

DRAFT – FOR AWMSG ENDORSEMENT

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*AWMSG Medicines Assessment Process for Licensed and Off-label
Medicines*

AWTTC Equality and Health Impact Assessment (EqHIA) form for the above
resource

Equality and Health Impact Assessment

AWMSG Medicines Assessment Process for Licensed and Off-label Medicines

AWMSG and AWTTC will consider and complete an Equality and Health Impact Assessment in parallel with each development stage of our policies. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 28/05/2024

1.	AWTTC contact details	Tel: 02921 826900; email: awttc@wales.nhs.uk
2.	State the objectives of the policy.	To provide timely advice on medicines that are of most value to patients and the NHS in Wales. To achieve this, AWMSG will adapt and update their existing medicine assessment processes into one overarching process.
3.	<p>Evidence and background information considered. For example:</p> <ul style="list-style-type: none"> • population data • staff and service users' data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory.</p>	<p><u>Background</u> Since 2002, the All Wales Medicines Strategy Group (AWMSG) has provided health technology assessment (HTA):</p> <ul style="list-style-type: none"> • on medicines that have not been included in the National Institute for Health and Care Excellence (NICE) work programme; or • if there might be a benefit in AWMSG assessing a medicine before NICE. <p>After assessment, AWMSG's recommendations are ratified by Welsh Government and published as 'AWMSG advice'.</p> <p>In 2015, the One Wales Medicines process (previously known as the One Wales Interim Commissioning process) was introduced to give an alternative way to assess and allow access to medicines for clearly defined and specific cohorts (groups) of patients in the absence of HTA by NICE or AWMSG.</p>



		<p>HTA is the gold standard for evaluating the clinical effectiveness and cost-effectiveness of a medicine. However, sometimes a medicine with a service benefit or patient need might fall outside the established scope for HTA, by NICE or by AWMSG, and the medicine does not meet the current criteria for assessment through the One Wales Medicines process. This may include medicines that are routinely available elsewhere in the UK through routes of access that do not apply in Wales. AWMSG should provide timely advice on medicines that are of most value to patients and the NHS in Wales. Therefore, AWMSG will adapt and update their existing medicine assessment processes into one overarching process to achieve this aim.</p> <p>The All Wales Therapeutics and Toxicology Centre (AWTTC) supports AWMSG in providing evidence-based assessment processes. Medicines are identified for assessment through the AWTTC horizon scanning process, which includes engaging with key stakeholders:</p> <ul style="list-style-type: none">• healthcare professionals;• the pharmaceutical industry;• patient organisations;• patients, their families and carers; and• the general public. <p>Once a licensed or an off-label medicine is identified, the AWMSG Scrutiny Panel will use pre-defined criteria to decide if the medicine is suitable for assessment by AWMSG. AWMSG's two sub-groups: the Licensed One Wales Medicines Assessment Group (LOWMAG), and the One Wales Medicines Assessment Group (OWMAG), will assess and recommend medicines for AWMSG to endorse and Welsh Government to ratify.</p> <p>LOWMAG replaces the New Medicines Group (NMG), and considers and provides recommendations on medicines that are licensed. OWMAG considers and provides recommendations on off-label medicines. Once</p>
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ratified by Welsh Government, these recommendations will ensure equitable and consistent funding of these medicines across the NHS in Wales.

Needs assessment

AWMSG will consider a medicine for assessment in Wales only if there is a clear identified clinical need or benefit to NHS Wales and the people it serves. Available routes for licensed medicines will either be full or interim HTA or a limited assessment. Off-label medicines will continue to be assessed via the One Wales Medicines (OW) process ([separate EqHIA available for OW process](#)).

Assessments are carried out for a specific group of people according to the medicine's indication and clinical need. Assessments could be for medicines providing treatment for any sub-population within Wales and for any condition/disease. A separate EqHIA will be carried out for each medicine/indication being appraised.

Assessment criteria for each route are:

Criteria for health technology assessment (HTA)

Medicines which require a clinical and cost-effectiveness assessment may meet the criteria for full HTA if they are likely to have a significant impact (service and/or budget) to the NHS in Wales and when one of the following apply:

- a new licensed medicine or licence extension not on the NICE TA/HST work programme;
- the commercial arrangement as part of the NICE advice is not applicable to the NHS in Wales.

