

Business and Regulatory Impact Assessment

1. Title of Proposal

The National Health Service (Scotland) Act 1978 (Independent Health Care) Modification Order 2024 (“the Modification Order”)

The Public Services Reform (Scotland) Act 2010 (Commencement No. 8) Order 2024 (“the Commencement Order”)

The Healthcare Improvement Scotland (Fees) Regulations 2024 (“the Fees Regulations”)

2. Purpose and Intended Effect

Background

The Scottish Government wants all healthcare provided to people in Scotland to be safe, effective, reliable and carried out by those who are appropriately trained.

To achieve this vision, independent healthcare services provided in Scotland need to be effectively regulated. Regulation should reflect the current landscape of provision through encompassing pharmacists and pharmacy technicians who provide services in independent clinics (which will not include registered pharmacies and/or services provided under a NHS contract), and independent medical agencies, including those that operate entirely online based in Scotland.

It should be a key consideration that regulation of independent healthcare services is self-funded by Healthcare Improvement Scotland (“HIS”) through registration and continuation fees collected from registered independent healthcare services. The fees must be based upon a set market cost in order to facilitate the regulation and inspection of the varied types of independent healthcare services.

Objective

For the purpose of this Business and Regulatory Impact Assessment (BRIA), we considered what impact the amendments made by the Modification Order would have on independent healthcare services in Scotland and their business. We also took into consideration, the commencement of HIS functions in relation to independent medical agencies, and the proposed increase of fees charged by HIS in order to fund the regulation and inspection activities of registered services. Our hope is that these changes will support HIS in their work to ensure a better-regulated and self-funding system within the independent healthcare sector.

In broad terms, the proposed package of Scottish statutory instruments (the Modification Order, the Commencement Order and the Fees Regulations) make the following changes:

1. Enabling HIS to regulate independent clinics where services are provided by pharmacists and pharmacy technicians. In response to the consultation in 2020, 90% of respondents agreed that services provided by pharmacists who

undertake independent healthcare services outwith the terms of an NHS contract should be regulated by Healthcare Improvement Scotland. We are aware that some pharmacy professionals are offering non-surgical cosmetic procedures and other services, such as travel advice or weight loss clinics, in premises other than registered pharmacies.

2. Enabling HIS to de-register independent healthcare services that fail to pay their continuation fees. Currently, HIS have no meaningful recourse against providers who fail to pay continuation fees owed. The Scottish Government are currently providing £260,000 as recurring funding to HIS for their regulation of independent healthcare. Making this regulatory change would be an important step in moving to a self-funded model.
3. Enabling HIS to regulate independent medical agencies, including online-only based in Scotland. This is achieved by bringing into force HIS functions in relation to independent medical agencies (“IMAs”) by virtue of the Commencement Order. As part of the proposal to commence HIS’ functions in relation to IMAs, the definition of IMAs will be amended to be aligned with the list of healthcare professionals in the definition of an independent clinic, including the addition of pharmacists and pharmacy technicians. This amendment is being made by virtue of the Modification Order. The amendments will come into force on the same day as the provisions in the Commencement Order are commenced.
4. This SSI will enable HIS under Section 10Z5 of the National Health Service (Scotland) Act 1978 (“the 1978 Act”) to be able to prescribe the maximum fees which HIS may impose in respect of Independent Medical Agencies “IMAs” (IMAs; not previously included as a service in fees regulations); and raise the maximum fees which may be imposed by HIS on all independent healthcare services in respect of applications for registration or cancellation of registration of independent healthcare services; the annual continuation of any such registration; and applications for the variation or removal of a condition of registration. In prescribing the maximum fees, HIS will have regard to its reasonable expenses in being able to carry out its functions, as required under section 10Z5(3) of the 1978 Act. It is important for patient safety reasons that healthcare is adequately regulated and this SSI will form part of measures to commence provisions in the 1978 Act in respect of IMAs.

Along with the Modification Order, the Commencement Order and the Fees Regulations, we are laying regulations (“the Inspection Regulations”) to amend the Healthcare Improvement Scotland (Inspections) Regulations 2011. The amendments made relate to inspection of medical records and we do not consider that this directly impacts businesses.

