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Dear Stuart,

Thank you for your letter of 29 October to the Cabinet Secretary for Health and Social Care regarding the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill. As Member in Charge of the Bill, the Cabinet Secretary has agreed that I would be best placed to respond.

I have provided some initial responses to your questions below, but I am keen to give further consideration to the important points raised by the Committee. I would therefore be happy to provide a further update to you in the coming weeks.

In the first instance, regarding the Committee's concerns about the powers contained in the Bill, I am keen to ensure that the legislation is flexible and future proofed. This is a fast-changing sector, and we must ensure we can respond to potential shifts in the availability of training and qualifications, changes in the professional landscape, new evidence on risks or safety and of course the likely emergence of novel procedures. We have been engaging closely with the sector in the initial development of the Bill, but I believe this must continue to be a joint endeavour with stakeholders to ensure the Bill is as effective as it possible can be.

I note the concerns you raise about the substantive provision in the Bill of the core regulatory scheme, and I agree there are factors such as the impact of the UK Internal Market Act (UKIMA) which have changed the nature of what can be provided on the face of the Bill.

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Whilst no additional powers are taken specifically to address these issues, the Bill in its current form seeks to take action where we are able to do so in the current devolved context. As introduced, the Bill seeks to restrict the types of premises in which non-surgical procedures listed in the Bill may take place to 'permitted premises'. It ensures that these procedures only take place in a setting where a healthcare professional with a full all-round knowledge of anatomy and physiology, and full prescribing rights, is available – in the case of independent clinics registered with Healthcare Improvement Scotland (HIS), that is a medical or dental practitioner or a prescribing nurse, midwife or pharmacist. This means that while the Bill does not stipulate that healthcare professionals must perform any of the procedures themselves, it ensures they will be on hand if they are needed to provide face-to-face consultations with clients, prescribe any necessary medications or intervene in the event of any complications.

Those settings included in the definition of a permitted premises are already subject to wider regulation or oversight in Scotland. For instance, settings registered with HIS must meet the requirements set out in the Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011 (and supported by wider guidance).

However, I do also recognise the Committee's views on the need to further work through the impact of the UKIMA. In particular regarding the regulation of standards of training and qualifications which we know to be an area in which respondents to the consultation held by the Scottish Government are keen to see more action. I am keen to reassure the Committee that it is our intention to continue to work through the impact of the UKIMA so that provision relating to qualifications and experience are workable and enforceable. We are engaging with the UK Government, and we have also begun to examine what a minimum training and/or qualification standard should look like through discussions with practitioners and with training providers. It would be our intention that any specific training requirements would have to be set in regulations and guidance if the Bill is passed, as it is possible that the list of procedures in schedule 1 of the Bill may change during consideration of the Bill, and the exact details of training requirements will not be clear until the Bill has completed its passage and is in its final form. I am happy to keep the Committee updated on the UKIMA issues and have asked my officials to give further consideration and advice on the resolution of these issues as swiftly as possible.

I am aware, and am grateful to you for your previous interest in this issue, and would also like to offer to meet you to discuss the Bill, as well of course to making myself available to the committee if appropriate.

In response to the Committee's specific questions:

1. Rationale for introducing the Bill before UKIMA position is resolved

The Committee will be aware of the prevalence of concerns around the harms that can arise from non-surgical procedures and there is a keenness from stakeholders and Members across Parliament that action be taken quickly. The Bill, for example, addresses the

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substantial concern about the suitability of procedures for young people, by including a new offence of performing a non-surgical procedure on anyone under the age of 18. This is a significant provision as it immediately upon commencement gives protection to children and young people, for whom the majority of these procedures are not appropriate, and who are subject to social media and other pressure with regard to the way they look.

However, as I have set out earlier in this letter, I do recognise the Committee's concerns about UKIMA. I am therefore happy to keep the Committee updated on the progress of discussions with the UK Government and I note the Scottish Government's intention to seek resolution to these complex issues as quickly as possible.

2. Breadth of the enabling power in section 5(1)

As set out in the Delegated Powers Memorandum, the non-surgical procedures sector is a rapidly evolving one. New procedures are being developed and coming on to the market all the time, and ways of performing existing procedures are changing, for example with the use of new technology or in attempts to make procedures more 'convenient' for busy clients. It is important that the Bill is responsive to these changes and that is the intention behind including the powers in section 5.

