

Equality and Health Impact Assessment

Policy* title: Understanding unlicensed 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.

*** The term “policy” is used throughout to cover: policies, strategies, functions, practices, procedures.**

Date: 17/05/2023

1.	Names of the policy lead(s); AWTTC contact details	AWTTC Tel: 02921 826900; email: awttc@wales.nhs.uk
2.	State the objectives of the policy. <i>(include what outcomes will be measured and who by, when, any other details? Perhaps who else will be involved?)</i>	To provide guidance for improving the management of unlicensed ‘specials’ and off label medicines in all sectors of healthcare in NHS Wales. This guidance is aimed at healthcare professionals who prescribe or review unlicensed ‘specials’ and off label medicines, pharmacists who dispense these medicines and patients who are treated with these medicines.
3.	Evidence and background information considered. For example: <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 	MHRA. Off-label or unlicensed use of medicines: prescribers’ responsibilities. 2014. Available at: https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities . General Medical Council. Prescribing unlicensed medicines. 2021. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines



	<ul style="list-style-type: none">• 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>Statswales.gov.wales</p> <p>Population aged 15 and under, per health board (and as a % of total health board population) – mid-year population estimates for 2020:</p> <ul style="list-style-type: none">• Aneurin Bevan 110,465 (18.5%)• Betsi Cadwaladr 123,650 (17.6%)• Cardiff and Vale 92,912 (18.4%)• Cwm Taf Morgannwg 82,649 (18.4%)• Hywel Dda 65,293 (16.8%)• Powys 21,069 (15.8%)• Swansea Bay 66,692 (17.1%) <p>Wales 668,590 (17.8%)</p> <p>Population aged 65 and over, per health board (and as a % of total health board population) – mid-year population estimates for 2020:</p> <ul style="list-style-type: none">• Aneurin Bevan 120,386 (20.1%)• Betsi Cadwaladr 164,699 (23.4%)• Cardiff and Vale 81,645 (16.2%)• Cwm Taf Morgannwg 88,317 (19.6%)• Hywel Dda 97,530 (25.0%)• Powys 36,801 (27.7%)• Swansea Bay 79,212 (20.3%) <p>Wales 668,590 (21.1%)</p>
4.	Who will this policy affect?	Local Health Boards General Public Medical and non-medical prescribers in primary and secondary care Pharmacists

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

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

Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

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>This guidance is intended to focus on all patients as the principles of prescribing unlicensed 'special' and off label medicines stated in this document apply to all age groups. However, children (aged under 18 years) and the elderly (over 65 years) are more likely to receive unlicensed medicines.</p> <p>The benefits (e.g. better safety, appropriate awareness of unlicensed status of medicines) could be more pronounced in both children and the elderly populations. Greater awareness of unlicensed medicines could result in more queries /</p>	<p>Produce document to help answer any questions patients may have regarding an unlicensed medicine.</p>	<p>Patient information leaflets have been developed to address additional queries and questions from patients.</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.
	questions relating to medicines in these age categories.		
<p>5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.</p>	<p>People with mental health conditions may be more likely to receive unlicensed medicines.</p> <p>The benefits (e.g. better safety, appropriate awareness of unlicensed status of medicines) could be more pronounced in this group.</p> <p>People with learning disabilities, dyslexia or visual impairments may require patient information to be provided in accessible, understandable formats.</p>	<p>Produce document to help answer any questions patients may have regarding an unlicensed medicine.</p> <p>Ensure patient information is provided in a range of accessible and understandable formats.</p>	<p>Patient information leaflets have been developed to address additional queries and questions from patients.</p> <p>AWTTC is exploring how we can best provide all our patient information in a range of accessible formats (including Easy-read). Once a process for production of these additional formats has been piloted, it will be applied to already-published patient information leaflets, including those associated with this resource.</p>
<p>5.3 People of different genders: Consider men, women, people undergoing gender reassignment. NB Gender-reassignment is anyone who proposes to, starts,</p>	<p>We do not expect that this guidance will affect individuals unequally based on their gender.</p>	<p>N/A</p>	<p>N/A</p>



