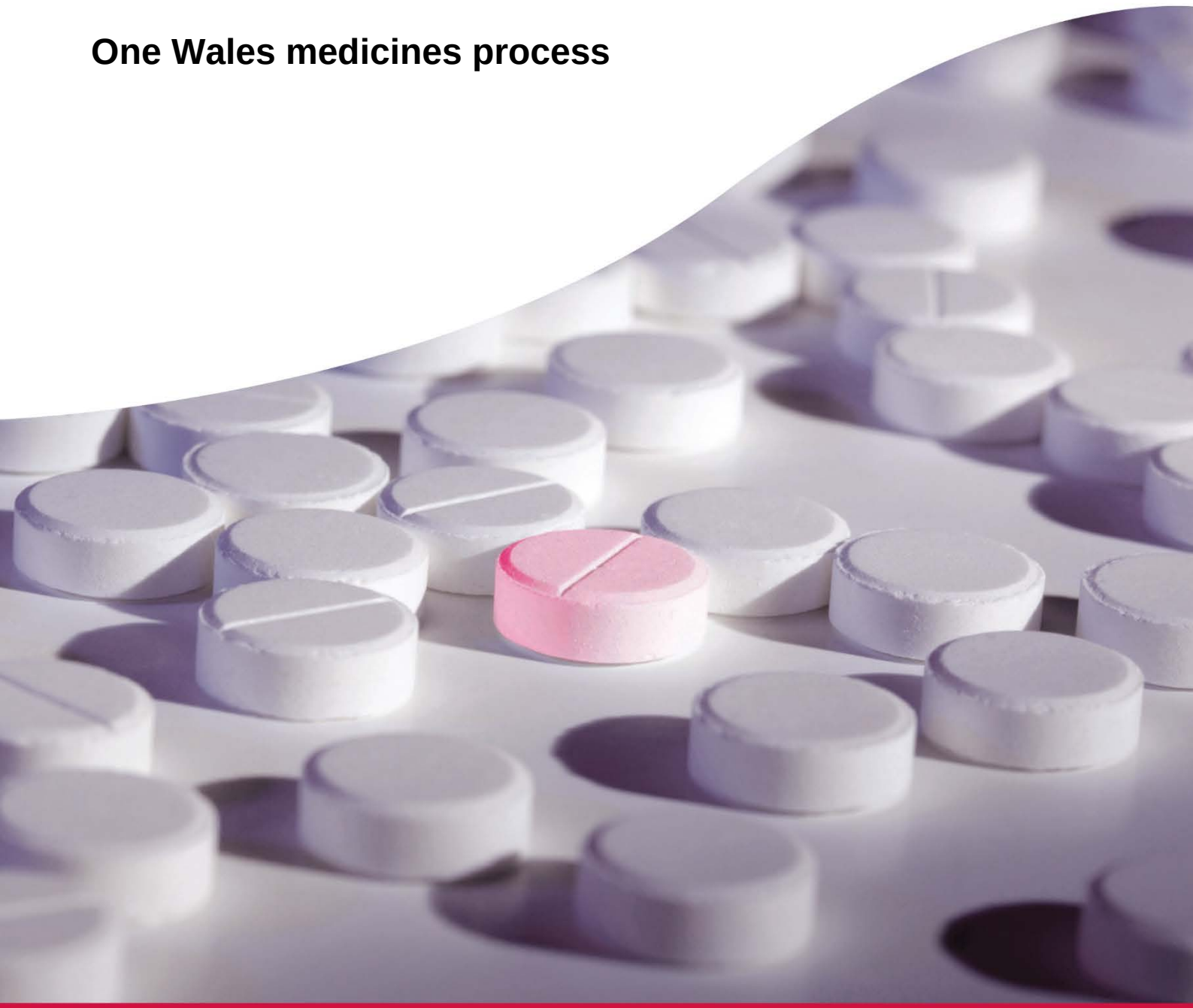
AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

One Wales medicines process



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This policy has been prepared by the All Wales Therapeutics and Toxicology Centre (AWTTC).

