

## Equality and Health Impact Assessment

**Appraisal of cytisine for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.**

**AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. 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: 08/05/2024**

1.	AWTTC contact details	Tel: 02921 826900 Email: <a href="mailto:awttc@wales.nhs.uk">awttc@wales.nhs.uk</a>
2.	State the objectives of the project.	Cytisine will be appraised by New Medicines Group and All Wales Medicines Strategy Group for routine prescribing in Wales. The outcome will be a recommendation which may be endorsed by Welsh Government
3.	Evidence and background information considered. For example: <ul style="list-style-type: none"> <li>• population data</li> <li>• staff and service users' data, as applicable</li> <li>• needs assessment</li> <li>• engagement and involvement findings</li> <li>• research</li> <li>• good practice guidelines</li> <li>• participant knowledge</li> <li>• list of stakeholders and how stakeholders have engaged in the development stages</li> <li>• comments from those involved in the designing and development stages</li> </ul>	Smoking is one of the main causes of inequalities in health in Wales with smoking rates higher in more deprived areas. Some people are unable to use nicotine replacement therapy to help them quit smoking. This group may be eligible for cytisine, which is available as tablets. If recommended cytisine will be prescribed by NHS staff offering a further option for those who want to quit smoking. The treatment would be available to eligible people in Wales aged between 18 years and 65 years, which would include NHS staff.  AWTTC has engaged with Public Health Wales and Smoking Cessation Pharmacists to seek their perspectives on cytisine and the treatments which are used to help people quit smoking today.  Cytisine is a plant alkaloid with a chemical structure similar to nicotine. The use of cytisine allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms. Cytisine competes with nicotine for the same



<p><a href="#">Population pyramids</a> are available from Public Health Wales Observatory.</p>	<p>receptors and gradually displaces nicotine due to its stronger binding (ref SPC). It has been used as a smoking cessation treatment for several decades in many European countries and Canada. It is available over the counter in several countries, and it is now licensed in the UK. Cytisine has been used in Europe by several million people who smoke, and up to January 2024 there has been no evidence of any serious adverse events (link to ref NCSCT guide to cytisine Jan 2024).</p> <p>Nicotine replacement therapy is the most frequently prescribed treatment for smoking cessation – this can be given as patches, gum, lozenges, sublingual tablets, inhalator, oral spray, and nasal spray. However, some people may not be able to take NRT or may not want to use it. Another treatment, varenicline was available as a tablet form for smoking cessation therapy, this has however subsequently been withdrawn and is no longer available. Clinicians believe that cytisine would offer an alternative to NRT and may be suited to those who would have received varenicline in the past. Prescribing data indicates that approximately 2,000-3,000 treatment courses of varenicline were prescribed in 2020-2021 (this was the maximum volume prescribed versus previous years) and this is an estimate of the possible uptake of cytisine.</p> <p>Guidelines are available:</p> <ul style="list-style-type: none"><li>• All Wales Medicines Strategy Group (AWMSG) endorsed an All Wales Guide: <a href="#">Pharmacotherapy for Smoking Cessation in February 2018</a></li><li>• The National Institute for Health and Care Excellence (NICE) published a guideline in 2021, updated in 2023: ‘Tobacco: preventing uptake, promoting quitting and treating dependence’ (NG209)<sup>14</sup>. In February 2024 an <a href="#">exceptional review to NG209</a> was published which included the recommendation that cytisine should be considered an option alongside other interventions for smoking cessation</li></ul>
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4.	Who will this project affect?	Staff and patients who wish to stop smoking may benefit from cytisine because it offers another treatment option for smoking cessation.

