Regulatory Impact Assessment

A Regulatory Impact Assessment on proposals to amend the Selected List Scheme (SLS) in Wales

Introduction and Guidance

Regulatory Impact Assessments (RIAs) provide Welsh Ministers, the Accounting Officer, Senedd Cymru and stakeholders with information on the likely impacts of proposed legislation. RIAs can be regarded as:

- a process to help Welsh Ministers consider the impact of proposed regulation on individuals, groups and organisations;
- a tool to enable Welsh Ministers to weigh the costs and benefits of all available options before implementing a policy; and
- a means of presenting evidence on the positive and negative effects of legislative interventions.

The Welsh Government has undertaken a review of prescribing restrictions contained within the Selected List Scheme (SLS). The SLS, set out in Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004, restricts NHS prescribing of specific medicines to defined patient groups or clinical circumstances.

This RIA assesses the likely costs, benefits and risks associated with proposed amendments to the SLS consisting of:

- removal of clobazam from the SLS;
- removal of Locabiotal® aerosol from the SLS;
- removal of Niferex® Elixir 30 ml Paediatric Dropper Bottle from the SLS;
- removal of Nizoral® 2% cream from the SLS;
- removal of restrictions on drugs used in the treatment of erectile dysfunction; and
- removal of the ministerial notification and local virological confirmation requirements associated with oseltamivir and zanamivir.

Options

Option 1 – Do Nothing

Retain all current restrictions within the SLS with no legislative change.

Under this option:

- obsolete and discontinued products would remain listed within legislation;
- existing restrictions on clobazam would continue;
- restrictions on prescribing medicines used in the treatment of erectile dysfunction would remain unchanged; and
- ministerial notification and local virological confirmation requirements for oseltamivir and zanamivir would continue.

This option would maintain the current level of statutory control and avoid any potential increase in prescribing activity arising from the proposed changes.

However, retaining the status quo would mean that the prescribing framework would continue to contain restrictions that may no longer reflect current clinical practice, existing evidence, medicines stewardship arrangements, prescribing governance systems or contemporary medicine costs.

For these reasons, this option is not preferred.

Option 2 – Remove all restrictions contained within the SLS

This option would remove all prescribing restrictions currently contained within Schedule 2.

Whilst this would simplify the legislative framework and maximise clinical discretion, it would also remove restrictions which Welsh Ministers continue to consider necessary or appropriate.

This option would therefore go beyond the scope of the review and is considered disproportionate.

For these reasons, this option has been discounted.

Option 3 – Revise the current framework through targeted amendments to the SLS (Preferred Option)

Under this option, specific restrictions would be removed where they are no longer considered clinically appropriate, proportionate or necessary.

The amendments would:

- remove entries relating to obsolete or discontinued products;
- remove restrictions relating to clobazam;
- remove restrictions relating to medicines used in the treatment of erectile dysfunction; and
- remove administrative requirements relating to oseltamivir and zanamivir.

This option allows the legislative framework to be updated whilst continuing to rely on established prescribing governance mechanisms, including:

- NICE guidance;
- local and national formularies;
- medicines optimisation arrangements;
- prescribing indicators;
- professional accountability; and
- health board oversight arrangements.

This option is the Welsh Government's preferred approach.

Welsh Government Costs

The proposals are not expected to generate significant costs for Welsh Government.

Minor costs will arise from:

- translation and publication; and
- implementation communications.

These costs will be met from existing budgets and staffing resources.

No additional programme funding is required.

Public Sector Costs

The principal public sector costs relate to the possibility that removal of selected prescribing restrictions may lead to increased prescribing activity in some areas.

Erectile Dysfunction Medicines

Removal of restrictions may increase NHS prescribing of medicines used in the treatment of erectile dysfunction.

Any increase in prescribing activity could increase NHS medicines expenditure. However, the current cost environment differs significantly from that which existed when restrictions were originally introduced, with many relevant medicines now available as lower-cost generic products.

In addition, improved access may reduce reliance on private purchasing and support earlier engagement with healthcare services.

The scale of any increase in prescribing remains uncertain.

Oseltamivir and Zanamivir

Removal of ministerial notification and local virological confirmation requirements may increase prescribing activity during periods of influenza circulation.

Any increase in expenditure may be partially offset through:

- more timely treatment;
- improved access for clinically eligible patients;
- avoidance of complications; and
- reduced demand on other parts of the healthcare system.

Current prescribing data suggest antiviral prescribing in Wales is relatively low, indicating that the existing controls are restrictive.

Clobazam

No significant financial impact is anticipated.

The proposal is primarily intended to remove unnecessary administrative requirements and reduce complexity associated with prescribing and dispensing.

Local Authorities

The implementation and enforcement of these proposals will not constitute additional costs for local authorities.