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One Wales Medicines process

Improving access to medicines for patient cohorts

Approved by:	All Wales Medicines Strategy Group
Issued:	November 2015 (Revised February 2021 and April 2023)
Review date:	April 2026
Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a positive impact. Key actions have been identified and these can be found in the One Wales Policy EHIA document.
Documents to read alongside this process	NHS Wales Policy Making Decisions on Individual Patient Funding Requests (IPFR). June 2017

The One Wales Medicines Process, (previously known as the One Wales Interim Commissioning process) was developed in 2015, following a review of the individual patient funding request process. It introduced an alternative route to access a medicine (or medicines) for a clearly defined and specific cohort of patients in the absence of health technology appraisal advice. One Wales decisions are based on the available evidence of clinical effectiveness and cost-effectiveness. Once approved, these interim decisions ensure that there is equitable access to these medicines across NHS Wales. This document explains when this process may be used and how it works.

1. Background

The All Wales Medicines Strategy Group (AWMSG) and the National Institute for Health and Care Excellence (NICE) provide Health Technology Assessment (HTA) guidance on the introduction of new licensed medicines within NHS Wales. Whilst recognising that timely HTA is always the preferred means to routinely fund[1] a medicine, in the absence of AWMSG/NICE advice, the individual patient funding request (IPFR) process may be used by clinicians to access a licensed medicine when it is not routinely available in NHS Wales. Similarly, in the absence of a licensed medicine that will meet the patient's needs, a clinician may apply for funding of an unlicensed medicine[2] via the Health Board's IPFR panel. However, medicines will only be funded under IPFR where it has been demonstrated that

[1] A licensed medicine is considered to be routinely funded/available if:

- it has been appraised by NICE or AWMSG and received a positive recommendation or,
- it has not been appraised due to the appraisal criteria and is listed on local formularies.

[2] An unlicensed medicine is defined by the General Medical Council (GMC) as medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. There are clinical situations when the use of unlicensed medicines or medicines outside the terms of the licence (i.e. 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. Unlike licensed medicinal products, unlicensed products may not have been assessed by the Licensing Authority against the criteria for safety, quality and efficacy. Where an off-label product can meet the individual need of the patient this should be used in preference to an unlicensed product. (*Refer to the GMC website for Prescribing Guidance: Prescribing unlicensed medicines* and Medicines and Healthcare products Regulatory Agency (MHRA): *The Supply of unlicensed medicinal products ['specials']*).

the patient's clinical condition is significantly different to that of the general population of patients and that the medicine is considered to provide particular clinical benefit to the individual and provide value for money. Where several patients may benefit from the medicine (or medicines), the IPFR process (with its emphasis on the individual patient) may not be appropriate and may result in funding variation and differential access across Wales. To address this, AWTTC developed the One Wales Medicines Process in conjunction with representatives from Welsh Health Specialised Services Committee (WHSSC) and IPFR panel co-ordinators. In the absence of health technology appraisal advice, it introduced the means to access a medicine (or medicines) for a clearly defined and specific cohort of patients for an unmet need.

For licensed medicines, the process may be utilised when there is a clearly identified cohort of patients with unmet clinical need[3] and

- in the absence of a negative recommendation from either AWMSG/NICE for the indication in question, or
- when the requested use of the medicine or medicines is/are outside of accepted treatment pathway, i.e. the specific sequence of treatment/s has not been approved by NICE/AWMSG.

In both circumstances, there is a clear and binding commitment to engagement in a future HTA by the marketing authorisation (MA) holder(s).

One Wales advice will be ratified by Welsh Government and will be interim to any NICE and/or AWMSG health technology final appraisal guidance. Appraisal guidance supersedes One Wales advice. One Wales advice enables an equitable, consistent and timely decision based on the best available evidence to support clinicians who wish to access these medicines for their patients.

It may also enable consideration and access to an unlicensed medicine[2] where:

- the medicine is not licensed for the indication of interest, or
- the requested use of the medicine is outside of an accepted treatment pathway, i.e. the specific sequence of treatment/s has not been approved by NICE/AWMSG, and
- there is no routinely available licensed medicine that will meet the patient's needs

There are clinical situations when the use of an unlicensed medicine may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. The assessment of an unlicensed medicine (or medicines) will take into account nationally agreed criteria, including consideration of the suitability of any licensed medicine for the same patient cohort, and evaluation of the clinical efficacy versus the clinical risk of unlicensed medicines that may help patients with life-threatening, long lasting or seriously debilitating illnesses. Before prescribing a medicine that may not have a UK marketing authorisation for the use listed it is important that prescribers refer to relevant guidance on prescribing unlicensed medicines.

