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## Health, Social Care and Sport Committee

# Stage 1 Report on the Patient Safety Commissioner for Scotland Bill



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# Health, Social Care and Sport Committee

To consider and report on matters falling within the responsibility of the Cabinet Secretary for Health and Social Care and matters relating to drugs policy.



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# Committee Membership



**Convener**  
**Clare Haughey**  
Scottish National Party



**Stephanie Callaghan**  
Scottish National Party



**Sandesh Gulhane**  
Scottish Conservative  
and Unionist Party



**Emma Harper**  
Scottish National Party



**Gillian Mackay**  
Scottish Green Party



**Carol Mochan**  
Scottish Labour



**Paul Sweeney**  
Scottish Labour



**David Torrance**  
Scottish National Party



**Evelyn Tweed**  
Scottish National Party



**Tess White**  
Scottish Conservative  
and Unionist Party

# Membership changes

1. The following changes to Committee membership occurred during the Committee's scrutiny:
  - On 18 April 2023, Clare Haughey MSP replaced Gillian Martin MSP.
  - On 25 April 2023, Carol Mochan MSP replaced Paul O'Kane MSP.

# Summary of recommendations

## Establishment

2. The Committee highlights the importance of ensuring public confidence and trust in the healthcare system in Scotland. For this reason, the Committee agrees that the Patient Safety Commissioner for Scotland should be independent from the Scottish Government and endorses proposals, as set out in the Bill, that the Commissioner be appointed by the Scottish Parliamentary Corporate Body and accountable to the Scottish Parliament.
3. The Committee recognises the view that those with lived experience of patient safety issues should have a meaningful role in the process of recruiting a Patient Safety Commissioner for Scotland. It therefore calls on the Scottish Government to review Part 2 of Schedule 1 of the Bill, with a view to finding the best way to include people with lived and living experience in recruitment for the role.

## Purpose and principles - functions

4. The Committee supports the primary functions of the Patient Safety Commissioner for Scotland as being to advocate for systemic improvements and to amplify the voice of patients.
5. The Committee recognises stakeholder concerns that the Commissioner will not address individual complaints, but also recognises that there are established processes in place for handling individual cases and complaints. However, given that some of the common themes from the Independent Medicines and Medical Devices Safety Review related to patients feeling they were not listened to and the length of time taken for their problems to be acknowledged, the Committee considers marketing and raising public awareness, as well as managing expectations, in relation to the role of Patient Safety Commissioner to be paramount. While recognising the independent status of the Commissioner, the Committee believes it will be important for the Patient Safety Commissioner for Scotland, once appointed, to put in place the mechanisms for addressing these considerations as an initial priority.
6. The Committee is supportive of giving the Commissioner the necessary operational freedom to determine their initial goals and priorities for the role as well as how they will accomplish their overall purpose. The Committee recognises that the remit of the Patient Safety Commissioner for Scotland is wider than its counterpart in England and, in this context, highlights the particular importance of being very focused in terms of defining priorities that are manageable and deliverable within the constraints of available resources.
7. The Committee supports the Scottish Government's rationale for not including social care within the Commissioner's initial remit. However, the Committee calls on the Scottish Government to confirm the Commissioner would be able to investigate and make recommendations to reflect the voice of patients on issues

that intersect with, or transcend, health and social care.

8. The Committee recognises the role of staff in raising patient safety concerns, and the existing processes in place to raise those concerns, for example, in relation to whistleblowing. The Committee welcomes the then Minister's commitment to clarify the Bill to provide clarity around the Patient Safety Commissioner's role in listening to staff, to the extent this supports the Commissioner's primary purpose of amplifying the patient voice, and looks forward to further detail at Stage 2.

## **Purpose and principles - principles and communication**

9. The Committee recognises the importance of giving the Commissioner the freedom to define and establish their own principles, following commencement of the role. However, it also recommends that the Bill should require the Commissioner to consult with stakeholders on these principles. The Committee recommends that such provisions should follow a similar process to the Commissioner's duty to consult on their strategic plan.
10. Recognising that the interventions highlighted in the Independent Medicines and Medical Devices Safety Review all affected women, the Committee calls for the principles underpinning the work of the Patient Safety Commissioner to include an explicit commitment to listening to and supporting under-represented voices.
11. The Committee also agrees with the Royal College of Nursing that the Commissioner should be required to take account of existing legislation when drafting the principles and recommends that provision for such a requirement should be made on the face of the Bill.
12. The Committee takes a view that, unless the Scottish Government can demonstrate the specific added value provided by those provisions of the Bill on inclusive communication, they should be considered superfluous given the pre-existing reasonable adjustment duty provided by the 2010 Equality Act and should therefore be removed.

## **Strategic planning**

13. The policy memorandum states that amplifying the patient voice is one of the Bill's main purposes. The Committee is of the view that the principles and the strategic plan underpinning the work of the Commissioner should be developed in consultation with those it seeks to represent, alongside other patient safety stakeholders and organisations. The Committee recommends that the Scottish Government strengthen Section 6 of the Bill to ensure proper consultation with patient safety stakeholders and organisations as part of their development. In so doing, we also ask the Scottish Government to consider to what extent co-production can be incorporated into this approach.

## **Formal investigations**



14. Given the situations that gave rise to the Independent Medicines and Medical Devices Safety Review, whereby patients were routinely not believed and dismissed, and no actions were taken to address patient safety concerns, the Committee considers it vital that the Commissioner has the necessary capabilities to follow-up on the implementation of its recommendations. The Committee recommends that the relevant sections of the Bill be amended to give the Commissioner the necessary powers to undertake such follow-up, whether that is with the 'person' the recommendation is addressed to, or with a regulatory or patient safety partner.

