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Dear Clare.

I am grateful to members of the Health, Social Care and Sport Committee for their comprehensive stage 1 report on the Patient Safety Commissioner for Scotland Bill, and for the recommendation that the general principles of the Bill are agreed to.

This letter sets out the Scottish Government's response to the other recommendations in the report.

Establishment

Involvement of people with lived experience in recruitment

I note the recommendation that Part 2 of schedule 1 should be reviewed to find a way to include people with lived experience in recruitment to the post. The Bill states that the Patient Safety Commissioner will be appointed by His Majesty. The process for Royal appointments is governed by the Parliament's Standing Orders (principally Rule 3.11). They provide that a cross-party selection panel will be established by the Presiding Officer with a relevant convener and between four and seven MSPs taking account of the balance of political parties of the Parliament. I recognise that involving people with lived experience will be key to the success of the Commissioner. If members share that view and wish to codify this involvement, the Parliament could modify its Standing Orders to adjust the process for nominating a Patient Safety Commissioner. I note that Standing Orders already contain

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bespoke arrangements for particular appointments (for example in Chapter 3A). I would suggest the matter is one for the Parliament's Standards, Procedures and Public Appointments Committee to consider in the first instance.

Purpose and principles - functions

Marketing and public awareness

I agree with the Committee's view on the importance of the Patient Safety Commissioner using marketing and public awareness to inform patients and the public about the parameters of the role and to manage expectations around areas where the Commissioner will not replace existing processes, such as the resolution of individual complaints. I agree that it will be important for whoever is appointed to the role to put in place mechanisms to address these considerations.

Ability to consider issues cutting across health and social care

I note that, while the Committee agrees that the Patient Safety Commissioner's remit should not include social care, it recommends the Commissioner should be able to investigate and make recommendations to reflect the voice of patients on issues that intersect with, or transcend, health and social care. I feel strongly that the Commissioner's focus must be on patient safety, but I agree it is important that the Commissioner is free to look into issues at the intersection of health and social care that also have a significant bearing on patient safety in Scotland. The Commissioner's remit covers the safety of "health care" irrespective of where it is delivered. I believe this means that they will have the requisite scope to examine issues at the intersection of health and social care and to work with any and all stakeholders and partners of their choice in doing so.

Role in listening to staff

I recognise it is important that the Patient Safety Commissioner can listen to the views of staff to support their overall purpose of amplifying the patient voice. The Scottish Government will consider how this could be clarified.

Purpose and principles – principles and communication

Consultation on principles

I accept the Committee's recommendation that the Bill should require the Patient Safety Commissioner to consult with stakeholders on the development of the principles. I also agree with the Committee that it will be important that the Commissioner takes account of existing legislation when drafting the principles, and that the principles should include an explicit commitment to listen to and support underrepresented voices.

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Inclusive communication

I am content to accept the Committee's recommendation that section 4 of the Bill on inclusive communication should be removed because it is superfluous given the duties that will fall to the Commissioner under the Equalities Act 2010.

Strategic planning

Consultation and co-production

I agree with the Committee that consultation with those the Patient Safety Commissioner seeks to represent will be an important part of the development of the role's principles and strategic plan. I accept the recommendation that section 6 of the Bill is strengthened to ensure this consultation happens. I am also happy to commit to exploring the extent to which co-production could be incorporated into this approach.

Formal investigations

Following-up recommendations

I thank the Committee for their recommendation that the Bill is amended to give the Patient Safety Commissioner powers to follow-up on the implementation of recommendations. I agree that it will be important that the Commissioner is able to ensure that recommendations instigate positive change, particularly in the light of Baroness Cumberlege's finding that action has too often not been taken to address patients' concerns. My officials will explore this issue in more detail.

Clarifying collaborative approach to formal investigations

The Committee recommended that the Bill is strengthened to set out more clearly the collaborative approach to formal investigations outlined by my predecessor, along with the parameters of those investigations. Related to this, the Committee also recommended that the Bill should attribute responsibility for determining which organisation is best placed to undertake an investigation in any given circumstance.

I agree that clarity is important on how the Commissioner's formal investigations will work, and in particular on the collaborative approach we expect the Patient Safety Commissioner to take when engaging with other organisations. The Scottish Government will undertake further work on this.

However, I am unconvinced that attributing formal responsibility for determining which organisation is responsible for undertaking investigations in any given circumstance is consistent with this collaborative approach; I believe this is more likely to cause friction between organisations, or to impede their initiative if they expect to have to wait to be told whether the Commissioner wants them to investigate an issue or not. None of this would be in the interest of patients. Furthermore, the various roles of different organisations with responsibilities for patient safety are defined in legislation. It would not be appropriate for the

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Patient Safety Commissioner to have a role in deciding how that legislation is interpreted or applied.

Gathering and use of information

Requiring information from private companies

I agree in principle with the Committee's view that the powers to compel organisations to provide information under section 12 of the Bill should encompass private companies that provide medicines and medical devices. The Medicines and Healthcare products Regulatory Agency (MHRA) has responsibility for the regulation of manufacturers and sellers of medicines and medical devices across the whole of the UK. Further consideration is needed as to how the role of the Patient Safety Commissioner will interact with the remit of the MHRA. The Scottish Government will explore this issue further.

Sharing confidential information with regulators and the Health and Safety Executive

I note the Committee's recommendation that the Scottish Government gives consideration at Stage 2 to amending the list of organisations authorised to receive confidential information from the Patient Safety Commissioner to assist with those organisations' statutory functions at section 15(2)(d) of the Bill include professional regulators and the Health and Safety Executive.