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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.			
5.4 People who are married or who have a civil partner.	We do not expect that this guidance will affect individuals unequally based on their marital/civil partnership status	N/A	N/A
5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Women who are expecting a baby may be more likely to receive unlicensed medicines. The benefits (e.g. better safety, appropriate awareness of unlicensed status of medicines) could be more pronounced in this group.	Produce document to help answer any questions patients may have regarding an unlicensed medicine.	Patient information leaflets have been developed to address additional queries and questions from patients.
5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers.	We do not expect that this guidance will affect individuals unequally based on their race nationality, colour, culture or ethnic origin.	N/A	N/A



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.
5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief.	We do not expect that this guidance will affect individuals unequally based on their religion or beliefs.	N/A	N/A
5.8 People who are attracted to other people of: <ul style="list-style-type: none"> • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual). 	We do not expect that this guidance will affect individuals unequally based on their religion or beliefs.	N/A	N/A
5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.  Well-being goal – A Wales of vibrant culture and thriving Welsh language	Any patient-facing materials produced as part of the resource (Patient Information Leaflets etc) will need to be produced in Welsh in time for final publication.	Produce any Patient Information Leaflets bilingually in time for final publication.	Patient information leaflets sent for translation.
5.10 People according to their income related group. Consider people on low income, economically inactive, unemployed/workless, people	We do not expect that this guidance will affect individuals unequally based on their income.	N/A	N/A




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who are unable to work due to ill-health.			
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.	This may be impacted by the fact that there is an unequal distribution of individuals aged 18 years and under and over 65 years across Wales. We do not expect that the availability of this resource will negatively impact individuals based on where they live.	N/A	N/A
5.12 Consider others who face health inequalities: <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.	We do not expect that this guidance will affect individuals unequally based on health inequalities.	N/A	N/A




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.
<ul style="list-style-type: none">• 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.			
5.13 Consider any other groups and risk factors relevant to this project.	<p>People receiving end of life care may be more likely to receive unlicensed medicines.</p> <p>The benefits (e.g. better safety, appropriate awareness of unlicensed status of medicines) could be more pronounced in this group.</p>	<p>Produce document to help answer any questions patients may have regarding an unlicensed medicine.</p>	<p>Patient information leaflets have been developed to address additional queries and questions from patients.</p>

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. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

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>There is an unequal distribution of individuals aged 18 years and under and over 65 years across Wales (and therefore potentially more demand for services catering to this demographic in some areas).</p> <p>A reduction of adverse events – one of the desired outcomes of using the resources – could possibly reduce demand on hospital services.</p> <p>We do not expect that the availability of this resource will negatively impact individuals being able to access services.</p>	N/A	N/A
<p>6.2 People being able to improve or maintain healthy lifestyles.</p>	<p>Implementation of the resource being developed should improve safety and quality of life for patients, through greater</p>	N/A	N/A




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>Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the 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>awareness and understanding of unlicensed medicines.</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>No impact.</p>	<p>N/A</p>	<p>N/A</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. 	No impact.	N/A	N/A



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 resilient Wales			
<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>	No impact.	N/A	N/A
<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>	No impact.	N/A	N/A



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 globally responsible Wales			



7. Please complete section 7 after completing the EqHIA, and complete the action plan.

<p>7.1 Please summarise the potential positive and/or negative impacts of the policy.</p>	<p>This guidance is aimed at all patients however, certain groups are more likely to be prescribed unlicensed medicines (children, the elderly (aged over 65 years), people with mental health conditions, women expecting a baby and patients receiving end of life care). Implementation of this guidance should improve transparency and understanding around medicines patients are receiving.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken
<p>7.2 What are the key actions identified as a result of completing the EqHIA?</p>	<p>No outstanding actions have been identified at this point.</p>			
<p>7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?</p> <p>This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a</p>	<p>N/A</p>			



	Action	Lead(s)	Timescale	Actions taken
more formal and full consultation is required?				
7.4 What are the next steps?	Needs no major change	AWTTC	N/A	N/A

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