### **Gathering and use of information**

15. The Committee takes the view that powers given to the Patient Safety Commissioner for Scotland under Section 12 of the Bill to compel organisations to provide evidence must include private companies who provide devices or medicines. It considers there is a lack of clarity in the Bill as introduced as to whether these powers will apply to private companies and believes this needs to be clarified at Stage 2 to ensure that they do.
16. The Committee has heard strong evidence in support of extending the list of organisations authorised to receive confidential information for the purpose of assisting them in exercising their statutory functions to include:
  - professional regulators, and
  - the Health and Safety Executive

It therefore calls on the Scottish Government to give consideration at Stage 2 to amendments to Section 15(2)(d) of the Bill that would give effect to this recommendation.
17. The Committee notes evidence from the Patient Safety Commissioner for England that having in place sufficient and suitable data analytics capability will be crucial to the Patient Safety Commissioner fulfilling their role effectively. It therefore calls on the Scottish Government, in advance of Stage 2, to address what level of resource will be required to put this capability in place.

### **Sanctions**

18. The Committee acknowledges views on the importance of sanctions, but also believes that the overarching priority of the Patient Safety Commissioner must be to avoid creating or exacerbating blame cultures and to foster a culture of openness, learning and collaboration. The Committee therefore concludes that the powers set out in the Bill strike an appropriate balance in this regard.

### **Advisory group**

19. The Committee agrees with Irene Oldfather that the wording in Section 16(4)(c) of the Bill requires further review and should be amended to specify that individuals appointed to the advisory group 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.
20. The Committee also agrees that all advisory group members should be properly supported and remunerated to be able to contribute effectively to the group's work. It concludes that all patient representatives on the advisory group should be entitled to such reimbursement, regardless of their employment status. The Committee further recommends that calculating the rate of travel expenses payable to patient representatives must take due account of the particular circumstances of those travelling from remote and rural areas and potentially higher travel costs they may face.

### **Miscellaneous provisions**

21. The Committee is content with sections 17, 18 and 19 of the Bill and, in particular, welcomes that section 18 will enable the Commissioner to carry out their work effectively, without fear of being subject to actions of defamation.

### **Final provisions**

22. The Committee is for the most part content with the provisions set out in Sections 20 to 25 but believes there would be benefit in including a definition of 'patient safety' on the face of the Bill. It calls on the Scottish Government to address this directly in responding to this report.
23. The Committee is also content with the ancillary provisions set out in Schedule 2 of the Bill.

### **Delegated powers**

24. The Committee notes the conclusion of the Delegated Powers and Law Reform Committee that it is content with the delegated powers provisions contained in the Bill.

### **Role of the Parliament - resources**

25. Throughout consideration of this Bill, the Committee has heard evidence of the need for the Bill to set out more clearly how it will be ensured that the Patient Safety Commissioner for Scotland does not duplicate investigatory work by other bodies. The Committee welcomes clarification provided by the then Minister regarding the collaborative role the Commissioner is expected to adopt by working with existing organisations, thereby limiting the requirement for the

Commissioner to undertake its own investigations. The Committee recommends that the Bill is strengthened to set out more clearly this collaborative approach and, related to this, the parameters of Commissioner investigations. It should also attribute responsibility for determining which organisation is best placed to undertake an investigation in any given circumstance.

26. The Committee recognises that resource requirements of the role will be likely to change over time. Further, given the potential scope of the role, the Committee recognises stakeholder concerns that the financial memorandum may underestimate the resources which may be needed to support the delivery of the Patient Safety Commissioner for Scotland's functions.
27. The Committee acknowledges the concerns of the Finance and Public Administration Committee, as expressed in its letter of 31 January 2023, regarding the increasing number of parliamentary commissioners and their associated costs.
28. The Committee recommends that budget allocations to the Scottish Parliamentary Corporate Body (SPCB) should make adequate provision to meet the importance and scale of the Patient Safety Commissioner's functions.
29. The Committee calls on the Scottish Government to 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.
30. The Committee recommends the SPCB and Scottish Government review the resourcing provision for the Office of the Commissioner at the end of Financial Year 2025/26 (the estimated first full financial year where only running costs will be incurred). If this review indicates that further resource is required in subsequent years, the Committee calls on the Scottish Government to provide a written guarantee that any such requirement will be fully covered by a transfer of funds from the Scottish Government to the SPCB.
31. The Committee also calls for the Commissioner to report on any resourcing pressures anticipated future requirements for increased budget, as part of the annual reporting process to the Parliament.

### **Role of the Parliament - review and evaluation**

32. The Committee recognises the need for robust monitoring and evaluation to ensure that patients' voices are heard and that there is public confidence in the Patient Safety Commissioner for Scotland and the wider system for reviewing and addressing patient safety issues. The Committee notes provisions in Part 5 of Schedule 1 which require the Commissioner to prepare and publish a report on their activities in respect of each financial year. The Committee recommends that these provisions should be strengthened to require the Commissioner to undertake ongoing monitoring and evaluation of their work and incorporate the outcome of this process into their annual report.