Interim HTA may be suitable for some licensed medicines or for some license extensions if there is a delay in NICE advice and they are likely to have a



		<p>significant impact (service and/or budget) to the NHS in Wales when one or more of the following apply:</p> <ul style="list-style-type: none">• there is no suitable licensed medicine available that will meet the patient's needs;• further evidence/data needs to be collected to strengthen a submission for full HTA;• there is a commercial arrangement for the NHS in Wales. <p>The outcome of AWMSG interim assessments for licensed medicines will be time limited and subject to regular review,</p> <p>Criteria for limited assessment of licensed medicines In some circumstances an assessment may be required but review of the clinical evidence and budget impact may be sufficient. This more limited assessment might be suitable for some licensed medicines or for extensions of a medicine's licence. A limited assessment is likely if there is a clear need for AWMSG advice, if the medicine and its indication is not on the NICE work programme and there is no anticipated service impact to NHS Wales and at least one of the following apply:</p> <ul style="list-style-type: none">• the medicine has a small net budgetary impact, or is cost saving to NHS Wales;• the medicine is included in national guidelines• the medicine represents standard-of-care for a particular indication;• there is national commissioning advice in another area of the UK;• the medicine offers significant benefit to the NHS in Wales in terms of service delivery or patient experience. <p>Criteria for assessment of off-label medicines (One Wales Medicines process) AWMSG will consider assessment of off-label medicines when;</p>
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- a clearly defined group of potential patients has been identified who may benefit from access to the medicine; and
- the medicine is not licensed for the indication of interest; or
- the requested use of the medicine is outside the specification of the marketing authorisation (for example a change in dosing to that authorised) and
- there is no suitable licensed medicine available that will meet the patient's needs.

The assessment of an off-label medicine (or medicine combination) considers nationally agreed criteria, including the suitability of any licensed medicine for the same patient group, and evaluation of the clinical efficacy versus the clinical risk of off-label medicines that may help patients with life-threatening, long-lasting or seriously debilitating conditions.

All recommendations for off-label medicines after AWMSG assessment are interim and subject to regular review.

Engagement and Involvement Findings

All changes to the assessment process were considered by stakeholders e.g. representatives from across health boards and trusts, patient organisations, Welsh Government and pharmaceutical industry. Stakeholders (via their established committees and meetings) were invited to comment on each stage of the revised process. The public and individual patients were given opportunity to provide their perspectives during a four-week public consultation.

Guidelines

For medicines recommended which are off-label (medicines used outside of their terms of licence) the One Wales advice refers prescribing clinicians to consult relevant UK guidelines for prescribing unlicensed medicines.



		<p>All current One Wales recommendations are available on the AWTTC website: One Wales Medicines interim decisions - All Wales Therapeutics and Toxicology Centre (nhs.wales).</p> <p>All current appraisal recommendations are available on the AWTTC website: Home - All Wales Therapeutics and Toxicology Centre (nhs.wales)</p> <p>Good practice guidelines</p> <ol style="list-style-type: none">1. AWMSG process for industry engagement
4.	Who will this policy affect?	<p>AWTTC staff prepare the documentation required to support the assessment of the medicines. Clinicians provide information on the condition being treated and the place of the medicine within the clinical care pathway. Committees which include pharmacists, doctors, nurses, lay members and, representatives of the pharmaceutical industry appraise the medicines. Patients, carers and prescribers will benefit from the medicines which are recommended for use. Pharmacists are required to make the medicines available on health board formularies.</p>

5. EQIA - How will the policy impact on people?

Questions in this section relate to the impact on people based on their 'protected characteristics'.