No additional costs to the justice system, emergency services or policing are anticipated.

Cost to Individuals

The proposals are expected to have either neutral or positive impacts on individuals.

The most significant impact relates to medicines used in the treatment of erectile dysfunction.

Current restrictions may require some individuals to purchase treatment privately or seek alternative routes of access. Removal of restrictions may reduce out-of-pocket costs and improve access based on clinical need rather than ability to pay.

The proposals are not expected to increase costs for patients.

Cost to Community Pharmacies and Pharmaceutical Suppliers

No significant costs are anticipated.

Community pharmacies would continue to dispense medicines through existing NHS arrangements.

Some increase in dispensing activity may occur if prescribing volumes increase. However, no new compliance requirements, reporting obligations or regulatory burdens would be imposed.

Manufacturers and wholesalers may experience modest changes in demand for affected medicines, although the scale of any impact is considered to be low.

Benefits

Modernisation of Legislation

The proposals will ensure that the statutory prescribing framework better reflects:

- contemporary clinical practice;
- current evidence;
- existing medicines governance arrangements; and
- current medicine costs and availability.

Improved Access

Removal of selected restrictions may improve access to clinically appropriate treatment where restrictions are no longer considered necessary.

This is particularly relevant to:

- medicines used in the treatment of erectile dysfunction; and

- influenza antivirals.

Reduced Administrative Burden

The proposals are expected to reduce unnecessary administrative complexity for:

- prescribers;
- pharmacists;
- health boards; and
- Welsh Government.

This is particularly relevant to clobazam and influenza antivirals.

More Proportionate Regulation

The proposals support the principle that statutory restrictions should be retained only where there remains a clear and evidence-based justification.

Equity of Access

Removal of restrictions on medicines used in the treatment of erectile dysfunction may reduce financial barriers and support more equitable access to treatment for individuals who are unable to access private alternatives.

Risks

Increased Prescribing Activity

Removal of restrictions may lead to increased prescribing and medicines expenditure in some areas.

Increased Demand on Primary Care

Some proposals may generate additional consultation activity within primary care settings.

Variation in Prescribing Practices

Greater reliance on non-statutory controls could lead to variation in prescribing practices between clinicians or health boards.

These risks are expected to be mitigated through:

- NICE guidance;
- local and national formularies;
- prescribing indicators;

- medicines optimisation teams;
- routine monitoring; and
- health board governance arrangements.

Conclusion

The preferred option is **Option 3 – Revise the current framework through targeted amendments to the Selected List Scheme**.

The proposals are expected to:

- update the statutory prescribing framework;
- remove obsolete and unnecessary restrictions;
- improve access to clinically appropriate treatment;
- reduce administrative burden; and
- support a more proportionate approach to prescribing regulation.

While some increases in prescribing activity and expenditure may occur, these are expected to be manageable through existing NHS Wales governance arrangements.

On balance, the benefits of updating the SLS are considered to outweigh the potential costs.

Competition Assessment

Competition Filter Test

Question	**Response**
Does any firm have more than 10% market share?	unknown/not assessed
Does any firm have more than 20% market share?	unknown/not assessed
Do the three largest firms together have at least 50% market share?	unknown/not assessed
Would costs affect some firms substantially more than others?	No

Question	Response
Is the regulation likely to affect market structure?	No
Would the regulation lead to higher set-up costs for new suppliers?	No
Would the regulation lead to higher ongoing costs for new suppliers?	No
Is the sector characterised by rapid technological change?	No
Would the regulation restrict the ability of suppliers to choose price, quality, range or location?	No

Conclusion

The proposed amendments are not expected to have a significant effect on competition. The proposals do not create new regulatory requirements, impose additional compliance costs, restrict market entry, alter licensing arrangements, or favour particular manufacturers or suppliers. Instead, they remove or amend selected prescribing restrictions within the NHS prescribing framework.

While the proposals may result in modest changes to demand for certain medicines, particularly medicines used in the treatment of erectile dysfunction and influenza antivirals, any such effects are expected to arise from changes in prescribing behaviour rather than from restrictions on competition. The proposals apply equally to all suppliers of affected medicines and do not influence the ability of manufacturers, wholesalers or pharmacies to compete within the market.

On this basis, the proposals are not considered likely to have a significant adverse impact on competition.

Post-Implementation Review

The impact of the legislative changes will be monitored through existing NHS Wales prescribing and medicines governance arrangements.

Monitoring will include:

- prescribing volumes for affected medicines;
- expenditure trends;
- variation between health boards;

- implementation feedback from stakeholders;
- prescribing governance data; and
- identification of any unintended impacts on access, equity or service demand.

A post-implementation review should be undertaken approximately 12–24 months after implementation to assess whether the policy objectives have been achieved and whether any further amendments to the SLS are required.