The One Wales Medicines Process promotes the application of formal HTA via NICE or AWMSG for licensed medicines. The One Wales Medicines Process cannot be applied to the licensed use of medicines that have been appraised by NICE/AWMSG and received a negative recommendation. In this case funding should be progressed via re-submission for HTA approval with additional or significant new evidence or via IPFR. This is to ensure the One Wales Process does not undermine

[3] An unmet clinical need relates to a condition for which treatment or diagnosis is not addressed adequately by a routinely funded/available licensed medicine/therapy.

the principle that HTA is the most robust and transparent approach to ensuring patients have consistent access to clinically and cost-effective medicines.

2. How the One Wales Medicines Process works

2.1 Identifying medicines and related potential patient cohorts/How to request?

Medicines and potential patient cohorts (clearly defined and specific) are identified by Health Board IPFR panels, WHSSC, Chief Pharmacists, formulary pharmacists, Drugs & Therapeutics committees or clinical experts (usually through their specialist group or network). These healthcare professionals can request that a medicine(s) be considered for One Wales by completing a medicine request form, available on the AWWTC website or by contacting AWTTC directly. AWTTC also has a central co-ordinating role in the IPFR process, enabling the identification of potential patient cohorts at an early stage, by using All Wales IPFR data. The decision as to whether or not the One Wales Medicines Process should be initiated is proposed by AWTTC and approved by the AWMSG Steering Committee.

2.2 MA holder engagement

Once the need to initiate a One Wales decision has been agreed for a **licensed medicine**, AWTTC contacts the MA holder and explores their willingness to make a binding commitment to:

- engage in a future NICE or AWMSG HTA (within a specified time, normally 12 to 18 months), and
- provide the evidence to progress the One Wales Medicines Process.

If there is sufficient evidence to demonstrate clinical and cost-effectiveness, then an early HTA is always the preferred approach. However, in the absence of such evidence and if the decision to proceed with the One Wales Process is confirmed by the AWMSG Steering Committee, AWTTC will proceed to produce an Evidence Status Report (ESR). This will be compiled in collaboration with the MA holder (see Appendix 1 One Wales Process Flow Diagram) and clinicians.

As part of the One Wales Medicines Process, for licensed medicines that do not have positive NICE or AWMSG guidance in another indication(s), the MA holder is asked to submit a confidential commercial arrangement in the form of a simple discount. For medicines that have been approved by NICE or AWMSG for another indication and a commercial arrangement is already in place, the MA holder is asked to confirm that the existing arrangement can be extended to the medicine/indication under consideration. For medicines approved for another indication by NICE or AWMSG, without a PAS or commercial arrangement, companies are asked to consider submitting a commercial arrangement in the form of a simple discount. Commercial arrangements should be agreed **prior** to drafting the ESR. See Appendix 2 for details.

Once the need to initiate a One Wales decision has been agreed for an **unlicensed medicine**, AWTTC contacts the MA holder to inform them that an ESR is being produced. AWTTC also invites them to submit any supportive information, including any evidence or experience of using the medicine to demonstrate its safety, efficacy, clinical and cost-effectiveness (see Appendix 1 One Wales Medicines

Process flow diagram). The MA holder must inform AWTTC of any plans to license the medicine for the indicated cohort under consideration. There will be an obligation for the company to submit for HTA if marketing authorisation is granted.

2.3 Gathering the evidence

For licensed medicines, the MA holder is expected to provide AWTTC with clinical evidence demonstrating the potential for the medicine(s) in question to address an unmet clinical need. Any available budget impact and cost-effectiveness evidence should also be submitted to AWTTC.

If the One Wales Medicines Process is to proceed for a licensed medicine, the MA holder must submit sufficient/appropriate evidence to AWTTC to inform an ESR.

For unlicensed medicines, the requesting clinician or organisation should provide supporting evidence with their request and further evidence will be gathered by AWTTC from all possible sources.

AWTTC works closely with clinical networks, patient groups and IPFR panels in producing the ESR that supports decision-making. AWTTC is keen to build on good working relationships with colleagues in the pharmaceutical industry by maintaining a collaborative approach to ensure that the evidence base on which One Wales decisions are made is robust, comprehensive and clearly identifies the place of treatment in relation to alternative treatment strategies for the identified cohort of patients. Costs used in the report will aim to be reflective of those procured by NHS Wales and may be confidential. The draft ESR is circulated to the MA holder and clinicians identified through the process for comment before finalising.