How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
<p>5.1 Age For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> • under 18 years; • between 18 and 65 years; • over 65 years. 	<p>Positive: The process will have a positive impact on medicine access for a defined age/population where a medicine has received an AWMSG positive recommendation and this is subsequently ratified by the Minister for Health and Social Services.</p> <p>Negative: Negative impacts may be the potential for adverse effects of the prescribed medicine.</p>	<p>Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed. The prescribing clinician should refer to the summary of product characteristics (SmPC) for information on known adverse effects. Healthcare professionals should follow relevant professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines in line with MHRA guidance on off-label or unlicensed use of medicines.</p>	<p>The clinical effectiveness section of the AWMSG assessment report makes reference to adverse effects/safety of the medicine. The Minister for Health and Social Services ratifies the recommendation. Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
<p>5.2 Persons with a disability as defined in the Equality Act 2010</p> <p>Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.</p>	<p>Positive</p> <p>The process will have a positive impact on medicine access for people with a disability where a medicine is prescribed for this protected characteristic and it has received an AWMSG positive recommendation, subsequently ratified by the Minister for Health and Social Services.</p> <p>Negative:</p> <p>The patient may be negatively impacted by adverse effects of the prescribed medicine.</p>	<p>Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed. The prescribing clinician should refer to the SmPC for information on known adverse effects. Healthcare professionals should follow relevant professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines in line with (MHRA guidance on off-label or unlicensed use of medicines). It is the prescribing clinician's responsibility to ensure that patients and their guardians receive accessible</p>	<p>The clinical effectiveness section of the AWMSG assessment report makes reference to adverse effects/safety of the medicine. The Minister for Health and Social Services ratifies the recommendation. All documents published on the AWTTC website will meet accessibility requirements.</p> <p>Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
		information about the impact of the treatment. All documents published on the AWTTC website will meet accessibility requirements. Staff have attended Learning Disability Wales training course to help make patient-facing materials easy to read, so that people with learning disabilities can understand them. Patient facing materials will be produced in Welsh and English.	
5.3 People of different genders: Consider men, women, people undergoing gender reassignment. NB Gender-reassignment is anyone who proposes to, starts, is going through or who	Positive The process will have a positive impact on medicine access for people of different genders where a medicine is prescribed for this protected characteristic and it has received an AWMSG positive recommendation,	The prescribing clinician should refer to the SmPC for information on known adverse effects. Healthcare professionals should follow relevant professional guidance and take full	The clinical effectiveness section of the AWMSG assessment report makes reference to adverse effects/safety of the medicine. The Minister for



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
<p>has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender.</p> <p>Stonewall</p> <p>Gender Identity Research & Education Society – Improving the Lives of Trans People (gires.org.uk)</p>	<p>subsequently ratified by the Minister for Health and Social Services</p> <p>Negative The patient may be negatively impacted by adverse effects of the prescribed medicine.</p>	<p>responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines in line with MHRA guidance on off-label or unlicensed use of medicines.</p> <p>Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>	<p>Health and Social Services ratifies the recommendation. Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>
<p>5.4 People who are married or who have a civil partner.</p>	<p>We do not expect this process to have a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.</p>	<p>There are no recommendations for improvement/ mitigation necessary at this time.</p>	<p>There is no action necessary at this time.</p>
<p>5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.</p>	<p>Positive The process will have a positive impact on medicine access for women who are expecting a baby, after having a baby or who are breastfeeding where a medicine is</p>	<p>The prescribing clinician should refer to the SmPC for information on known adverse effects/associated risks in pregnancy or in women of childbearing</p>	<p>The clinical effectiveness section of the AWMSG assessment report makes reference to adverse effects/safety of the medicine. The Minister for</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
<p>They are protected for 26 weeks after having a baby whether or not they are on maternity leave.</p>	<p>prescribed for this protected characteristic and it has received an AWMSG positive recommendation, subsequently ratified by the Minister for Health and Social Services.</p> <p>Negative The patient may be negatively impacted by adverse effects of the prescribed medicine. Some medicines are contraindicated during pregnancy or in females of childbearing potential. Some medicines may be unsuitable to prescribe during breast feeding.</p>	<p>potential or who are breastfeeding. Healthcare professionals should follow relevant professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines in line with MHRA guidance on off-label or unlicensed use of medicines.</p> <p>Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>	<p>Health and Social Services ratifies the recommendation. Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>
<p>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</p>	<p>We do not expect this process to have a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin.</p>	<p>There are no mitigation or recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
The Runnymede Trust	People of different race and ethnicities can have varying responses to medicines. A medicine may be considered for a condition which does affect one particular race more than others.		
<p>5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief.</p> <p>Implications of religious beliefs on selection of medicines (BMJ)</p> <p>In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)</p>	<p>Negative Some medicines contain ingredients derived from animal products and some people might not want to take them because of religion or ethical reasons.</p> <p><i>Religions include:</i> <i>Buddhists/Hindus/Muslims/Jews/Sikhs Rastafarians/Seventh day Adventists.</i></p>	The prescribing clinician should refer to the SmPC for information on animal-derived components in the medicine of concern. It is the prescribing clinician's responsibility to ensure that patients and their guardians receive patient information leaflet on the medicine. Healthcare professionals should follow relevant professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label	Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
		or unlicensed medicines in line with MHRA guidance on off-label or unlicensed use of medicines.	
<p>5.8 People who are attracted to other people of:</p> <ul style="list-style-type: none"> the opposite sex (heterosexual); the same sex (lesbian or gay); both sexes (bisexual). <p>Stonewall</p>	<p>We do not expect this process to have a potential negative, or unequal, impact on people based on who they are attracted to. This aspect will be further considered within the EqHIA for each separate medicine.</p>	<p>There are no recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>
<p>5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.</p> <p>Well-being Goal – a Wales of vibrant culture and thriving Welsh language</p>	<p>Positive AWTTC have a process in place to produce bilingual patient facing information in line with the Welsh language Standards.</p> <p>We do not expect this process to have a potential negative, or unequal,</p>	<p>Any patient-facing materials will be produced in Welsh and English, including easy read booklets. Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>	<p>Any patient-facing materials will be produced in Welsh and English, including easy read booklets. Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
	impact on people who communicate using the Welsh language.		
5.10 People according to their income related group. Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health.	Positive The process will have a positive impact on medicine access for people who are economically inactive or on low income as people living in Wales can claim for free medicine prescriptions. There might be an impact on a person's ability to work due to the severity of disease. Making treatments available might increase a person's chance to regain employment as their symptoms improve. Negative Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back. Patients might have issues with meeting these costs	The prescribing clinician and multi-disciplinary clinical team are responsible for monitoring and implementation of treatment. Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.	Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
	of travel and of being given time out of work to receive treatment		
5.11 People according to where they live. Consider people living in areas known to show poor economic and/or health indicators, people unable to access services and facilities.	Positive The process will have a positive impact on medicine access for people who are economically inactive as some medicines are prescribed for home care administration following an AWMSG positive recommendation and subsequently ratified by the Minister for Health and Social Services. Negative Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back. Patients might have issues with meeting these costs of travel and of being given time out of work to receive treatment.	Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.	Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
<p>5.12 Consider others who face health inequalities, such as:</p> <ul style="list-style-type: none">• Looked after and accommodated children and young people.• Carers: paid/unpaid, family members.• People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&Bs.• Those involved in the criminal justice system: offenders in prison or on probation, ex-offenders.• People with addictions and substance misuse problems.• People who have poor literacy.• People living in remote, rural and island locations.	<p>We do not expect this process to have a potential negative, or unequal, impact on people who face health inequalities.</p>	<p>There are no recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by). Refer to where the mitigation is included in the document, as appropriate.
5.13 Consider any other groups and risk factors relevant to this policy/project.	This aspect will be further considered within the EqHIA for each separate medicine.	Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.	Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.