Rationale for Government intervention

The Modification Order includes amendments to bring the regulation of independent clinics where services are provided by pharmacists and pharmacy technicians under HIS regulation. The purpose is to increase public safety and ensure that where pharmacists and pharmacy technicians provide services from independent clinics to service users in Scotland (which will not include registered pharmacies and/or premises where services are provided under an NHS contract), that those clinics can be regulated by HIS.

The changes regarding independent medical agencies (“IMAs”), including online services, are particularly urgent. Currently, medical agencies providing online-only services in Scotland are not required to be registered with HIS. In order to bring these services under the regulation of HIS, it is necessary to commence HIS functions relating to independent medical agencies. As part of the proposal to commence HIS’ functions in relation to IMAs, the definition of IMAs will be amended to be aligned with the list of healthcare professionals in the definition of independent clinic, including the addition of pharmacists and pharmacy technicians.

The fees model that was set up should have allowed HIS to self-fund the regulation of independent healthcare, however, in recent years this has become increasingly challenging, mainly due to the diverse landscape of the sector. From 2022-2023, a baselined allocation of £260,000 has been provided to HIS from SG to cover the shortfall in order sufficiently regulate the sector.

With these changes HIS will be able to set an appropriate and service specific registration and continuation fee structure that will allow them to tailor the fees to cover the cost in a variety of independent healthcare regulatory activities including inspections, risk assessments, information gathering, complaints investigation and enforcement.

In relation to cancellation of registration, although fees defaulters would not be the sole reason for HIS struggling to self-fund, the changes made by the Modification Order will provide HIS with a meaningful sanction against registered providers who fail to pay their continuation fees. We assess that this deterrent is likely to have a positive impact on the willingness of providers to pay the fees they owe.

3. Consultation

Within Government

The Independent Healthcare policy team met with Pharmacy colleagues to discuss the proposed amendments, in particular the introduction of regulation of independent clinics and medical agencies provided by pharmacists and pharmacy technicians.

In addition, the draft consultation (see below) was shared with colleagues in the Chief Medical Officer Directorate, Chief Dental Officer Directorate, Chief Nursing Officer Directorate, and Regulation of Healthcare Professionals team.

Public Consultations

We ran our first public consultation on the Modification Order, the Commencement Order, and the Inspection Regulations between 1 February 2023 and 26 April 2023. The consultation was drafted with input from the teams within Scottish Government who are responsible for Independent Healthcare Regulation and the sponsorship of HIS.

We received 67 responses to the consultation, of which 20 were from healthcare and related organisations (both independent and publicly funded), and 47 from members

of the public. An analysis of the responses and the Scottish Government response has been published on the Scottish Government website. Where respondents gave permission for their responses to be made public, we will also publish these on the Scottish Government website. We have taken full account of the consultation responses in preparing the Modification Order, the Commencement Order and the Inspection Regulations.

It was noted that the first consultation did not include an assessment of the fees for commencement of regulation of IMA's. Therefore, a further consultation to introduce the proposed new fees for IMA's had to be conducted, which gave the opportunity to consult on the overall regulation fees for independent healthcare services at this stage before taking all proposals forward.

The second consultation undertaken, was a shortened, technical consultation as the fees issue is specific to independent healthcare services and we targeted independent healthcare service providers to seek their views. The consultation opened on 16 October 2023 and closed on 11 December 2023.

We received 105 responses to the independent healthcare fees consultation, of which 22 identified themselves as responding on behalf of healthcare and related organisations (both independent and publicly funded), and 83 from individuals, however, many of them identified as working in the independent healthcare sector.

As with the first consultation, an analysis of the responses will be published on the Scottish Government website, and where respondents gave permission for their responses to be made public, we will also publish these on the Scottish Government website. We have taken full account of the consultation responses in preparing the Scottish Statutory Instruments.

Business

The changes to the regulatory framework (brought about by the Modification Order, the Commencement Order and the Fees Regulations) are expected to have an impact on how independent healthcare services operate in Scotland. The scope of the changes will require independent clinics where services are provided by pharmacists and pharmacy technicians, and medical agencies (including wholly online services based in Scotland) to adhere to certain safety standards and inspections by HIS.

Moreover, although the changes will also allow HIS to provide a meaningful sanction against registered providers who refuse to pay their continuation fees it has been recognised that within the ongoing cost of living crisis an increase in fees could potentially impact businesses operating within the independent healthcare sector.

