Consultation on proposed amendments to the Selected List Scheme (SLS) in Wales

Children's Rights Impact Assessment

1. Policy objectives

- What decision are you impact assessing?

  The purpose of the proposed changes is to amend Schedule 2 ("Drugs and medicines to be ordered only in specified circumstances") to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004, commonly referred to as the Selected List Scheme (SLS). The proposed amendments would remove a number of statutory prescribing restrictions and administrative requirements that are no longer considered clinically appropriate or proportionate, while retaining reliance on existing clinical guidance, prescribing governance arrangements and medicines stewardship mechanisms. The policy objective is to ensure that the regulatory framework governing NHS prescribing in Wales remains aligned with current clinical practice, reflects contemporary evidence and cost contexts, and supports timely access to clinically appropriate treatment.

  The consultation does not include the restrictions relating to gonadotrophin releasing hormone (GnRH) analogues prescribed to children and young people with gender incongruence or gender dysphoria. Those restrictions were introduced in 2024 following publication of the independent review of gender identity services for children and young people (the Cass Review) and subsequent legislative changes in Wales. Given the relatively limited time that has elapsed since those changes were made, officials did not consider it appropriate or proportionate to revisit those restrictions as part of the current review of the Selected List Scheme. The restrictions remain in force and are therefore outside the scope of the current proposals, which focus on a separate group of medicines and prescribing restrictions that have not been subject to recent review.

2. Gathering evidence and engaging with children and young People

- What existing research and data on children and young people is available to inform your specific policy? Your policy objective may impact on other policy areas – discussions with other policy teams will be an important part of the impact assessment process ensuring you have gathered a range of information and evidence.

The primary evidence used to inform this policy comprises the evidence review undertaken by the All Wales Therapeutics and Toxicology Centre (AWTTC), relevant national clinical guidance, prescribing policy, prescribing data, and consideration of the current statutory restrictions contained within the Selected List Scheme (SLS).

The proposals are largely concerned with prescribing governance rather than services specifically targeted at children and young people. Nevertheless, consideration has been given to areas where children and young people may be affected. In particular:

- Clobazam is used in the treatment of some forms of epilepsy in children and young people.
- Oseltamivir and zanamivir may be prescribed to children and young people in clinically at-risk groups in accordance with national clinical guidance.

Evidence relating to influenza management, prescribing pathways and timely access to treatment has therefore been considered.

The consultation does not include the restrictions relating to gonadotrophin releasing hormone (GnRH) analogues prescribed to children and young people with gender incongruence or gender dysphoria. These restrictions remain in force and are outside the scope of the current proposals.

- Using this research, how do you anticipate your policy will affect different groups of children and young people, both positively and negatively? Please remember policies focused on adults can impact children and young people too.

  Overall, impacts on children and young people are expected to be limited and predominantly positive or neutral.

  The majority of the proposed amendments are unlikely to affect children and young people directly. The removal of obsolete products and the proposed changes relating to medicines used in the treatment of erectile dysfunction relate primarily to adult populations and are not expected to have a direct impact on children and young people.

  For children and young people with epilepsy who are prescribed clobazam, removal of the SLS restriction may have a small positive impact by reducing the potential for administrative barriers or prescribing delays. The proposal does not alter clinical eligibility, standards of care, prescribing guidance or access to treatment.

  For children and young people within clinically at-risk groups for influenza, removal of the ministerial notification and local virological confirmation requirements associated with oseltamivir and zanamivir may support more

timely access to treatment where clinically appropriate. The proposal does not change eligibility criteria or clinical decision-making thresholds.

No specific adverse impacts have been identified. The proposals do not remove access to treatment, reduce service provision, introduce new restrictions affecting children and young people, or alter established safeguarding, prescribing or clinical governance arrangements. Existing clinical guidance and medicines governance mechanisms will continue to apply.

On this basis, the proposals are considered unlikely to adversely affect children's rights and may have a small positive impact in relation to Article 24 of the UNCRC (the right to the highest attainable standard of health) through the reduction of unnecessary administrative barriers to treatment.

- What participatory work with children and young people have you used to inform your policy? If you have not engaged with children and young people, please explain why.

No direct engagement with children and young people has been undertaken during the development of these proposals.

This approach was considered proportionate because the proposals concern amendments to a statutory prescribing framework rather than services specifically designed for children and young people. The majority of the proposed amendments have either no direct relevance to children and young people or relate to regulatory and administrative prescribing arrangements rather than changes to clinical treatment pathways.

However, the public consultation will provide an opportunity for a wide range of stakeholders, including patient groups, representative organisations, clinicians, carers and members of the public, to comment on the proposals and identify any impacts on children and young people that may not have been identified during policy development.

Officials consider that direct participation by children and young people is not necessary or proportionate in relation to these proposals given the limited nature of the anticipated impacts, but consultation responses will be reviewed to determine whether any additional child-specific considerations emerge before final decisions are taken.

3. Analysing the evidence and assessing the impact

- Using the evidence you have gathered, what impact is your policy likely to have on children and young people? What steps will you take to mitigate and/or reduce any negative effects?