33. Given the high-profile nature of this role, the anticipated level of public expectation around it, and the Committee's consideration in this report on enforcement, the Committee seeks reassurance from the Scottish Government that the legislation would be reviewed if the Scottish Parliament finds, during its scrutiny, that the Commissioner does not have sufficient powers to fulfil their functions effectively, or their remit requires amendment.
34. The Committee has heard evidence emphasising the importance of providing recourse to an independent process that will enable the Patient Safety Commissioner to be held to account for their conduct. The Committee believes it will be important, either by means of a code of conduct or some other mechanism, to develop such a process in the course of establishing the role of Patient Safety Commissioner for Scotland.

# Introduction

35. The Patient Safety Commissioner for Scotland Bill (“the Bill”) was introduced in the Parliament by the then Cabinet Secretary for Health and Social Care, Humza Yousaf MSP, on 6 October 2022. The Parliament designated the Health, Social Care and Sport Committee as the lead committee for Stage 1 consideration of the Bill.
36. Under the Parliament’s Standing Orders Rule 9.6.3(a), it is for the lead committee to report to the Parliament on the general principles of the Bill. In doing so, it must take account of views submitted to it by any other committee. The lead committee is also required to report on the [financial memorandum](#) and [policy memorandum](#), which accompany the Bill.

## Policy objectives of the Bill

37. In the [Policy Memorandum](#), the Scottish Government states that the purpose of the Bill is to establish a new Parliamentary Commissioner, the Patient Safety Commissioner for Scotland (hereafter referred to as ‘the Commissioner’), independent of the NHS and government. The Bill establishes the office of the Commissioner and provides for its purposes in relation to:
  - the identification of patient safety issues in the provision of healthcare in Scotland
  - amplifying the voices of patients in relation to these safety issues and
  - making recommendations to address the safety issues identified.
38. The Commissioner’s remit will cover all healthcare providers operating in Scotland, including NHS, NHS-contracted and independent healthcare providers. The policy memorandum also states that the Commissioner will work collaboratively with other organisations to improve patient safety, adding value to the patient safety system in Scotland rather than duplicating the work of existing organisations.

## Health, Social Care and Sport Committee consideration

39. The Committee issued a call for evidence which ran between 26 October 2022 and 14 December 2022 and received [54 written responses](#). A summary of written submissions is included in the [Bill briefing](#), produced by the Scottish Parliament Information Centre (SPICe).
40. The Committee took evidence on the Bill at four meetings in February and March 2023 (see further Annex A)-
  - On 31 January 2023, the Committee held a private session with the Bill team from the Scottish Government, then heard from Baroness Julia Cumberlege, Chair and Simon Whale, Review Member and Communications Lead, Independent Medicines and Medical Devices Safety Review.
  - On 7 February 2023, the Committee took evidence from two panels; the first

comprising representatives from patients and patient groups, the second with organisations relating to patient safety.

- On 21 February 2023, the Committee took evidence from two panels; the first from representatives of industry bodies and professional organisations, the second with the Patient Safety Commissioner for England.
- On 14 March 2023, the Committee concluded its oral evidence programme by taking evidence from the then Minister for Public Health, Women's Health and Sport.

# The Independent Medicines and Medical Devices Safety Review

41. In February 2018, the Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP announced an [Independent Medicines and Medical Devices Safety Review \(IMMDS Review\)](#)<sup>i</sup>. The review, chaired by Baroness Julia Cumberlege CBE DL, was established to examine how the health system responds to reports from patients about patient safety concerns related to medicines and medical devices.
42. The IMMDS Review was in response to patient-led campaigns on the following:
- Primodos - this was a hormonal pregnancy test drug, administered to women from the 1950s to the late 1970s and associated with miscarriages and birth defects.
  - Sodium valproate in pregnancy - this has been a treatment for epilepsy since it was licensed in the 1970s. However, academic literature from the early 1980s suggested an association between sodium valproate exposure in utero, and birth defects if taken by women of childbearing age.
  - Transvaginal mesh - concerns about the use of surgical mesh in the treatment of pelvic organ prolapse and stress urinary incontinence emerged in the 2000s when women began to report severe complications.
43. The IMMDS Review report contained nine recommendations, including:
- ” The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices<sup>1</sup>.
44. The UK Government responded to this recommendation by tabling amendments to the [Medicines and Medical Devices Bill](#) to introduce a new role of Patient Safety Commissioner. Dr Henrietta Hughes was appointed to the role in July and began the appointment on 12 September 2022<sup>2</sup>. This [Patient Safety Commissioner factsheet](#) notes the remit of the role:
- ” The *PSC* will be a champion for patients. The commissioner's core role will be to promote the safety of patients and the importance of the views of patients in relation to medicines and medical devices.

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<sup>i</sup> The IMMDS Review is also referred to informally as the 'Cumberlege Review', after the Chair of the Review.

## Implementing the IMMDS Review recommendations in Scotland

45. The [policy memorandum](#) notes that although the review was commissioned by the UK Government and focused on England, "it also took evidence from Scottish residents and its findings were recognised by healthcare practitioners to apply to all four UK nations".
46. The Scottish Parliament [debated the IMMDS Review report](#) on Tuesday 8 September 2020. The then Cabinet Secretary for Health and Sport, Jeane Freeman MSP, confirmed that the Scottish Government would implement all of the recommendations of the Cumberlege report that fell within devolved competence, including the creation of a Patient Safety Commissioner for Scotland.
47. The Scottish Government included the proposal for a Patient Safety Commissioner in its [2020-21 Programme for Government](#) and [consulted on the proposal](#) for a Commissioner focused initially on medicines and medical devices in 2021.
48. The current Bill would extend the remit of the Patient Safety Commissioner for Scotland beyond medicines and medical devices to include patient safety more broadly. In relation to the Commissioner's proposed remit, the [policy memorandum](#) acknowledges that the majority of stakeholders were content that the role should focus on medicines and medical devices, while 29% of responses were in favour of a wider scope.
49. The Scottish Government state its rationale for the extended scope in the Bill in the policy memorandum:
  - ” Although the option chosen only received minority support, this was still substantial (29% of responses) and on balance, the Scottish Government has assessed that this is most consistent with creating a Commissioner who can take a truly system-wide view of patient safety issues in Scotland. It will be for the Commissioner themselves to set their initial goals. It is reasonable to anticipate that they will choose particular areas to focus on at different times.
50. The Committee explores the scope of the Commissioner's role [later in this report](#).