## 5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<p><b>5.1 Age</b></p> <p>For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> <li>• under 18 years;</li> <li>• between 18 and 65 years;</li> <li>• over 65 years.</li> </ul>	<p>We do not expect a potential negative, or unequal, impact on people based on their age.</p> <p>[Note: For prescription medicines we expect the prescriber to have prescribed or advised their use within the terms of their UK marketing authorisations. Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring needs for the medicine. These are explained in the <a href="#">Summary of Product Characteristics (SmPC)</a>. Healthcare professionals should follow relevant professional guidance and take</p>	<p>Cytisine is not licensed for people less than 18 years or over 65 years old. This is because no evidence was submitted for these age groups at the time of the original license.</p>	<p>The SmPC criteria specify which people are excluded from treatment due to the associated risks.</p>



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines. This includes considering the contraindications, warnings, monitoring requirements and other safety recommendations for the medicine ( <a href="#">MHRA guidance on off-label or unlicensed use of medicines</a> )		
<b>5.2 Persons with a disability as defined in the Equality Act 2010</b> Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.	The <a href="#">summary of product characteristics</a> contradicts use in those with a history of recent myocardial infarction, clinically significant arrhythmias, a history of recent stroke or pregnant or breastfeeding. <a href="#">It is not recommended for those with renal or hepatic impairment.</a>	All related documents published on the AWTTC website will meet accessibility requirements.  Any patient-facing materials will be also be produced as easy read booklets in Welsh and English.	N/A



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by).</b>
<b>5.3 People of different genders:</b> Consider men, women, people undergoing gender reassignment. <b>N.B.</b> Gender-reassignment is anyone who proposes to, starts, is going through or who 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.	We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment.	None required	N/A
<b>5.4 People who are married or who have a civil partner.</b>	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.	None required	N/A
<b>5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.</b> They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Cytisine is not recommended for women who are pregnant or who want to become pregnant. Please refer to the <a href="#">SmPC</a> .	Prescribers should take account of the Summary of Product Characteristics (SmPC) when prescribing any medicines for women who are pregnant, or who are breastfeeding.	The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment. This will be identified for consideration of any change to the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women.



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<p><b>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</b></p> <p><a href="#">The Runnymede Trust</a></p>	<p>We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin.</p> <p>People of different race and ethnicities can have varying responses to medicines.</p>	<p>Note in the project document that people of different race and ethnicities can have varying responses to medicines.</p>	<p>N/A</p>
<p><b>5.7 People with a religion or belief or with no religion or belief.</b></p> <p>The term 'religion' includes a religious or philosophical belief.</p> <p><a href="#">Implications of religious beliefs on selection of medicines (BMJ)</a></p> <p><a href="#">In practice: guidance on religion, personal values and beliefs</a> (General Pharmaceutical Council)</p>	<p>We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion or belief.</p> <p>Some medicines are made from certain animal products and people might not want to take them because of religion or belief.</p>	<p>None required</p>	<p>N/A</p>
<p><b>5.8 People who are attracted to other people of:</b></p> <ul style="list-style-type: none"><li>• the opposite sex (heterosexual);</li><li>• the same sex (lesbian or gay);</li></ul>	<p>We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.</p>	<p>None required</p>	<p>N/A</p>



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by).</b>
<ul style="list-style-type: none"><li>both sexes (bisexual).</li></ul> <a href="#">Stonewall</a>			
<b>5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.</b>	We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language. Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	N/A
<b>5.10 People according to their income related group.</b>	Twenty two percent of adults from the most deprived groups of Wales smoke, compared to 6.6% from the least deprived. Smoking cessation treatments would therefore be expected to have more impact on those with lower incomes. Furthermore those who quit will no longer spend income on smoking.	None required	N/A
<b>5.11 People according to where they live.</b>	Smoking cessation would be expected to have a greater	None required	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	positive impact on more deprived areas.		
<b>5.12 Consider others who face health inequalities, such as:</b> <ul style="list-style-type: none"><li>• Looked after and accommodated children and young people</li><li>• Carers: paid/unpaid, family members</li><li>• People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&amp;Bs</li><li>• People involved in the criminal justice system: offenders in prison or on probation, ex-offenders</li><li>• People with addictions and substance misuse problems</li><li>• People who have poor literacy</li><li>• People living in remote, rural and island locations</li></ul>	Cytisine provides an option for smoking cessation for those with nicotine addiction..	None required	N/A