Following the first consultation, the Scottish Government reached out to a number of organisations who believed they might be impacted by the proposed changes seeking specific feedback on how the changes would impact their business.

The following organisations agreed to provide feedback:

- Circle Health Group
- British College of Aesthetic Medicine

- Community Pharmacy Scotland
- Dermal Clinic
- Beautox Clinic
- Beautifulm Aesthetics Medical Clinic

Ultimately, we only received feedback from one business, and details of their response can be found in Section 8: Scottish Firms Impact Test.

The low number of responses we gathered on our first Scottish Firms Impact Test was not a useful measure of how our proposed changes would impact independent healthcare businesses. With that in mind, following the second consultation, we decided to re-ask how the changes proposed in the first consultation may impact individual business, along with the changes in fees as detailed in the second consultation. We also reached out to a significantly larger number of organisations and received a much higher response rate, details of which can be found in Section 8: Scottish Firms Impact Test.

- A&M Acupuncture Clinic
- Ash Aesthetics
- Beauty Health Aesthetics
- Bethesda Hospice
- DentOutline
- Diverse Diagnostics
- Espacio Medical Aesthetics
- Flying Smiles
- GP PLUS
- Harbour Clinic Aesthetics
- Liver Scan Group
- Nichola Maasdorp No 4 Clinic
- Platinum Medi Cosmetic Clinic
- Radox Health London Ltd
- Ruth McWilliam Acupuncture
- Simply Skin Facial Aesthetics
- The Canmore Clinic
- Unity Aesthetics
- Waverley Dental
- Alert Health Ltd
- Ayrshire Eye Clinic
- Belle Viso Medical Aesthetics Ltd
- British Dental Association
- Dermal Clinic Limited
- Enhanced Facial Aesthetics
- Esthetique Inverness Ltd
- Glasgow Medical Rooms
- Hampden Sports Clinic
- Life Fit Wellness
- LL Aesthetics
- Ohh! Oral Health Hygienist Ltd
- Proclaim Care
- Revive MS Support
- Sharon Muir Medical Aesthetics
- Tayside Complete Health
- United Healthcare Global Medical
- Wassmuth-Gibbs Ltd – Teviot Dental FACE
- Westbourne Medical Studios

4. Options

Option 1 – Bring forward the Modification Order, Commencement Order, and Fees Regulations

Modification Order

Amends the National Health Service (Scotland) Act 1978 to:

- Enable HIS to regulate independent clinics where services are provided by pharmacists and pharmacy technicians.
- To amend the definition of Independent Medical Agencies (“IMAs”) to be aligned with the list of healthcare professionals in the definition of independent clinic, including the addition of pharmacists and pharmacy technicians.

- Give HIS power to de-register independent healthcare providers who fail to pay continuation fees.

Commencement Order

Commences provisions in the National Health Service (Scotland) Act 1978 to:

- Allow HIS to regulate independent medical agencies (“IMAs”), including online-only independent medical providers based in Scotland.

Fees Regulations

Revoke and replace the Healthcare Improvement Scotland (Fees) Regulations 2016 in order to:

- Enable HIS to prescribe the maximum fees in which HIS may impose in respect of Independent Medical Agencies (“IMAs” not previously included as a service in the fee regulations);
- Enable HIS to raise the maximum fees which may be imposed by HIS on all independent health care services in respect of applications for registration or cancellation of registration of independent health care services; the annual continuation of any such registration; and applications for the variation or removal of a condition of registration. This will aid HIS in being able to cover the costs of a variety of regulatory activity including inspections, risk assessments, information gathering, complaints investigation and enforcement.

Option 2 – Non Regulatory

There are no viable non-regulatory options available to us which could possibly achieve the desired outcomes.

Modification Order:

- Guidance could be issued to independent pharmacists and pharmacy technicians on best practice, but could not be enforced if standards are not seen to be met.
- Without legislative change, HIS cannot de-register providers who do not pay fees, no non-regulatory option exists.

Commencement Order:

- Guidance could be issued to IMAs, but nothing enforced without regulatory change.
- The definition of IMAs cannot be amended without legislative change.

Fees Amendment:

- HIS cannot charge more than the legislation permits. There is no viable non-regulatory option available to achieve the same goal.