# Patient safety, governance and regulation in Scotland

51. The Committee has heard evidence from a number of stakeholders of the complexity of the existing clinical governance and regulatory landscape, and the potential for the functions of a Patient Safety Commissioner for Scotland to overlap with current governance structures and systems.
52. In Scotland, there are extensive systems and structures for ensuring good clinical governance in the NHS<sup>ii</sup>. Ultimately, clinical governance is the responsibility of each NHS board. NHS boards have a number of mechanisms to ensure patient safety detailed in [Annex A](#). A summary of legislations that has introduced relevant duties on NHS boards is detailed in [Annex B](#).
53. Responsibility for monitoring and improving the safety of patient care is shared amongst several organisations, alongside NHS boards themselves. These include Healthcare Improvement Scotland, the Mental Welfare Commission, NHS National Services Scotland, the Scottish Public Services Ombudsman, and professional regulators. The main body responsible for safety of medicines and medical devices is the Medicines and Healthcare Regulatory products Authority (MHRA). Functions of these organisations are detailed in [Annex C](#).
54. Stakeholders noted concerns over the current role of the patient voice in regulating patient safety, the potential for overlap and duplication of roles and responsibilities within the system, and the future role of the proposed Commissioner within an already complex landscape.
55. Fraser Morton, an individual who was among a number of families who called for a public inquiry into infant deaths at Crosshouse hospital maternity unit, set out his thoughts on the failures of the existing regulatory framework for patients. He highlighted how the media can often be a de facto driver for change in the absence of other drivers:
- ” The current situation is that the media in Scotland are, by default, our healthcare regulator. We do not have a healthcare regulator. The media are also the patient safety commissioner and family advocate rolled into one<sup>3</sup>.
56. Matthew McClelland from the Nursing and Midwifery Council highlighted the negative impact on individuals in terms of having to retell their stories to multiple regulators/bodies in the current system. In relation to those who have suffered harm, he stated:

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<sup>ii</sup> Clinical governance refers to processes of accountability by which the quality of healthcare is monitored and assured.

” They might be engaged with multiple regulators—the system regulators, multiple professional regulators and the police— and they might be taking legal action. All those bits of engagement require them to relive the issues and produce witness statements for all the bodies [...] There are really good examples of organisations collaborating, but we too often hear stories about individual patients and their battles and difficulties with multiple organisations. It is really important that the commissioner brings co-ordination <sup>4</sup> .

57. Several stakeholders recognised the need for better communication between organisations to ensure the patient experience is heard and acted on. Rosemary Agnew, the Scottish Public Services Ombudsman, set out concerns around the number of organisations in the current system, and the limitations on their ability to share information as a barrier to patients sharing their experiences:

” Nevertheless, there is a gap or a lacuna in which the voice of what might almost be the patient equivalent of a whistleblower is not always heard. Patients end up having to go to one organisation after another. It is not that we, across that landscape, do not want to share issues and talk about these things; it is that we often cannot do so, because the way in which our legislation is set up precludes it. There is absolutely a gap with regard to patients being able simply to tell their story and describe their feelings, their views and, in particular, their experience, and to know—not just hope—that they will be heard <sup>5</sup> .

58. Dr Henrietta Hughes, the Patient Safety Commissioner for England, described her views on her role going forward:

” I think that the fact that we have multiple organisations that each have their own part to play shows the complexity of system. What is important is that we speak to one other and meet regularly and are able to understand the remit of one other’s organisations and roles, so that we can be effective in supporting patients who have concerns.

It is about having good relationships with the regulators, understanding what is already known and what steps have already been taken, and opening mindsets so that we are able to look at things in a patient-centred way. The more we can get the patient voice into all the different aspects of care—the provision and regulation of care and all the other areas—the better <sup>6</sup> .

59. Simon Whale, review team member and communications lead for the IMMDS Review, set out the review’s rationale for recommending the establishment of a Patient Safety Commissioner role within such a complex landscape and where he thought the role could add value:

” You are absolutely right in saying that the landscape is cluttered. Although it is cluttered, it is also siloed, which leads to increased risk around patient safety and increased risk of avoidable harm. We feel that a patient safety commissioner’s role is to encourage—if not to require—the system to act in a more coherent way. Because the role’s focus is purely on patient safety and there is nothing else to distract it from that, the commissioner will be able to require and encourage the system to act in a more coherent way <sup>7</sup> .