Responsibilities:

- **AWTTC**: to carry out a comprehensive literature search and compile all available evidence into an ESR.
- **MA holder**: to provide clinical and cost-effectiveness evidence and budget impact information for licensed medicines (and where available for unlicensed medicines), and to make comment on the draft ESR.
- **Clinician**: to provide information on suitable comparators, to confirm unmet clinical need, to make comment on the draft ESR and respond to queries from the One Wales team compiling the report.
- **Patient organisations**: to provide a patient perspective on the unmet clinical need for the medicine, in particular the potential impact on quality of life for patients and their carers.

2.4 One Wales Medicines Assessment Group (OWMAG)

The One Wales Medicines Assessment Group (OWMAG) considers and discusses the evidence presented in the ESR and provides a clear and robust recommendation, with rationale, to the All Wales Medicines Strategy Group (AWMSG). AWMSG is asked to endorse the OWMAG recommendation which is then considered by Welsh Government for ratification.

OWMAG reports to Welsh Government and its membership is primarily drawn from IPFR Panels (see Appendix 3 - Terms of Reference). Whenever possible, all of the IPFR panels are represented at every meeting (with alternates [deputies] attending when the main member is unavailable). OWMAG convenes on a monthly basis or as needed for optimum timeliness. OWMAG makes interim recommendations in accordance with relevant guidance on unlicensed medicines[4], and also makes interim recommendations for licensed medicines ahead of appraisal by NICE/AWMSG when deemed appropriate.

The OWMAG recommendation, reached following a majority vote, may be either positive, positive with specific restrictions related to its use (restricted), or negative. OWMAG may defer a recommendation pending a request for further information. OWMAG will agree start/stop criteria for treatment as appropriate.

A clinical expert is invited to attend the OWMAG meeting to observe proceedings, answer questions and input into discussions to enable OWMAG members to gain a better understanding of the clinical context. Clinical experts are usually nominated by their specialist group or network and, therefore, should not express personal opinion or promote the use of a medicine.

A patient organisation representative is also invited to attend the OWMAG meetings to observe proceedings, answer questions and input into discussions to enable OWMAG members to gain a better understanding of the patient/carer perspective. Representatives are expected to relay broad views of the organisation rather than expressing a personal view.

Clinical expert and patient organisation representatives are asked to declare any personal or non-specific interests and will leave the meeting prior to the vote.

2.5 All Wales Medicines Strategy Group (AWMSG)

The recommendation from OWMAG with the decision rationale and the evidence status report will be provided to AWMSG members for consideration at the following AWMSG meeting. AWMSG will be asked to endorse the recommendation from OWMAG. AWMSG will not be asked to review the substance of the evidence supplied to OWMAG but confirm that the OWMAG process has been completed robustly and consistently. In exceptional circumstances, where AWMSG is unable to endorse the recommendation by OWMAG, the reasons for non-endorsement must be fully justified and will be raised with OWMAG for further consideration. This will allow for recommendations to be re-considered by AWMSG subject to further information being supplied by OWMAG.

2.6 <u>One Wales Decision</u>

Following confirmation of AWMSG' endorsement, the One Wales recommendation will be sent to Welsh Government for ratification. Once ratified, the recommendation will be disseminated to the Service for implementation (see section 2.7). It is expected that health boards will fund the medicine in accordance with the recommendation.

[4] Judicial treatment in Bayer Plc v NHS Darlington CCG and others, has clarified issues surrounding unlicensed treatment in preference to a licensed medicine, where clinical effectiveness is equivalent. OWMAG will continue to monitor jurisprudence relevant to medicines management.

2.7 Informing the service/stakeholders

NHS Wales, the MA holder and any clinical experts and patient groups involved with the process are informed of the final decision by AWTTC by email (see Appendix 1 – One Wales Medicines Process flow diagram). All One Wales decisions are displayed on the AWTTC website; the final decision may include starting and stopping criteria for the medicine by prior agreement with OWMAG and clinicians. In the interests of transparency, the OWMAG decision rationale, ESR and meeting minutes are made available on the AWTTC website. Health boards should ensure the medicine or medicines is/are included on their formulary.