Option 3 – Do Nothing

We could do nothing and not amend or commence the existing legislation. Should we do nothing, services that are provided by pharmacists and pharmacy technicians (other than where services are provided in a registered pharmacy or from premises where services are provided under an NHS contract) would be able to continue to operate without being subject to HIS regulation and inspection. This could have a potential impact on public safety as there is no guarantee that the services that are being provided are adhering to safe practice.

Independent medical agencies, in particular online services based in Scotland, would be able to continue to operate unregulated, posing a public health and reputational risk as other UK nations have existing regulation in this area.

In relation to cancellation of registration, HIS currently has no meaningful sanctions within their power for registered providers who do not pay their continuation fees. The Scottish Government would have to continue to provide funding (or potentially increase funding) to HIS each year to support regulation of independent healthcare services, instead of this work being self-funded.

5. Sectors and Groups Affected

For the amendments relating to continuation fees, any business that is registered with HIS as a provider of independent health care services is liable to have registration cancelled should they fail to pay their continuation fees.

As a result of the changes made by the Modification Order and the Commencement Order the following businesses would require to register with HIS, be required to meet specific standards and be inspected in order to continue to operate:

- Independent clinics where services are provided by pharmacists and pharmacy technicians
- Independent Medical Agencies including services provided by dental practitioners, registered nurses, registered midwives, dental care professionals, pharmacists and pharmacy technicians and wholly online services based in Scotland

The changes made by the Fees Amendment will impact all independent healthcare services which are regulated by Healthcare Improvement Scotland. Fees for all businesses would potentially increase.

6. Benefits

With Option 1, the proposed changes will permit HIS to regulate independent medical agencies, which includes wholly online agencies based in Scotland, and services provided by pharmacists and pharmacy technicians from independent clinics, which will benefit public safety as these services will have to meet the strict health and safety as required by HIS regulated services.

Regulation ensures providers are aware of the standards for safety and quality of a healthcare service, and provides the public with assurance that the service they are using meets specific safety and quality standards. HIS, through inspection, will ensure providers keep track of how well they are complying with these standards, protecting the public interest.

The Scottish Government currently provides funding to HIS for their regulation of independent healthcare, even though this is meant to be self-funded. Making the changes in relation to cancellation of registration would be an important step in moving back towards to a self-funded model.

Allowing HIS to increase maximum fees is a precautionary measure, giving HIS the flexibility to address unforeseen circumstances or exceptional changes in the economic landscape. However, the primary focus remains on gradual and predictable adjustments that keep pace with the cost of living and/or the costs of regulating these services. The costs should reflect the amount of time, type of service and resource HIS spends regulating the sector.

The benefits foreseen for Options 2 & 3 would be identical to each other. Services who currently operate with no regulation would continue not to be regulated, and thus they would incur no additional expenses. The benefits to the public would be no pass through cost to them as service users, however, there cost does not mitigate the continued potential risk to public safety.

7. Costs

There is no direct cost to the Scottish Government in taking forward the proposed changes in Option 1.

There will likely be additional costs for HIS under Option 1, in carrying out inspections of businesses newly required to register with them. HIS will charge registration and continuation fees to these providers in order to help cover these costs.

The registration fee is an additional cost to businesses, but provides the public with an indicator that the business is reputable and meets safety and quality standards. The fees amendment will have a direct cost on independent healthcare providers (see Section 8 – Scottish Firm Impact Test for more details on the impact to businesses).

There are no cost implications to Option 2 & 3.

8. Scottish Firms Impact Test

On 12 April 2023, the Scottish Government reached out to 6 organisations (see Section 3 for details) after they agreed to provide BRIA specific feedback on the proposed Modification Order and Commencement Order:

We asked them the following questions:

1. Will any of the proposed amendments to the regulation of independent health care services in Scotland directly affect your business or service? If so, please provide details on what form this might take.
2. Can you see any benefits your business or service would gain from the proposals?
3. Do you foresee any specific negative outcomes or impacts on your business from the proposed amendments?
4. Do you believe the proposals will cause variation in the regulatory burden between self-employed, micro, small, medium, or large businesses?
5. Should there be compliance flexibility options to assist smaller businesses to meet the regulatory requirements set by Healthcare Improvement Scotland (HIS)? If yes, to what extent should HIS provide flexibility?