60. A number of stakeholders identified the potential for the Commissioner to be a 'golden thread' that unifies and unites patient safety and clinical governance structures. In its written submission, NHS Tayside highlighted the potential of the Commissioner role to unify organisations across the patient safety landscape:
- ” People require a system for raising concerns and being heard and that landscape currently is complex. This role needs to engage and collaborate with existing mechanisms to address patient safety issues such as SPSP<sup>iii</sup>, AEM framework<sup>iv</sup>, SPSO<sup>v</sup> and DoC<sup>vi</sup> and if this role can provide clarity and encourage improvement in the system, that is not only welcome, but required <sup>8</sup> .
61. Simon Watson from Healthcare Improvement Scotland also highlighted the potential of the Commissioner to add an additional dimension to existing structures:
- ” It is particularly important that the issues that matter to the public and to patients get the prominence that they deserve and inform what we do. Our organisation definitely sees potential for the patient safety commissioner to help to identify such issues, get them on the table and hold everybody, including ourselves, to account for ensuring that they inform our actions to improve healthcare <sup>9</sup> .
62. During evidence, the then Minister for Public Health, Women's Health and Sport further set out the importance of the role as a way of bringing together patient safety organisations:
- ” [...] our ambition should be to be as broad as possible to ensure that we can deal with all of the concerns that patients raise. As I have said before, it is a complex landscape with many people operating in different ways. It is really important to have a patient safety commissioner who will help to draw all the information together <sup>10</sup> .

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iii Scottish Patient Safety Programme

iv Adverse Event Management

v Scottish Public Services Ombudsman

vi Duty of Candour

# The Bill

## Establishment

63. Section 1 of the Bill establishes the office of Patient Safety Commissioner for Scotland and introduces Schedule 1. Schedule 1 makes detailed provision for the appointment, status, disqualification, terms of office and remuneration, pension and subsequent appointments of the Commissioner, and other administrative provisions.

### Independence and appointment

64. Current systems of clinical governance operate within NHS structures and report to Scottish Ministers. The Bill proposes that the Commissioner will be a Parliamentary Commissioner and Schedule 1 of the Bill sets out provisions relating to status, independence and appointment of the Commissioner. The Commissioner will be appointed by the King on nomination by the Scottish Parliament and will therefore be accountable to the Scottish Parliament. The [policy memorandum](#) explains that this will achieve the independence envisaged by the IMMDS Review.
65. All stakeholders providing evidence welcomed the statutory basis to the role and its independence from Government. This was seen as necessary to build public trust. Dr Arun Chopra from the Mental Welfare Commission for Scotland stated:
- ” The Mental Welfare Commission is independent of the Scottish Government and the NHS. I, too, treasure that. It is vital to be demonstrably independent from both those organisations. It matters to people. People notice biases or perceived biases, so that independence is crucial <sup>11</sup> .
66. The equivalent role, already established in England, differs from the Bill's proposals for a Patient Safety Commissioner for Scotland in that it is sponsored by the Department of Health and Social Care and appointed by the Secretary of State. The rationale for that decision is set out in a [factsheet on the role in England](#) as follows:
- ” A relationship with DHSC would allow the commissioner a powerful place within the system. A commissioner which is entirely removed from the policy department can be more easily overlooked by government.
67. Witnesses did not report any concerns that the Commissioner for Scotland would be overlooked as a result of this differing approach. Instead, it was felt that complete independence was preferable.
68. Dr Arun Chopra stated that the extent to which the Commissioner is embedded in the overarching system depends less on their sponsoring body and more on how they operate and function day-to-day:

” ...how the commissioner remains embedded in the system while retaining their independence, is an issue of resources. It is about how the commissioner discharges their function, how they do their outreach, how they do their broadcast, how they hear from people, and how they visit and see hospitals or communities. We need to move the focus into communities and social care. That will be the important bit. How will the commissioner receive intelligence? That will allow them to be embedded in the system and yet maintain their independence <sup>12</sup> .

69. Bill Wright, from Haemophilia Scotland highlighted the ongoing scrutiny role this Committee would have to play with respect to the Commissioner:

” [...]any progress that was made in the early years of this Parliament was thanks to the efforts of your predecessors on the health committee. I anticipate that, given that the report from the PSC will come to Parliament, it will probably end up on your doorstep, which would be entirely appropriate.

[...] I anticipate, hope and pray that time would be devoted to the commissioner's annual report in your business plan for the year. It is vital that there be follow-up on the bill once it has passed; we rely on you and successive health committees to ensure that that happens. I also hope that you invite us back when issues arise, in order for us to say whether we think that the PSC is doing their job properly <sup>13</sup> .

## Recruitment

70. Some stakeholders suggested that recruitment for the Commissioner, whose purpose is to "promote and improve patient safety by amplifying the patient voice within the patient safety system <sup>14</sup> ", should involve people with lived experience. In its written evidence, NHS National Services Scotland noted that "It may be appropriate to involve patient safety champions/former champions in the appointments process <sup>15</sup> ."
71. Other stakeholders thought this could be problematic, especially in terms of ensuring meaningful engagement and the challenges of making decisions about who represents people with lived experience on such a recruitment panel.
72. The Committee heard that patient representatives were involved in the process to recruit for the equivalent role in England. However, Marie Lyon from the Association for Children Damaged by Hormone Pregnancy Tests, did not feel their feedback was utilised:
- ” We were asked, as a panel of people with lived experience, to do a pre-assessment of the candidates, which we did virtually. [...] We were allowed to look at the candidates and give our feedback, but I am not sure how helpful it was [...] I would not say that we made much of a difference <sup>16</sup> .
73. Bill Wright from Haemophilia Scotland spoke about the difficulties of deciding who is included as a representative on a recruitment panel and any advisory group, an issue which is addressed in greater detail [later in this report](#):

” I am always wary of using the word “represent”[...] There might have to be some sort of application process—you would need to have an application process for the panel that will then receive the applications from the prospective patient safety commissioner. It is a very tricky issue, because it also relates to the advisory group that is supporting the patient safety commissioner. The issue that I would find among my community, and Charlie Bethune and Marie Lyon would find the same, would be that people would ask why it is those people rather than someone else <sup>17</sup> .