2.8 Prescribing unlicensed medicines

For positive One Wales decisions relating to unlicensed medicines, the responsibility associated with prescribing the medicine falls on the prescriber. Prescribers should pay particular attention to the risks associated with using unlicensed medicines and must discuss the risks and benefits with individual patients, their families and carers. These risks may include: adverse reactions; or discrepant product information or labelling (e.g. potential confusion for patients or carers when the Patient Information Leaflet [PIL] is inconsistent with a medicine's unlicensed use). Prescribers should consult the relevant guidance on prescribing unlicensed medicines before any off-label medicines are prescribed.

2.9 Discontinuation and retirement of a One Wales decision

The duration of a One Wales decision is decided on a case-by-case basis. For licensed medicines, it is unlikely to exceed 18 months and would normally be 12 months or until publication/ratification of NICE technology appraisal guidance/AWMSG recommendation. All One Wales decisions will be reviewed on an annual basis (refer to section 4). Decisions regarding unlicensed medicines may be discontinued if the medicine receives an MA for the indication or if an alternative licensed medicine becomes routinely available (funded)[1] for the same cohort of patients. In the former circumstance the MA holder will be expected to progress the medicine through the usual HTA routes.

If the MA holder for a licensed medicine fails to make a submission to either AWMSG or NICE for HTA, the One Wales decision will be withdrawn. People having treatment may continue to do so, until they and their NHS clinician consider it appropriate to stop. AWTTC will inform AWMSG that the One Wales decision is withdrawn. On agreement, they will forward to Welsh Government for ratification.

Similarly, the advice for a medicine may be retired. This may apply, for example, when national guidance endorses the routine use of this medicine for the same indication or specified patient cohort. Subsequent availability of this medicine within NHS Wales may not be affected by retirement of the One Wales decision. AWTTC will inform AWMSG of the medicine that is retired and will forward to Welsh Government for ratification.

Responsibilities:

- **AWTTC**: to monitor NICE and AWMSG guidance, monitor unlicensed medicines for MA, monitor new medicines for the same indications.
- **MA holder**: to inform AWTTC of new evidence or of plans to license an unlicensed medicine.

3. Monitoring Outcomes

It is crucial that appropriate patient outcomes are monitored for all One Wales decisions for both licensed and unlicensed medicines. Outcome data, including patient numbers, are an important part of the review process and are used by AWTTC to inform the review report (see section 4). For licensed medicines, an outcome(s) or data collection tool may be developed by the MA holder in collaboration with clinicians in order to capture relevant data (including quality of life). This 'real world' data may subsequently provide supporting information for the MA holder to submit to either NICE or AWMSG, especially where the current dataset is immature or limited in terms of clinical effectiveness, or where economic modelling would benefit from the input of values derived from the use of the medicine. For both licensed and unlicensed medicines, clinicians are responsible for providing patient numbers and outcome data to AWTTC.

Responsibilities:

- **MA holder**: for licensed medicines, opportunity to develop and use a data collection tool and liaise with clinicians to implement data collection, and to collate outcome data for AWTTC.
- **AWTTC**: for all unlicensed medicines to liaise with clinicians to ensure patient numbers and outcome data are collected.
- **Clinicians**: to monitor and record outcomes and patient numbers and provide data to AWTTC in a timely manner.

4. Review process

4.1 Context

For all One Wales decisions a review is usually scheduled a minimum of 12 months (maximum of three years) from the date of advice. For licensed medicines it is expected that the MA holder will provide a full submission to NICE or AWMSG within 12 to 18 months of service notification of the One Wales decision. Providing the submission is on schedule AWTTC will conduct a literature search at 12 months to ensure no major safety or effectiveness issues have been raised. If a submission is not provided within these timescales the One Wales decision may be withdrawn. NICE technology appraisal guidance or AWMSG recommendations would supersede One Wales advice. For unlicensed medicines the principle of the review is to ensure that any new evidence is considered and that outcome data are in line with expectations from both a clinical and budgetary perspective. A decision may be reviewed earlier than 12 months if significant new evidence becomes available which may change the decision. For those medicines that have a review date that is longer than 12 months, AWTTC will conduct a literature search annually from the date of the last decision and may contact clinicians to request outcome data. If new significant information is found, a full review will be undertaken (see sections 4.2 to 4.4).

4.2 Preparing the review report

Approximately two to three months prior to the review date AWTTC will gather evidence that includes:

- a literature search for any literature published since the first assessment or last review,
- any changes to current clinical guidelines including starting and stopping criteria,
- new HTA advice from NICE or AWMSG for the same medicine or for a different medicine for the same indication,
- consultation with clinical experts on new information and clinical need,
- consultation with MA holders to inform them of the review and request information on updates to licence status and any new evidence they are aware of,
- outcome and usage data from the MA holder or clinicians collected as a pre-requisite for medicines supported by the One Wales Medicines process (see section 3).