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by).</b>
<b>5.13 Consider any other groups and risk factors relevant to this project.</b>	None identified	None required	N/A

## 6. HIA - How will the project 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.

<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
<b>6.1 People being able to access the service offered.</b>	We do not expect a potential negative, or unequal, impact on people's ability to access the service offered. Smoking cessation advice is available free of charge via telephone or in person through the help me quit service.	None required	N/A
<b>6.2 People being able to improve or maintain healthy lifestyles.</b>	We expect a potential positive impact on people's ability to improve or maintain healthy lifestyles. Patient organisations, the committee's lay members and clinicians have the opportunity to inform the group about how smoking affects the lifestyle of smokers and their families and the effects of treatment.  The use of cytisine provides a further option (along with other	Patient organisation summaries will only be available where patient confidentiality is ensured.  Availability of cytisine supports national and local health promotion campaigns.	N/A



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
	treatments such as nicotine replacement therapy) for a gradual reduction of nicotine dependence by relieving withdrawal symptoms. The treatment will be available as an option in local smoking cessation services.		
<b>6.3 People in terms of their income and employment status.</b>	People who quit smoking would anticipate a positive impact on their income.  In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income or employment status.	None required	N/A
<b>6.4 People in terms of their use of the physical environment.</b>	People quitting smoking would have a positive impact on the environment due to reduced secondary smoking and reduced smoking related waste/litter.	None required	N/A



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
<b>6.5 People in terms of social and community influences on their health.</b>	<p>We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health.</p> <p>Patient organisations, the committee's lay members and clinicians have the opportunity to inform the group about how the disease affects the social and community influences of patients and the effects of treatment.</p>	Patient organisation summaries will only be available where patient confidentiality is ensured.	N/A
<b>6.6 People in terms of macro-economic, environmental and sustainability factors.</b>	<p>We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors.</p> <p>Research has provided clear and indisputable evidence that tobacco cultivation is not sustainable. Harmful impacts include pollution, soil degradation and deforestation, contributing to adverse climate</p>	The pharmaceutical industry aligns medicine manufacturing with sustainability practices and in line with the policy on <a href="#">climate change-international federation of pharmaceutical manufacturers association</a> .	N/A



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
	change and biodiversity losses ( <a href="http://ASH.org.uk">ASH.org.uk</a> ).		

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

<p><b>7.1 Please summarize the potential positive and/or negative impacts of the project.</b></p>	<p>None expected. This is an oral treatment with similar monitoring requirements to conventional therapy.</p>
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**Action plan for mitigation or improvement and implementation**

	<b>Action</b>	<b>Lead(s)</b>	<b>Timescale</b>	<b>Actions taken (<i>state who by</i>)</b>
<p><b>7.2 What are the key actions identified as a result of completing the EqHIA?</b></p>	<ul style="list-style-type: none"> <li>• Consult with Public Health Wales, Pharmacist specializing in smoking cessation in Wales;</li> <li>• Consult with smoking pressure group representatives in Wales (or the UK)</li> <li>• Invite comments through the AWTTC website</li> </ul>	<p>AWTTC</p>	<p>April-July 2024</p>	<p>AWTTC team has been liaising with Public Health Wales, help me quit service and smoking pressure group representatives.</p>
<p><b>7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?</b></p>	<p>No</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>
<p><b>7.4 What are the next steps?</b></p>	<p><b>Process continues unchanged</b></p> <ul style="list-style-type: none"> <li>• Proceed to NMG</li> <li>• Publish report of this impact assessment on the AWTTC</li> </ul>	<p>AWTTC AWTTC</p>	<p>June 2024 June 2024</p>	



	<b>Action</b>	<b>Lead(s)</b>	<b>Timescale</b>	<b>Actions taken (<i>state who by</i>)</b>
	website <ul style="list-style-type: none"><li>• Proceed to AWMSG Steering committee</li><li>• Proceed to AWMSG for endorsement.</li><li>• Monitor and review</li></ul>	AWTTC AWTTC	June 2024 July 2024	
<b>7.5 Review of project and EqHIA</b>		AWTTC	[TBC]	

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