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

Integrated Impact Assessment

What action is the Welsh Government considering and why?

In narrative form, please describe the issue and the action proposed by the Welsh Government. How have you applied / will you apply the five ways of working in the Well-being of Future Generations (Wales) Act 2015 to the proposed action, throughout the policy and delivery cycle?

The consultation concerns proposed amendments to the Selected List Scheme (SLS) in Wales. The SLS restricts NHS prescribing of a limited number of medicines to defined patient groups or clinical circumstances set out in legislation. Welsh Government is proposing to remove a number of restrictions that no longer appear necessary or proportionate, including restrictions relating to clobazam, Locabiotal® aerosol, Niferex® Elixir, Nizoral® 2% cream, drugs used in the treatment of erectile dysfunction, and the ministerial notification and local virological confirmation requirements for oseltamivir and zanamivir. The central issue is whether statutory restrictions introduced for historic reasons remain justified in light of current clinical practice, product availability, generic pricing and the existence of alternative prescribing controls such as formularies, national guidance and prescribing indicators.

The proposals reflect a long-term approach to maintaining a prescribing framework that remains relevant as evidence, products and services evolve. Some restrictions now relate to discontinued or obsolete products and no longer provide clinical or financial benefit. Others reflect changes in the wider prescribing context, including the availability of lower-cost generics and established stewardship mechanisms. For example, restrictions on erectile dysfunction treatments were introduced before widespread generic availability, while clobazam remains subject to statutory control despite broader benzodiazepine stewardship arrangements. For influenza antivirals, the proposal reflects the need for a more responsive approach to changing epidemiology and service pressures. In England, central notification requirements were removed in October 2025, supporting more timely clinician-led prescribing.

From a prevention perspective, the proposals seek to reduce harm arising from outdated administrative controls and restricted access where these are no longer the most effective means of managing risk. Removal of obsolete entries reduces legislative complexity and the potential for confusion. Removal of clobazam restrictions may reduce delays in treatment where endorsement requirements are

not met. Removal of restrictions on erectile dysfunction medicines may improve equity of access, reduce reliance on unregulated supply, and support earlier identification of underlying conditions. Removal of notification requirements for antivirals may improve timely access for at-risk patients. These changes do not remove the need for stewardship, which will continue through clinical guidance, formularies and prescribing oversight mechanisms.

The proposals demonstrate integration across public policy objectives. They support proportionate use of legislation, improve access to services, reduce administrative burden and align with established prescribing governance in NHS Wales. The erectile dysfunction proposal has links to equality and early intervention, while the antivirals proposal supports public health preparedness and winter resilience within existing clinical criteria.

In terms of collaboration, the consultation is aimed at NHS organisations, prescribers, pharmacists, professional bodies, manufacturers and the public. The policy rationale draws on evidence from NICE guidance, Public Health Wales surveillance, Welsh prescribing data and established national oversight arrangements. Delivery of the proposals will continue to rely on collaboration between Welsh Government, health boards, primary care and national bodies to ensure that removal of statutory controls is supported by clear guidance, local implementation and monitoring arrangements.

The consultation also supports involvement by inviting views not only on agreement with each proposal but also on potential impacts and unintended consequences. The people most affected include patients, prescribers, pharmacists and NHS organisations. Issues likely to be identified include access to treatment, prescribing clarity, workload, affordability, equity and patient safety. The consultation provides an opportunity to test assumptions about prescribing volume, system impact and equity, particularly for the erectile dysfunction and influenza antiviral proposals, where impacts are likely to be greater than for the removal of obsolete products.

The main arguments in favour of the proposals are that some SLS entries are obsolete, some restrictions no longer reflect current costs or practice, statutory controls are slow to update, and alternative stewardship mechanisms already exist. The main arguments against are that removal of restrictions could increase prescribing, expenditure or inappropriate use, and may increase workload in primary care. These considerations vary by proposal: the case for removing discontinued products is clear, while changes affecting clobazam, erectile dysfunction medicines and antivirals require greater reliance on non-statutory controls. Evidence gaps remain, particularly regarding the scale of any increase in prescribing and overall system impact. These can be addressed through consultation responses, prescribing data monitoring and post-implementation review. Current prescribing data indicate

that antiviral use remains low in Wales, suggesting that existing controls are restrictive.

In terms of costs and savings, impacts are expected to differ by proposal. Removal of obsolete products is not expected to have a material cost effect. Removal of restrictions on erectile dysfunction medicines and antivirals may increase prescribing and expenditure, but this may be offset by lower generic prices, reduced administrative burden, earlier treatment and avoided downstream costs. These proposals would be funded through existing NHS prescribing arrangements. Costs can be mitigated through prescribing guidance, monitoring and collaboration with health boards. Overall, the proposals update the SLS to reflect current practice, remove redundant controls and place greater reliance on existing prescribing governance mechanisms.

Conclusion

How have people most likely to be affected by the proposal been involved in developing it?

The proposed amendments to the Selected List Scheme (SLS) have been informed by prescribing data, national clinical guidance, established prescribing governance arrangements within NHS Wales, and wider UK policy developments.

The principal mechanism for involvement will be a public consultation targeted at NHS organisations, prescribers, pharmacists, professional bodies, representative organisations, pharmaceutical manufacturers and suppliers, patients, carers and members of the public.

The consultation will seek views not only on the proposed changes themselves, but also on their potential impacts, including any unintended consequences. This includes impacts on access to treatment, prescribing behaviour, workload, equity and financial implications.

In line with the Well-being of Future Generations (Wales) Act 2015, the consultation provides an opportunity for people with protected characteristics and those who may experience barriers to accessing care to contribute their views.