74. The Committee highlights the importance of ensuring public confidence and trust in the healthcare system in Scotland. For this reason, the Committee agrees that the Patient Safety Commissioner for Scotland should be independent from the Scottish Government and endorses proposals, as set out in the Bill, that the Commissioner be appointed by the Scottish Parliamentary Corporate Body and accountable to the Scottish Parliament.
75. The Committee recognises the view that those with lived experience of patient safety issues should have a meaningful role in the process of recruiting a Patient Safety Commissioner for Scotland. It therefore calls on the Scottish Government to review Part 2 of Schedule 1 of the Bill, with a view to finding the best way to include people with lived and living experience in recruitment for the role.

## Purpose and principles

### Functions

76. Section 2 of the Bill provides for the Commissioner's two general functions. These are
  1. to advocate for systemic improvement in the safety of health care, and
  2. to promote the importance of the views of patients and other members of the public in relation to the safety of health care.
77. It further provides that the Commissioner may do the following in exercising these functions:
  - gather information, for example patient feedback, relating to the safety of health care,
  - keep under review, analyse and report on information obtained,
  - make recommendations for systemic improvements in the safety of health care,
  - promote public awareness of safety practices in relation to health care,
  - promote co-ordination among health care providers.
78. Schedule 1, introduced in Section 1 of the Bill, also contains a general power for the

Commissioner to do anything "necessary or expedient in order to achieve, or in connection with the exercise of the Commissioner's functions".

79. The Bill further sets out that it would not be the role of the Commissioner to resolve past grievances by providing redress for any harms suffered, assisting individuals in seeking redress for harms suffered, or to provide an opinion on what actions others should take with respect to an individual to address a past incident. However, this does not preclude the Commissioner from investigating past incidents to inform what actions need to be taken to provide systemic improvements in care.
80. Stakeholders, including professional regulators, representative organisations, membership bodies, professional organisations and providers were on the whole, supportive of the establishment of the Commissioner. However, all individual members of the public [10 responses] who responded to the Committee's call for views were opposed to the Bill. These responses perceived the Bill to be a waste of money and took the view that a better approach to addressing patient safety would be to spend the money on safe staffing, increasing pay, improving the provision of social care and reducing the number of NHS managers.
81. During oral evidence the Committee took evidence from individuals, and organisations supporting individuals. The majority stated their support for the establishment of the Commissioner, setting out the difference such a role could have made in relation to their own experiences.

Charlie Bethune from Valproate Scotland stated:

” The people who have been affected by valproate think that having a patient safety commissioner would be a fantastic improvement. Valproate was first prescribed in the 1970s, and the issues around it were known about within a few years. It has been going on for almost 50 years, and nobody has listened. For years and years, the voices were just being ignored by the medical profession, the regulators—by everyone. Our view is that if there had been a patient safety commissioner at any point during the past 50 years, the time to get this resolved would have sped up <sup>18</sup> .

Bill Wright from Haemophilia Scotland stated:

” Such a commissioner might have championed our cause, and many years of fighting could have been avoided. One of the biggest, most important bits of evidence that has come out during the infected blood inquiry is the compounding of harm. Everyone here and their families have suffered. Obviously, the conditions bring elements of physical harm, but it is because of the obfuscation and our not getting answers to questions or having a champion that we need a patient safety commissioner <sup>19</sup> .

Marie Lyon from the Association for Children Damaged by Hormone Pregnancy Tests stated:



” A patient safety commissioner is there to listen and to champion. Had a commissioner been available when Primodos was around in the 1960s and 1970s, they would have had the authority to remove that drug from the market, ensure that it was safe before it was put back on, if it was to be put back on, and ensure that there was sufficient investigation into the regulator at the time to make sure that they were doing the job that they were paid to do<sup>20</sup> .

82. However, Fraser Morton whose son, Lucas, was designated as stillborn at Crosshouse hospital in November 2015, was unsure if the existence of a Patient Safety Commissioner would have made a difference to his case. He spoke of his view that in his situation there were:

- failures in the categorisation of incidents and death certification,
- failures in the reporting of the incident to the Scottish fatalities investigation unit, and wider, how the Crown Office audits and reviews reported deaths, and
- issues with how his family were treated following the incident and as they were seeking further investigation.

83. Mr Morton stated:

” If I think of our ain situation, I am not sure whether a patient safety commissioner would be of any benefit [...] all those issues and problems that people face when having to fight for years compounds their grief and makes it last longer. It will never leave ye. The way that we were treated after Lucas died was every bit as bad as losing Lucas. I am not sure that a patient safety commissioner would hold the health board to account on the issues that I just mentioned— and those are just some of the many issues that we have encountered over the past few years<sup>21</sup> .

84. Mr Morton's testimony highlights a concern raised by other stakeholders that the remit of the Commissioner does not include investigating individual cases and individual complaints. These concerns are addressed in more detail later in this section.

## Remit

85. The [policy memorandum](#) notes that the legislation gives the Commissioner the freedom to determine their own initial goals, priorities for the role, how the role should work and how they will accomplish their overall purpose.

86. The policy memorandum states the Commissioner's remit will cover all healthcare providers operating in Scotland, including NHS, NHS-contracted and independent healthcare providers. Healthcare is defined in the Bill as "services provided for or in connection with the prevention, diagnosis or treatment of illness".