Using the evidence gathered, the proposed amendments are expected to have a limited and predominantly positive or neutral impact on children and young people. The majority of the proposals either relate to obsolete or discontinued products or medicines primarily used in adult populations, and are therefore unlikely to have a direct effect on children and young people.

A small number of proposals may have indirect relevance. Clobazam is used in the treatment of some children and young people with epilepsy and removal of the Selected List Scheme restriction may reduce the potential for administrative delays associated with prescribing, without changing clinical eligibility, standards of care or access to treatment. Similarly, the removal of ministerial notification and local virological confirmation requirements for oseltamivir and zanamivir may support more timely access to treatment for children and young people in clinically at-risk groups, while retaining existing clinical eligibility criteria and prescribing guidance.

No significant adverse impacts on children and young people have been identified. The proposals do not remove access to treatment, introduce new restrictions affecting children and young people, alter clinical decision-making thresholds, or reduce the availability or quality of healthcare services. The consultation also excludes the existing restrictions relating to gonadotrophin releasing hormone (GnRH) analogues for children and young people, which remain outside the scope of the proposals.

As no significant negative impacts have been identified, no specific mitigation measures are considered necessary. However, existing clinical guidance, prescribing governance arrangements, medicines optimisation processes and professional oversight mechanisms will continue to apply. Consultation responses will also be reviewed to identify any child-specific impacts that may not have been identified during policy development, and any emerging issues will be considered before final decisions are taken.

- How does your proposal enhance or challenge children's rights, as stipulated by the UNCRC articles and its Optional Protocols? Please refer to the articles to see which ones apply to your own policy.

Overall, the proposals are considered compatible with Article 24 of the UN Convention on the Rights of the Child (the right to the highest attainable standard of health), as they are intended to reduce unnecessary administrative barriers and support timely access to clinically appropriate treatment, while maintaining existing clinical safeguards.

UNCRC Articles or Optional Protocol	Enhances (X)	Challenges (X)	Explanation
Article 24 – Right to the highest attainable standard of health	X		The proposals do not change clinical eligibility, standards of care or access to treatment for children and young people. Where relevant, removal of prescribing restrictions or administrative requirements may support more timely access to clinically appropriate treatment. No adverse impacts on children's access to healthcare have been identified.

- Consider whether any EU Citizens Rights (as referenced in the Equality Impact Assessment) relate to young people up to the age of 18.

  No specific impacts have been identified for EU, EEA or Swiss children and young people. The proposals do not affect rights of residence, access to healthcare, education or social security, and apply equally to all eligible children and young people accessing NHS services in Wales, irrespective of nationality.

4. Ministerial advice and decision

- How will your analysis of these impacts inform your ministerial advice?

  The outcomes of the CRIA will be included in the ministerial advice, providing assurance that the proposals are compatible with the rights and wellbeing of children and young people, including Article 24 of the UNCRC (the right to the highest attainable standard of health). The findings support proceeding with consultation, while ensuring that consultation responses are reviewed for any child-specific impacts or unintended consequences prior to final policy decisions being taken.

5. Communicating with Children and Young People

- If you have sought children and young people's views on your proposal, how will you inform them of the outcome?

No direct engagement with children and young people has been undertaken during the development of these proposals.

6. Monitoring and Review

It is essential to revisit your CRIAs to identify whether the impacts that you originally identified came to fruition, and whether there were any unintended consequences.

Where you are taking forward secondary legislation, it will not be sufficient to rely on the CRIA for the primary legislation; you will need to update the CRIA to consider how the details of the proposals in the regulations or guidance may affect children.

The policy lead can revisit the published version of their CRIA, rename it as a review of the original CRIA, and update the evidence of impact. The reviewed impact assessment should be presented to Ministers with any proposals to amend the policy, practice or guidance. This review CRIA should also be published.

- Please outline what monitoring and review mechanism you will put in place to review this CRIA.

  The impact of the proposed amendments on children and young people will be monitored through existing NHS Wales prescribing governance and monitoring arrangements. This will include review of prescribing data, implementation feedback from health boards and professional stakeholders, and consideration of any child-specific issues raised through the public consultation process. Particular attention will be given to medicines that may be relevant to children and young people, including clobazam and influenza antivirals, to identify any unintended consequences arising from the removal of prescribing restrictions or administrative requirements.

  The CRIA will be reviewed as part of the post-consultation policy development process and prior to any final decision on legislative amendments. Should the proposals be implemented, the CRIA will be revisited as part of any post-implementation review to assess whether the anticipated impacts on children and young people have materialised and whether any unforeseen impacts have emerged.

- Following this review, are there any revisions required to the policy or its implementation?

  At this stage, no revisions to the policy or its implementation have been identified as necessary as a result of the CRIA. The assessment has concluded

that the proposals are likely to have limited and predominantly positive or neutral impacts on children and young people and do not adversely affect access to treatment, clinical eligibility criteria, standards of care or existing safeguards.

However, the findings of the consultation and any subsequent monitoring will be considered before final decisions are taken. If evidence emerges of unintended impacts on children and young people, officials will consider whether revisions to the policy, implementation approach, guidance or monitoring arrangements are required to mitigate those impacts. At present, no such revisions are considered necessary.