6. HIA - How will the policy impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

How will the policy impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) Refer to where the mitigation is included in the document, as appropriate.
<p>6.1 People being able to access the service offered. Consider access for those living in areas of deprivation and/or those experiencing health inequalities.</p> <p>Well-being Goal - A more equal Wales</p>	<p>Positive The process will have a positive impact on medicine access for people who are economically inactive or living in areas of deprivation and/or with health inequalities as medicines are available via free prescriptions in Wales.</p> <p>Negative: Some services/treatments will only be available at certain locations meaning patients will need to travel further to access these.</p>	<p>The prescribing clinician and multi-disciplinary clinical team are responsible for monitoring and implementation of treatment.</p> <p>Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>	<p>Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>
<p>6.2 People being able to improve or maintain healthy lifestyles. Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the</p>	<p>Positive The process will have a positive impact on medicine access for a defined population where a medicine has received an AWMSG positive</p>	<p>The prescribing clinician should refer to the SmPC for information on known adverse effects. Healthcare professionals should follow relevant</p>	<p>Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) Refer to where the mitigation is included in the document, as appropriate.
<p>harm caused by alcohol or non-prescribed drugs plus access to services that support disease prevention (such as vaccination, falls prevention).</p> <p>Also consider impact on access to supportive services, including smoking cessation services, weight management services.</p> <p>Well-being Goal – A healthier Wales</p>	<p>recommendation and it is subsequently ratified by the Minister for Health and Social Services.</p> <p>This in turn may help people, eligible for treatment with the medicine, to improve or maintain a health lifestyle and thereby improve quality of life.</p> <p>Negative Adverse effects of the prescribed medicine may have a negative impact on health.</p>	<p>professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines in line with MHRA guidance on off-label or unlicensed use of medicines. Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.</p>	
<p>6.3 People in terms of their income and employment status.</p> <p>Consider the impact on the availability and accessibility of work, paid or unpaid employment, wage levels, job security, working conditions.</p>	<p>We do not expect this process to have a potential negative, or unequal, impact on people in terms of their income and employment status.</p>	<p>There are no recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) Refer to where the mitigation is included in the document, as appropriate.
Well-being Goal – A prosperous Wales			
6.4 People in terms of their use of the physical environment. Consider the impact: <ul style="list-style-type: none">• on the availability and accessibility of transport, healthy food, leisure activities, green spaces;• of the design of the built environment on the physical and mental health of patients, staff and visitors;• on air quality, exposure to pollutants;• safety of neighbourhoods, exposure to crime;• road safety and preventing injuries or accidents;• quality and safety of play areas and open spaces. Well-being goal – A resilient Wales	We do not expect this process to have a potential negative, or unequal, impact on people's use of the physical environment. This aspect will be further considered within the EqHIA for each separate medicine. Impact may depend on the medicine/treatment under assessment. There may be positive benefits for some treatments that don't require hospital or clinic attendance e.g. oral treatments rather than IV.	Recommendations for improvement/mitigation will be considered within the separate EqHIA for each medicine being assessed.	Appropriate actions will be considered within the separate EqHIA for each medicine being assessed.