We received only one response to our questions from the Dermal Clinic. Although the Dermal Clinic did not believe the changes would directly impact their business, unless fees were increased, they felt that the changes would provide “a more level playing field” for services included in regulation, but highlighted that they believed there would be limited actual impact on the wider independent healthcare landscape as non-medical services are not currently being regulated.

We did receive 20 responses to the first consultation from a wide array of Scottish businesses. The vast majority of these responses were very supportive of the proposals. Particular reference was made to the belief that all independent healthcare providers should be regulated, as this improves safety for any service user and confidence in the standards of quality being met. A number of responses made the point that well-regulated environments promote high clinical and behavioural standards, as well as robust clinical governance processes. In environments where medical professionals are able to effectively raise concerns, it has been evidenced that the safety of services and the wellbeing of those professionals is higher than those that do not.

As we developed the second consultation, we wanted to engage with a much wider range of stakeholders when it came to the BRIA Scottish Firms Impact Test. We asked HIS to directly contact independent healthcare providers who are registered with them and request they consider completing the questionnaire we developed.

We asked them the following questions:

1. Will any of the proposed amendments to the regulation of independent healthcare services in Scotland directly affect your business or service? If so, please provide details on what form this might take.
2. What benefits would your business or service gain from the proposals?
3. Do you foresee any specific negative outcomes or impacts on your business from the proposed amendments? If so, please provide details on what form this might take.
4. Should there be flexible options to assist smaller businesses to meet the financial requirements set by Healthcare Improvement Scotland (HIS)? If yes, to what extent should HIS provide flexibility?

5. If you do not agree with charging fees for regulation, can you suggest an alternative funding approach to ensure that all people in Scotland that are using Independent Healthcare services are receiving highest standard of safety and care?
6. Please add any other information you believe we should consider regarding the proposed amendments.

We received significantly more responses to the second BRIA Scottish Firms Impact Test; a total of 25 responses to the above questions from a range of independent healthcare services (see details in Section 3).

23 of the 25 responses (92%) indicated that the amendments to the fees increase would directly have a significant negative impact on the business or service they offered. 11 of which believed the increase of fees would actually force the closure of their business. If fees rise, then costs would have to be passed on to service users, and they would not be able to compete with non-medical practitioners who are not required to register with HIS.

21 responses (84%) believed there to be no benefit whatsoever to the proposals. It is important to consider that this second BRIA Scottish Firms Impact Test asked about both consultations and there were only 3 responses which covered the proposed changes in the first consultation.

The increase in fees proposal has resulted in a negative response, eclipsing consideration of and comment on the other proposed amendments around pharmacists, pharmacy technicians, de-registering services that fail to pay their continuation fees and IMAs. The few positive points made highlighted that oversight is generally beneficial and helps drive improvements in the independent healthcare sector.

When asked about flexible options, 16 responses (64%) stated that business size should be taken into account, with larger business and hospitals paying significantly more than their smaller counterparts; a tiered system to consider number of employees and turnover. Many commented that incremental payment plans would be beneficial in balancing finances and much more manageable to businesses with a lower turnover.

The regulation of more services, especially non-medical aesthetic practitioners was mentioned by 8 different respondents as an alternative to raising fees. Two suggested that HIS should be fully funded completely by the taxpayer.

Respondents were given the opportunity to share other thoughts and considerations on the proposals. There is a strong resistance to the fees increase, but a general agreement that the concept of fees and regulation is vital to ensure the quality of independent healthcare remains high.

The resistance centred on the lack of clarity from HIS on why fees were so much higher than other parts of the UK, how much an average inspection costs, and how the total HIS expenditure figure calculated.

9. Competition Assessment

We do not believe the proposed changes will have an impact on competition.

The four Competition and Markets Authority (CMA) competition assessment questions were used to determine that the proposed changes will not:

- directly or indirectly limit the number or range of suppliers;
- limit the ability of suppliers to compete;
- limit suppliers' incentives to compete vigorously; or
- limit the choices and information available to consumers.

10. Consumer Assessment

We believe the proposed changes will increase public safety and consumer confidence in the services being offered.

Using the Consumer Assessment questions in the associated guidance we determined that the proposed changes will not:

- affect the quality, availability or price of any goods or services in a market;
- affect the essential services market, such as energy or water
- involve storage or increased use of consumer data;
- increase opportunities for unscrupulous suppliers to target consumers;
- impact the information available to consumers on either goods or services, or their rights in relation to these; or
- affect routes for consumers to seek advice or raise complaints on consumer issues.