A proportionate Children's Rights Impact Assessment (CRIA) has been completed. While impacts on children and young people are expected to be limited, the assessment identified a connection to medicines that may be prescribed to children and young people and concluded that completion of a CRIA was appropriate.

Proportionate Equality and Welsh Language Impact Assessments have also been completed. Neither assessment identified any significant adverse impacts.

Consultation materials will be published bilingually in accordance with Welsh Language Standards.

The consultation therefore provides a proportionate and inclusive process through which those most likely to be affected can inform the development of the final policy.

What are the most significant impacts, positive and negative?

The most significant impacts of the proposed amendments relate to access to treatment, equity, system efficiency and prescribing governance. Overall, the impacts are assessed as predominantly positive but limited to moderate in scale.

Positive impacts

Improved access and timeliness of care

Removal of unnecessary statutory restrictions is expected to support more timely and consistent access to clinically appropriate medicines. This is particularly relevant to influenza antivirals, where removal of notification requirements may reduce delays in initiating treatment, and clobazam, where removal of endorsement requirements may reduce administrative barriers and the risk of prescription disruption.

Improved equity of access

Removal of restrictions on medicines used to treat erectile dysfunction is expected to improve equity of access by reducing reliance on private purchase or over-the-counter supply. This may particularly benefit individuals who are unable to afford treatment privately, helping to reduce inequalities in access.

Reduced administrative burden and improved system efficiency

The proposals remove obsolete products and outdated administrative controls, simplifying the prescribing framework, reducing unnecessary complexity for prescribers and dispensers, and supporting more efficient use of clinical and administrative resources.

More responsive prescribing governance

The proposals support greater reliance on clinical guidance, local and national prescribing oversight, and data-driven monitoring. This enables a more responsive and evidence-based approach to influencing prescribing behaviour than statutory controls alone.

Potential wider health benefits

Improved access to treatment may encourage earlier engagement with healthcare services and create opportunities to identify underlying health conditions. More timely access to influenza antivirals may also help reduce complications in clinically at-risk groups.

Negative or uncertain impacts

Potential increase in prescribing volume and expenditure

Removal of restrictions may increase prescribing in some areas, particularly for medicines used in the treatment of erectile dysfunction and influenza antivirals. This may increase NHS medicines expenditure, although the scale remains uncertain.

Potential increase in primary care workload

Greater access to treatment may generate additional consultations within primary care. Any increase in workload is expected to be modest and may be partly offset by reduced administrative requirements.

Risk of variation in prescribing practice

Greater reliance on non-statutory controls may create some variation in prescribing practice between health boards or individual clinicians if implementation is not supported by consistent guidance and communication.

Evidence gaps and uncertainty

Uncertainty remains regarding the scale of any increase in prescribing, the net financial impact of the proposals, and how clinicians and patients may respond to the removal of statutory restrictions.

Overall, the proposals are expected to improve access, equity and timeliness of care, reduce unnecessary administrative burden and maintain safety and effectiveness through existing prescribing governance arrangements. Any negative impacts are considered limited and manageable.

In light of the impacts identified, how will the proposal:

- **maximise contribution to our well-being objectives and the seven well-being goals; and/or,**
- **avoid, reduce or mitigate any negative impacts?**

The proposals have been designed to maximise benefits while managing potential risks through established systems of clinical governance and oversight.

Maximising positive impacts

Positive impacts will be supported through:

- clear communication and implementation guidance for prescribers and healthcare organisations;
- continued alignment with national clinical guidance, including NICE recommendations and public health advice;
- integration with health board formulary arrangements and medicines optimisation processes; and
- use of prescribing data, indicators and benchmarking to support evidence-based prescribing practice.

These measures will help ensure that improved access to treatment is accompanied by appropriate and clinically effective prescribing.

The proposals are also expected to contribute positively to a more equal Wales by reducing financial and administrative barriers to treatment, and to a healthier Wales by supporting timely access to clinically appropriate medicines.

Mitigating negative impacts

Potential increases in prescribing, expenditure or workload will be managed through:

- existing prescribing governance arrangements, including audit, feedback and health board oversight;
- prescribing indicators and benchmarking to identify unwarranted variation;
- professional judgement and clinical accountability;
- medicines optimisation support; and
- ongoing monitoring of prescribing patterns and expenditure.

Where evidence emerges of inappropriate prescribing, inequitable access or significant variation in practice, existing governance mechanisms can be used to provide additional guidance, targeted interventions or enhanced monitoring.

No specific mitigation measures are required in relation to equalities, children's rights, the Welsh language or biodiversity, as the relevant impact assessments did not identify any significant adverse impacts in these areas. The proposals do not remove stewardship arrangements; rather, they place greater reliance on prescribing

governance mechanisms that are more flexible and responsive than statutory controls.

How will the impact of the proposal be monitored and evaluated as it progresses and when it concludes?

The impact of the proposed amendments will be monitored and evaluated using existing data sources and governance arrangements within NHS Wales.

Monitoring will include:

- Prescribing data analysis, including volume, variation between health boards, and trends over time;
- Financial monitoring, assessing any changes in medicines expenditure associated with the affected products;
- Review of prescribing indicators, where available, to assess appropriateness and consistency of use; and
- Feedback from health boards, prescribers and stakeholders, including any issues identified during implementation.

Particular attention will be given to:

- prescribing of erectile dysfunction medicines following removal of restrictions;
- prescribing of influenza antivirals outside traditional notification processes; and
- any indication of unintended inequity or variation in access.

This approach ensures that the proposals can be assessed and refined over time, maintaining alignment with clinical practice, system priorities and the principles of prudent and proportionate prescribing.