The above evidence is collated by AWTTC to produce a summary review report.

4.3 Consideration by OWMAG

The review report is considered by OWMAG. For a review, OWMAG is not required to meet and may be consulted via email and submit votes electronically.

The recommendation from OWMAG, reached following by majority vote, may be either: to renew the One Wales decision for up to 3 years; renew with restrictions or amendments; discontinue or retire the One Wales recommendation; or fully re-assess the One Wales decision using newly available information. If OWMAG recommend that a full re-assessment is warranted, the full One Wales Medicines Process is followed as per section 2.0 above. If OWMAG renew, discontinue or retire the recommendation, the decision this will be forwarded to AWMSG for noting. If the MA holder for a licensed medicine fails to make a submission to either AWMSG or NICE for HTA within the agreed timeframe, the One Wales decision will be withdrawn (see section 2.9).

4.4 Ratification and informing the service

Following ratification by Welsh Government the final review decision is disseminated to the service and displayed on the AWTTC website as per sections 3.5 and 3.6 above.

Further Reading:

AWTTC: Access to medicines for patients in Wales (October 2020)
ABPI/WMPLAG: Medicines Access in NHS Wales (September 2019).
AWMSG. Prescribing Dilemmas. A Guide for Prescribers (April 2015).

Glossary and abbreviations

AWMSG - All Wales Medicines Strategy Group
A statutory advisory public body sponsored by the Senedd that provides advice to the Welsh Government on the managed introduction of new medicines into NHS Wales and on the appropriate use of existing medicines.

AWTTC - All Wales Therapeutics and Toxicology Centre
An NHS organisation providing advice and services in therapeutics and toxicology in Wales, liaising with, informing and assisting healthcare professionals, involving patients and the general public and advising Welsh Government, as well as engaging with the pharmaceutical industry.

IPFR – Individual Patient Funding Requests
IPFRs are defined as requests to a Health Board or Welsh Health Specialised Services Committee (WHSSC) to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a Health Board has arranged to routinely provide or commission.

MA Holder – Marketing Authorisation Holder
The company or other legal entity that has the authorisation to market a medicine in the UK.

NICE - National Institute for Health and Care Excellence
Established in 1998, it is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE provides guidance and advice to the NHS in England and Wales on a wide range of topics relevant to healthcare. NICE guidance includes technology appraisals on the use of medicines.

OWMAG – One Wales Medicines Assessment Group
OWMAG provides advice to NHS Wales regarding a medicine or medicines. The committee comprises representation from all IPFR panels, a lay member, industry representative, finance representative, a clinical pharmacologist and a health economist.

PASWG - Patient Access Scheme Wales Group
PASWG considers Wales Patient Access Scheme (WPAS) applications as part of the Health Technology Assessment (HTA) process, making recommendations to Welsh Government as to their feasibility of implementation

Welsh Health Specialised Services Committee (WHSSC)
WHSSC was established in 2010 by the seven Local Health Boards in Wales to ensure that the population of Wales has fair and equitable access to the full range of specialised services. WHSSC is responsible for the joint planning of Specialised and Tertiary Services on behalf of Local Health Boards in Wales.

WPAS - Wales Patient Access Scheme
A way for pharmaceutical companies to make high-cost medicines affordable for NHS Wales. The scheme is proposed by a pharmaceutical company and considered by the Welsh Government on advice from the Patient Access Schemes Wales Group (PASWG) as part of the AWMSG appraisal process.

Appendix 1

ONE WALES MEDICINES PROCESS

Medicine and Patient Cohort Identified and meets criteria for One Wales process
(via a medicine request form completed by IPFR panel / clinical experts / Chief Pharmacists or Welsh Health Specialised Services Committee, or through collection of cohort data)
Approval to proceed with the OW process sought by AWTTC from the AWMSG Steering Committee.

AWTTC informs the Marketing Authorisation (MA) holder of the intention to proceed via the One Wales Medicines Process and request best available evidence.
AWTTC identifies and contacts relevant clinician and patient groups to input into the process.
MA holder requested to submit a commercial arrangement (if applicable).
Patient Access Scheme Wales Group (PASWG) reviews commercial arrangement and inform One Wales team, MA holder and Commercial Medicines Access Team.