I recognise and share the desire to avoid the possibility that the Commissioner unintentionally impedes professional regulators or the Health and Safety Executive from exercising their important safety duties. However, I also believe this must be balanced with the need to encourage individuals and organisations to be forthcoming and cooperative with the Patient Safety Commissioner's own investigations.

I believe that any change in this area must maintain a balance between encouraging openness and learning while also ensuring regulators and the Health and Safety Executive can fulfil their important safety roles. I am content to commit the Scottish Government to giving further detailed consideration to the matter to see whether more can be done to achieve this balance.

Data analytics

I agree with the Committee that access to data analytics will be crucial to the Patient Safety Commissioner's effectiveness. Collaboration and partnership working will be key here. It will be important that the Commissioner does not duplicate the high-quality patient safety analysis routinely produced by other organisations such as Healthcare Improvement Scotland, and indeed is able to access this analysis. The Scottish Government will explore this issue further with the aim of providing more detail and reassurance to the Committee that the Commissioner will have access to the data analytics they need to carry out their role effectively.

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Sanctions

I welcome the Committee's agreement that Bill's provisions on sanctions strike an appropriate balance between encouraging openness and learning while still giving the Patient Safety Commissioner robust powers.

Advisory group

Selection of 'patient representatives'

I note the Committee's recommendation that the wording in section 16(4)(c) should be amended to specify that members of the advisory group who represent patients must actively demonstrate a commitment to representing the voice of patients, rather than simply appearing to the Patient Safety Commissioner to be representative of patients. Appointments to the advisory group will be subject to oversight by the SPCB, who will function as an external check on their appropriateness.

Remuneration

I agree with the Committee that it will be important that advisory group members are properly supported and remunerated to carry out their role effectively, and I note that section 16(5) of the Bill gives the Patient Safety Commissioner the ability to pay remuneration and allowances to the members. The level of payment is an operational matter for the Patient Safety Commissioner and the SPCB to determine.

Final provisions

Definition of 'patient safety'

I note the Committee believes there would be benefit in including a definition of "patient safety" on the face of the Bill and has asked for the Scottish Government to address this directly in responding to the report. I am not convinced that the absence of such a definition would make the Patient Safety Commissioner's role unclear or difficult to understand. The Bill only uses the phrase "patient safety" in the title "Patient Safety Commissioner"; otherwise, the Bill refers to the safety of healthcare when defining the Commissioner's purpose in section 2. I believe the meaning of "safety" is well understood by patients and the public. Adding a statutory definition of "safety" to the Bill over and above this would therefore be superfluous and would risk imposing an unhelpful and unnecessary legal restriction on the sorts of issues the Patient Safety Commissioner could decide to consider.

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Role of the Parliament - resources

Adequate provision to meet importance and scale of functions

I agree with the Committee that budget allocations from the Scottish Government to the Scottish Parliamentary Corporate Body should make adequate provision to meet the importance and scale of the Patient Safety Commissioner's functions.

Commitment to provide additional funding in the case of future role changes or resource pressures

The Committee has also recommended that:

- a) The Scottish Government should give a clear commitment to provide sufficient resources to the SPCB to support the work of the Commissioner if their role increases in response to Government policy or legislation, or more staffing is required to support their function.
- b) The SPCB and the Scottish Government should review the resourcing provision for the Commissioner at the end of the 2025/2026 financial year, and if this review indicates that further resource is required in subsequent years, the Scottish Government should provide a written guarantee that this will be fully covered by a transfer of funds to SPCB.

As the Committee will be aware, the Scottish Government provides a block grant to the Scottish Parliamentary Corporate Body to fund all parliamentary commissioners. This arrangement will include the costs of the Patient Safety Commissioner from 2025/2026.

In this context, I recognise the concerns expressed by the Finance and Public Administration Committee in its letter of 31 January 2023 about the increasing number of parliamentary commissioners and their associated costs. While it would not be right for me to make funding commitments now based on hypothetical developments in the future, I can commit that the Scottish Government will engage constructively with the SPCB to ensure that all parliamentary commissioners are funded appropriately, including the Patient Safety Commissioner.

Reporting on anticipated budgetary requirements and pressures

I agree with the Committee that the Patient Safety Commissioner should report on any resourcing pressures anticipating future requirements for their budget to be increased as part of their reporting to the Scottish Parliament.

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Role of the Parliament - review and evaluation

Commitment to future review of legislation

The Committee has rightly emphasised the high-profile nature of the Patient Safety Commissioner role and the accompanying public expectation around it, asking in this context for reassurance from the Scottish Government that the legislation will be reviewed if the Parliament finds that the Commissioner does not have sufficient powers to fulfil their brief, or that their remit requires amendment. I agree that review by Parliament will be important. The Scottish Government will consider whether there are mechanisms that could facilitate future amendment of the role.

Monitoring and evaluation

I also agree with the Committee that robust monitoring and evaluation of the Commissioner's role will be vital to ensure that patients' voices are heard and that public confidence in the role is maintained. The Scottish Government will consider this further.

Independent accountability process

Finally, I agree it will be important that there is an independent process to enable the Commissioner to be held to account for their conduct. My predecessor gave a commitment to the Presiding Officer that the Patient Safety Commissioner would be established in a way that is consistent with the arrangements for other Parliamentary Commissioners overseen by the Scottish Parliamentary Corporate Body. I have asked my officials to explore the arrangements for holding to account other Parliamentary Commissioners, with the aim that consistent arrangements can be put in place for the Patient Safety Commissioner.

I hope you find my comments helpful, and I look forward to hearing from the Parliament in the Stage 1 debate this week.

Yours sincerely,

Jenni Murt

Jenni Minto MSP

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