How will the policy impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) Refer to where the mitigation is included in the document, as appropriate.
<p>6.5 People in terms of social and community influences on their health. Consider the impact on:</p> <ul style="list-style-type: none"> • family organisation and roles; social support and social networks; • neighbourliness and sense of belonging; • social isolation; • peer pressure; • community identity; • cultural and spiritual ethos. <p>Well-being Goal – A Wales of cohesive communities</p>	<p>We do not expect this process to have a potential negative, or unequal, impact on people in terms of social and community influences on their health although providing an effective treatment may improve a person’s ability to socialize</p>	<p>There are no recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>
<p>6.6 People in terms of macro-economic, environmental and sustainability factors. Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate.</p> <p>Well-being Goal – A globally responsible Wales</p>	<p>Positive The process will have a positive impact on medicine access for people in Wales where a medicine has received an AWMSG positive recommendation and is subsequently ratified by the Minister for Health and Social Services. The pharmaceutical</p>	<p>There are no mitigation or recommendations necessary at this time.</p>	<p>There is no action necessary at this time.</p>



How will the policy impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) Refer to where the mitigation is included in the document, as appropriate.
	<p>industry aligns medicine manufacturing with sustainability practices and in line with the policy on climate change-international federation of pharmaceutical manufacturers association.</p> <p>Negative We do not expect this process to have a potential negative, or unequal, impact on people in terms of macro-economic, environmental and sustainability factors.</p>		

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

<p>7.1 Please summarise the potential positive and/or negative impacts of the policy.</p>	<p>The new process is expected to have a positive impact for the population of Wales. The new process will be developed focusing on access to medicines with a clearly identified patient/clinical need and added value to NHS Wales. Some of the groups may have a specific positive impact from the medicines approved. Negative impact includes side effects of the medicines prescribed. The prescribing clinician should refer to the SmPC for information on known adverse effects/associated risks of the recommended medicines.</p> <p>The impact on protected groups will be evaluated for each medicine assessed via an individual EqHIA.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
<p>7.2 What are the key actions identified as a result of completing the EqHIA?</p>	<p>The impact on the groups of people (above) will be considered within the separate EqHIAs for each medicine evaluated.</p> <p>The clinical effectiveness section of the AWMSG assessment report makes reference to adverse effects/safety of the medicine.</p> <p>Any patient-facing materials will be produced in Welsh and English, including easy read booklets.</p>	<p>Designated assessment team.</p>	<p>From start of AWTTTC assessment until final recommendation. Further actions may be identified during subsequent reviews of the assessment</p>	<p>Designated assessment team.</p>



	Action	Lead(s)	Timescale	Actions taken (state who by)
	All documents published on the AWTTC website will meet accessibility requirements.			
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?	An EqHIA will be carried out for each separate medicine.			
7.4 What are the next steps?	Endorsement of EqHIA along with the assessment policy by AWMSG. Publication of EqHIA and policy on AWTTC website. Monitor and review		June 2024 June 2024	

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.