The powers in section 5 may be exercised in response to a variety of developments. New procedures may emerge in the future which are not currently covered by the definitions included in Schedule 1 of the Bill, or alternatively developments in existing procedures may change the most appropriate way of mitigating the risks of such procedures. The use of liquid filler to augment the appearance of the buttocks, known as the Brazilian Butt Lift (BBL), is an example of a procedure which might not have been foreseen if this legislation had been drafted at an earlier juncture, but as stated in the Policy Memorandum we know through media reporting of a death in England following a BBL. Where we become aware of new procedures which may cause actual harm of this nature we must be able to act quickly in order to bring it within regulation to protect the public.

Beyond the emergence of new or changed procedures it may also be necessary to respond to new evidence about safe practice. When it is possible to establish training and qualification standards it will be necessary to keep such provision updated to respond to changes in the training landscape. Similarly when it is possible to restrict procedures to an appropriate healthcare professional it will be necessary to keep this provision updated to respond to changes in the professional landscape. In each case the changes will be necessary both to ensure that public safety is protected but also ensure that responsible and safe businesses can continue to operate and benefit from any safer ways of operating.

I do however appreciate the Committee's comments on this issue and I recognise the importance of continued engagement and consultation with stakeholders to ensure that legislation is proportionate and appropriate.

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The powers in section 5 are already restricted by the overall definition of a non-surgical procedure, for instance no provision can be made in respect of e.g. beauty treatments that do not pierce or penetrate the skin. It is my view that a public health purpose would not be appropriate. While this would allow Scottish Ministers to put in place additional restrictions, where that appeared justified by public health concerns it would not appear to justify any other changes that might be required. For instance, a public health purpose would not support any regulations that were designed to make restrictions less onerous for businesses or withdraw restrictions or provisions that no longer appeared to meet a public health need. This may be necessary if, for example, a new modality of a procedure included in Schedule 1 was developed that carried reduced risk, in which case amendment to exempt that modality from the Bill would support the sector but be neutral from a public health perspective.

3. Henry VIII power in section 5(2)(a)

Whilst this is a broad power, it is not without context. Any modification would be a modification governed by the terms of section 5(1). The ability to modify any enactment (including the Act that results from the Bill, if passed) is needed from a future-proofing perspective. As was set out in the Delegated Powers Memorandum, we may need to create new offences or to introduce training and qualification requirements. If the power is used, for example, to create new offences, it may be desirable to amend the Act that results from the Bill itself so that the regulation of non-surgical procedures is set out in one place rather than in separate regulations. This would make them easier for the reader to find and read those in context. This applies to other relevant Acts too, in particular the National Health Service (Scotland) Act 1978 ("1978 Act"). Limiting the amendment of other Acts to consequential etc. amendments would mean the more important provision would be in regulations, which may not be the best place for the reader to find it and understand how it fits in with related provisions. Appreciating that this is an issue of concern for the Committee, I am happy to provide an example of how this provision may be used. It is foreseeable that future changes may need to be made to the appropriate settings for a procedure to take place, and this may require settings to be regulated by HIS for the purposes of carrying out non-surgical procedures but not where other independent health care services are provided. Such a change is likely to require amendment to the definition of permitted premises in Section 4 of the Bill and also may require changes to the independent health care services definitions. In addition, it may be necessary to make related changes to HIS' inspection powers in the 1978 Act which would not be possible without the power in section 5 of the Bill.

4. Safeguards and scrutiny

I share the Committee's view on the importance of consultation with appropriate stakeholders, particularly clinical experts in the field, business owners, training providers, insurers and members of the public who are service users. We will continue to engage with stakeholders throughout the development of the Bill and I would be happy to write back to the Committee to set out what engagement has already taken place and what I intend to do in the coming months. This will include opportunities for MSPs to engage with me on the Bill and through the affirmative procedure which will provide the opportunity for Parliament to

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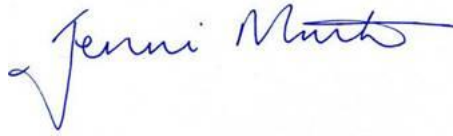
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scrutinise any secondary legislation and consider impact assessments carried out in support of any change. Putting additional requirements in place may reduce the ability of Scottish Ministers to respond to novel procedures and other developments in the market with appropriate rapidity, which could lead to an increased risk to the public.

Yours sincerely,



Jenni Minto MSP

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