Evidence received by AWTTC.
Draft Evidence Status Report (ESR) prepared by AWTTC and forwarded to MA holder and clinicians for comment.
ESR may be updated in light of comments received.

12 weeks

One Wales Medicines Assessment Group meeting convened
Final ESR and recommendation taken to next All Wales Medicines Strategy Group (AWMSG) meeting

Recommendation sent to Welsh Government for ratification.

NHS Wales and MA holder informed by AWTTC of decision by email
(Communicated to Medical Directors, Finance Directors, Chief Pharmacists, Directors of Planning, IPFR Panel Co-ordinators)

Post CEMT Endorsement - 2–3 months prior to review

Review Process
AWTTC requests new evidence, patient numbers and outcome data from clinicians and/or MA holder.

1 month prior to review weeks

AWTTC produces a review report including any new evidence, guidelines, patient numbers and outcome data.

Review date

OWMAG reviews the information included in the review report to decide whether the decision remains, is re-assessed, discontinued or retired. The relevant process is then followed.

≥ 12 months

The review decision is communicated to NHS Wales and the MA holder and displayed on the AWTTC website.

Appendix 2

COMMERCIAL ARRANGEMENTS FOR THE ONE WALES MEDICINES PROCESS

As part of the process, the MA holders for those medicines that are licensed for the indication under consideration will be asked to consider submitting a commercial arrangement which would allow a price that is lower than the list price of the medicine (previously agreed PAS or commercial arrangement, or new simple discount) to be considered as part of the One Wales submission. The commercial arrangement proposals will be reviewed by the Patient Access Scheme Wales Group (PASWG) to assess the feasibility of implementation using the principles set out in the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.

One Wales Medicines Process

- The One Wales team confirm with the MA holder that they wish to submit a commercial arrangement and inform the PASWG secretariat who can provide the MA holder with submission instructions.
- A commercial arrangement proposal template (see One Wales section on the AWTTC website) should be completed by the applicant to provide the information PASWG requires to assess the feasibility of implementing the proposed arrangement using the principles set out in the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.
- The completed commercial arrangement proposal template should be submitted to AWTTC via the email awttc@wales.nhs.uk.
- PASWG will review the feasibility of implementing the proposed commercial arrangement in relation to the NHS in Wales.
- The PASWG secretariat will inform in writing the company and One Wales team that the commercial arrangement is either considered to be feasible or not.
- Where the scheme is deemed feasible, OWMAG will take into consideration the acquisition cost based on the commercial arrangement.
- The commercial arrangement will be endorsed by Welsh Government as part of their final decision.
- The Commercial Medicines Access Team will be informed of the decision following ratification by Welsh Government and any contractual arrangements will be confirmed with the MA holder to ensure financial and governance compliance and establish audit/monitoring arrangements.
- The commercial arrangement will expire on subsequent receipt of ministerial ratification of AWMSG advice or publication of the NICE final appraisal document (FAD). The MA holder shall be notified by AWTTC one month prior to the expected date of expiry. All future arrangements should be in place on receipt of HTA advice.

Appendix 3

CONSTITUTION

ONE WALES MEDICINES ASSESSMENT GROUP

1. OBJECTIVES OF THE GROUP:

To advise the All Wales Medicines Strategy Group (AWMSG) regarding One Wales decisions for new treatments or treatments which are the subject of major uncertainty across NHS Wales and for which a clear clinical need within NHS Wales has been demonstrated. This may be because of the unlicensed status of the medicine for the proposed indication or because of uncertainties surrounding the evidence base for its use in a particular treatment pathway or sequence.

2. TERMS OF REFERENCE

2.1. OWMAG will complement other work of other medicine advisory bodies e.g. the All Wales Medicines Strategy Group (AWMSG) and National Institute of Health and Care Excellence (NICE) and will not duplicate the work programmes of these bodies.

2.2. The group will report to AWMSG.

2.3. It will consider the Evidence Summary Report (ESR) and clinician and patient organisation statements.

2.4. Its work-programme will be directed by AWMSG.

2.5. It will normally meet on a monthly basis and whenever appropriate, conduct its business online or by videoconference. For review recommendations the One Wales Medicines Assessment Group (OWMAG) may conduct its business by email.

2.6. It will advise in accordance with relevant guidance on prescribing unlicensed medicines.

2.7. It will obtain its professional and administrative support from the All Wales Therapeutics and Toxicology Centre (AWTTC).