11. Test Run of Business Forms

The proposed changes will not introduce any statutory business forms.

12. Digital Impact Test

One of the changes being proposed is aimed at increasing the power of HIS to regulate independent healthcare services who are based in Scotland and are either wholly based online or partially, and bring them in line with brick and mortar based businesses.

When developing the proposed amendments we considered changing digital technologies and markets, and the growing online healthcare service market. One goal was to prevent circumnavigation of regulations by business operating entirely online.

13. Legal Aid Impact Test

It is not anticipated that the proposed changes will have any effect on individuals' rights of access to justice through the legal aid fund.

14. Enforcement, Sanctions and Monitoring

HIS carries out their functions in line with their [enforcement policy](#). In the majority of cases, HIS are able to drive improvement and compliance using requirements in inspection reports and following compliant investigations. If these do not result in the required improvement of a service, HIS can limit the activity of a service with a "condition notice" or require improvement using an "improvement notice". Failure to make the required improvements set out in an improvement notice can lead to the cancellation of a registration.

As mentioned above, if a provider does not comply with the requirements of an improvement notice, then this can lead to the cancellation of their registration. If a provider continues to provide a service after their registration has been cancelled, this is an offence under section 10Z9(1)(a) of the National Health Service (Scotland) Act 1978 (providing an unregistered independent healthcare service).

HIS uses its statutory functions of inspection, compliant investigation and notifications to monitor the performance and compliance of independent healthcare (IHC) providers. Both inspections and compliant investigations are published and available to the public to help inform their choices when they are considering using an IHC service.

Providers are required to notify HIS of specific incidents that occur in their services. Many of these relate to occurrences that impact patient safety and allow HIS to ensure that the provider is meeting all of the legal requirements as well as taking forward any appropriate learning from the event, if that is relevant.

15. Implementation and Delivery Plan

HIS is in the process of developing an implementation plan on the proposed changes to independent healthcare regulation

16. Post-implementation Review

We commit to review whether the changes made by the proposed Orders and Regulations are fit for purpose within 10 years of them coming into force.

17. Summary and Recommendation

The case for amending the existing independent healthcare provisions is well established and supported by a range of stakeholders. The proposed Orders and Regulations will provide reassurance of quality of service and safety to any who use independent healthcare services.

The Scottish Government considers that Option 1 (Bring forward the Modification Order, the Fees Regulations and the Commencement Order) best supports the delivery of a number of national outcomes and is consistent with the Scottish Government's wider priorities for public service reform. It offers the most benefit and poses the least risk.

Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social - policy and administrative
1 – Bring forward the Modification Order, Commencement Order, and Fees Regulation	<p>Economic – will improve HIS’ financial situation by allowing them to increase the fees they charge in line with inflation.</p> <p>Environmental – no foreseeable benefit.</p> <p>Social – will help to improve public safety by enforcing health and safety regulations to more independent healthcare providers.</p>	<p>Economic – will increase expenses for individual businesses.</p> <p>Environmental – no foreseeable costs.</p> <p>Social – could have a negative impact on independent healthcare services who cannot afford increased expenses, or who are currently not regulated and are required to pay for improvements to reach acceptable standards.</p>
2 – Non-Regulatory	<p>Economic – no foreseeable benefit.</p> <p>Environmental – no foreseeable benefit.</p> <p>Social – would be well received by independent healthcare providers.</p>	<p>Economic – SG would have to provide funding for HIS to continue to function in the regulatory space, and this would likely continue to grow over time.</p> <p>Environmental – no foreseeable cost.</p> <p>Social – could have serious public health and reputational consequences.</p>
3 – Do Nothing	<p>Economic – no foreseeable benefit</p> <p>Environmental – no foreseeable benefit.</p> <p>Social – would be well received by independent healthcare providers.</p>	<p>Economic – SG would have to provide funding for HIS to continue to function in the regulatory space, and this would likely continue to grow over time.</p> <p>Environmental – no foreseeable cost.</p> <p>Social – could have serious public health and reputational consequences.</p>

18. Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Date: 24th April 2024

Minister’s name: Jenni Minto

Minister’s title: Minister for Public Health and Women’s Health

Scottish Government Contact point: Robert Law