3. MEMBERSHIP

3.1. Members will be appointed by the AWMSG Steering Committee in accordance with the arrangements set out in paragraph 3.2 below. Members will be drawn from Individual Patient Funding Request (IPFR) panels from different geographical areas across Wales.

3.2. The Group will consist of the following voting members:

- One Chair

- Seven health professional members, ideally drawn from the existing IPFR panels in Wales and Welsh Health Specialised Services Committee (WHSSC)
- One Health Economist – following nomination by the Welsh Health Economic Support Service
- A Finance Director or representative
- One representative from the Pharmaceutical Industry nominated by the Industry Forum
- One Lay representative
- One Clinical Pharmacologist – following nomination by AWTTC.

The following non-voting members may be invited to attend:

- Representative/s of AWTTC
- Individuals who are co-opted for advice on specialist subjects e.g. professional and patient groups
- Chairs of the AWMSG sub-groups
- Representative from Velindre Trust IPFR group

4. ALTERNATES

With the exception of the Chair, in the event of any voting member being unable to attend a meeting of the Group, a named alternate (deputy), who has been nominated by the appropriate nominating body will be expected to attend in their place and will have voting rights. It is the responsibility of the member to invite their alternate to attend in their absence. Appointed alternates for all voting and non-voting members of the Group, except for the Chair, may be elevated to the appropriate vacancy should a vacancy occur. A Vice Chair will be appointed in accordance with clause 6.2.

5. TERM OF OFFICE

Subject to paragraph 12, a voting member's term of office shall be 4 years. Appointees may serve 2 terms but the total period of appointment must not exceed 8 years. Reappointment is subject to a satisfactory attendance and performance appraisal, which for all voting members, except the Chair, will be undertaken by the Chair.

6. OFFICERS

6.1. The Chair will be appointed by the AWMSG Steering Committee. The term of office shall normally be 4 years. The Chair will be eligible for re-appointment for an additional term of office subject to a satisfactory performance appraisal but the total period of appointment must not exceed 8 years. A Vice-Chair will be elected from the voting membership and will serve for a usual term of 4 years. The Vice-Chair will be eligible for re-election for an additional term of office subject to a satisfactory performance appraisal but the total period of appointment must not exceed 8 years.

6.2. The Vice-Chair shall preside over meetings in the absence of the Chair. In the absence of both the Chair and the Vice-Chair, the other voting members may decide who amongst them, shall preside over the meetings.

7. MEETINGS

7.1. The Terms of Reference and roles and responsibilities of the Group should be readily available to any relevant party on request.

7.2. Secretariat services will be provided by AWTTC.

8. FINANCIAL OR PERSONAL INTERESTS

Members should declare, in advance, financial or personal interests, whether pecuniary or otherwise, in any related matter that is the subject of consideration. All declarations of interest made as a result of this provision, and any action taken, should be noted in the minutes of the meeting. Guidance on declaration of interests and participation by members is available on the AWMSG website.

9. VOTING

Any outstanding issues at the meeting should be resolved, if possible, by consensus or by a simple majority vote. Only the voting members will have voting rights. Alternates are eligible to vote. In the absence of a majority, the Chair, or in the absence of the Chair, the person presiding at the meeting will have a second casting vote.

10. QUORUM

The quorum for meetings of the Group is 7 voting members, 4 of which must be health board representatives.

11. VALIDITY OF PROCEEDINGS

The validity of the proceedings of the Group is not affected by any vacancy among the members or by any defect in the appointment of a member or an alternate.

12. VACANCIES IN MEMBERSHIP

Membership of the Group shall end if members:

i. resign by giving notice in writing to the Chair of the AWMSG Steering Committee

ii. are absent from three consecutive meetings, unless the Group is satisfied that the absence is due to a reasonable cause

iii. cease to belong to the IPFR panel which they represent

iv. term of office expires

v. death of member occurs.

13. CASUAL VACANCIES

Any casual vacancy will usually be filled by the appointed alternate.

14. POWERS OF THE COMMITTEE

The Group may seek independent advice as to particular aspects of therapeutics, health economics or the health service.

15. CONSTITUTION

The Constitution will be reviewed by the AWMSG Steering Committee at regular intervals and at least on an annual basis and amended as necessary to reflect policy and structural changes within the NHS in Wales.