87. The Patient Safety Commissioner for Scotland would have a broad remit encompassing patient safety in general, rather than being purely focused on medicines and medical devices as is the case for the Patient Safety Commissioner in England.

88. Generally, evidence to the Committee welcomed the extension of the



Commissioner's remit beyond medicines and medical devices although this is contrary to the original recommendation by the IMMDS Review. As an example, Irene Oldfather, from the Health and Social Care Alliance Scotland (the ALLIANCE), stated:

” In relation to the scope of the commissioner’s remit, I agree with my colleagues that we are looking for the commissioner to have the widest possible scope so that they can be future proofed against events or situations that we might not know about at this point in time. We do not want replication of the stories that we have heard today on mesh-injured women <sup>22</sup> .

89. Some stakeholders expressed concerns about the potential scale of the task the Commissioner would face in fulfilling this wider remit, given the all-encompassing nature of the term 'patient safety'. For example, the Royal Pharmaceutical Society argued that, for this reason, the initial remit of the Commissioner should be more limited:

” The scale of the role is potentially very large, therefore setting initial priorities is useful to help public understanding of what the PSC is be able to do. RPS is of the belief that the PSC should prioritise patient safety in a medicines and medical devices context, using the lessons already learned, to make improvements to patient safety and minimise the risk of harm. It should then be up to the PSC to work flexibly and set their own priorities as they see fit to ensure it can be directed to areas where patient safety is at risk and respond to issues the public raise. Expansion to the PSC role should be guided by the information received by them from stakeholder groups (i.e. patients, families, professional bodies, research, etc.) raising concerns over patient safety issues, where a trend has been identified or where an individual incident may give rise to the suspicion of a broader issue <sup>23</sup> .

90. Meanwhile, other stakeholders argued that the remit of the Commissioner was not wide enough and identified areas of concern which would not fall under the Commissioner's remit. For example:

- Healthcare Improvement Scotland noted concerns around legislative gaps in relation to non-surgical cosmetic procedures and other types of private healthcare <sup>24</sup> .
- Dr Chris Williams from the Royal College of General Practitioners noted ethical and professional concerns over decision making support through software and advances in technology <sup>25</sup> .
- The Professional Standards Authority for Health and Social Care noted concerns over variations in how governments respond to major failings in health and care, and in how findings and recommendations from reviews and inquiries are overseen and acted upon <sup>26</sup> .

91. Some stakeholders argued that ensuring care and compassion and a person-centered approach to care should be included within the Commissioner’s remit. For example Matthew McClelland from the Nursing and Midwifery Council stated:

- ” there is actually a very close link between compassion and safety—in particular, with regard to listening to patients and people who use services. There absolutely is scope for the patient safety commissioner to take a slightly broader look at things <sup>27</sup> .

## Social care

92. Section 2 sets out that the scope of the Bill is related to health care only and the [policy memorandum](#) further clarifies: "The Commissioner will be able to consider safety issues relating to any healthcare provided in Scotland." However, many stakeholders argued that the remit of the Commissioner should also cover social care.
93. The Scottish Public Services Ombudsman (SPSO) raised concerns over the timing of the legislation, in the context of the ongoing process of health and social care integration and Dame Sue Bruce's current review of the regulation of social care:
- ” This bill focuses specifically on healthcare at a time when there is increasing integration of health and social care and the National Care Service bill is also before Parliament [...] Given the potentially seismic changes in the health and social care landscape in Scotland, it is evident to the SPSO that a legislative separation between health and social care, which is embedded in this bill (which focuses solely on healthcare), may be becoming outpaced by other developments. Dame Sue Bruce is conducting a review of the changes that may need to be made to the scrutiny, and regulatory social care landscape as a result of the National Care Service and I question whether this bill could be better informed if it waits for the outcome of that review <sup>28</sup> .
94. Many stakeholders raised concerns over how the Bill would take account of the proposed National Care Service and the intersection of patient safety issues between health and social care. In its submission, Parkinson's UK Scotland stated:
- ” It is not clear that the Patient Safety Commissioner would be able to act on issues that involve those receiving care that cuts across traditional health and social care boundaries. For example, if groups of people who are rapidly discharged from hospital to step-up step-down beds in a community setting have poorer outcomes, could the patient safety commissioner intervene? What would happen if systemic safety issues emerged for people looked after in hospital at home or virtual wards? Another good example of this might be the decision to discharge untested or covid-positive older people from hospital straight into care homes during the covid crisis - a decision that undoubtedly impacted on safety for care home residents, thousands of whom died as a result <sup>29</sup> .
95. Other stakeholders were concerned about the impact of separating out health and social care safety issues for individuals. Matthew McClelland from the Nursing and Midwifery Council stated:

- ” People do not experience primary care, secondary care, social care or nursing care; they experience care. The boundaries and divisions that we impose over the top of that are constructs of management and the way in which we operate, rather than the way in which people experience care. The commissioner’s powers need to be broad enough that when issues occur with care, wherever that might be, the commissioner is able to deal with the matter effectively, make recommendations and investigate where necessary. That is quite important <sup>30</sup> .
96. The Royal College of Nursing raised concerns that, in its view, limiting the remit of the Commissioner to healthcare would cause divergence with existing safe staffing legislation:
- ” The Commissioner appears to have no proposed role with respect to care services or the proposed National Care Service (NCS). Given the fact that increasingly complex health care needs are being met within social care environments, the drive to integrate services and proposals to potentially transfer some services to a National Care Service, we question the proposal for a Patient Safety Commissioner who only covers health services. This is not the approach taken by the Health and Care (Staffing) (Scotland) Act 2019, wherein patient safety is enshrined with respect to both health care and social care <sup>31</sup> .
97. During evidence, the then Minister for Public Health, Women's Health and Sport set out the Scottish Government's position in relation to the potential extension of the Commissioner's remit to include social care:
- ” The patient safety commissioner will be very focused on patient safety. As social care develops, people are looking very carefully at how to build in some of the systems that are focused on safety that are used in the NHS. At the moment, however, the focus of the remit should be on healthcare. It should not cover social care. If it was to be broadened to cover social care, the role might well be too broad initially and we could lose the essence of what the patient safety commissioner is about. That would be the concern <sup>32</sup> .
98. Several stakeholders also raised concerns that the scope of the Commissioner's role was too broad and the focus should be on where the Commissioner could make the most difference. Alison Cave from the Medicines and Healthcare products Regulatory Agency stated:
- ” The scope is so broad that it might be impossible to achieve, so we really need to think about how the patient safety commissioner would amplify patient voices, which is absolutely key. I refer back to the question about sodium valproate that was asked right at the beginning: amplifying the patient voice earlier might have led to earlier action. It will be really important that the commissioner can identify gaps where systemic change could make a difference <sup>33</sup> .
99. Referring to the scope and remit of the proposed Commissioner, the SPSO stated the importance of the Commissioner being able to identify and investigate emerging issues:

” It is right that the remit should cover more than just the two areas of known problems. The remit must be wide enough to enable the commissioner to react to and follow up new issues. The challenge in that regard is the resourcing and strategic planning. [...]Therefore, we must collectively ensure that the commissioner is able to follow up on those voices as far as they need to <sup>34</sup> .

## Individual cases

100. Section 2 of the Bill states that:

- ” (3) It is not the Commissioner’s role to resolve, or facilitate the resolution of, grievances arising from past incidents; accordingly, the Commissioner has no power to—
- (a) make awards, or provide any other form of redress, for harms suffered,
  - (b) assist individuals in seeking redress for harms suffered,
  - (c) opine on the action that another person ought to take in respect of an individual in light of a past incident.
- (4) Nothing in subsection (3) precludes the Commissioner from investigating past incidents in order to inform the actions that the Commissioner, and others, may take to effect systemic improvement in the safety of health care.

The [policy memorandum](#) further clarifies that "the Commissioner will take a macro view of patient safety in Scotland and seek to improve overall safety rather than address individual cases."

101. While all stakeholders were agreed on the importance of amplifying the patient voice, there were differing views on whether the Commissioner should take on individual cases.

102. In the written responses to the Committee's call for evidence, most welcomed the focus on systemic issues while others thought this could create an artificial distinction. In her evidence, the SPSO stated concerns this could cause confusion for individuals:

” [...] over 51% of recommendations made by SPSO last year were for systemic improvements. It is important to recognise that when people raise issues, there is often personal impact resulting from their experience of systemic issues. Many, if not most, complaints to SPSO about NHS care include system improvements and safety, either directly or indirectly. It is also the case that many system failings also require the consideration of individual redress. The wholly artificial separation suggested in this bill is likely to mean people may feel compelled to complain to both the SPSO and the Commissioner, given we deliver different outcomes. Given one of the concerns was the difficulty in knowing where to contact and who to raise issues with, this will only put the patient and their families in a more difficult (and complex) position <sup>35</sup> .

103. Many stakeholders agreed that clarity would be needed to manage public expectations regarding the Commissioner's role in addressing individual cases. As part of the ALLIANCE's engagement around the Bill, some of its members

expressed concern that there may be a risk of confusion about the role and remit of the Commissioner and setting unreasonable expectations regarding the treatment of individual cases. One ALLIANCE member stated:

” If I saw ‘Patient Safety Commissioner’ I would think that’s someone I could go to, but if they only deal with certain domains I would feel utterly betrayed <sup>36</sup> .

104. In its written response, the Mental Welfare Commission for Scotland questioned the extent to which a Patient Safety Commissioner would be able to amplify the patient voice without hearing individual complaints:

” [...] a focus on amplifying the patient voice is welcome, however the remit of the role as described in the Bill does not appear to provide a mechanism for individual concerns that do not result in ‘investigations’ to be adequately amplified with a focus instead on requiring/collecting patient feedback that ought to be a focus for health boards and their governance mechanisms. The capacity to undertake ‘investigations’ will be necessarily limited by the resource constraints and there is a real risk that the role will not deliver on the amplification <sup>37</sup> .

105. Marie Lyon set out a differing view that the Commissioner does not need to take on individual cases to be able to address systemic issues:

” I think that there is a misconception. Individual cases should be looked at, reviewed, noted and documented. That information could form a pattern. She will not have time to solve each case and neither should she <sup>38</sup> .

Marie further went on to articulate the importance of follow up and feedback to individuals as part of the process:

” Following up is important. Things are said and listened to, but does anything happen afterwards? [...] The commissioner should listen, say what they have taken from that, find out if anyone else is in the same position and say what they have done. That is the step that seems to be missing every time. What has someone actually done? <sup>39</sup>

106. Dr Anna Lamont from NHS National Services Scotland addressed concerns about potential duplication and set out how the Commissioner might not necessarily take on individual cases, but would co-ordinate existing resources and functions to ensure the patient voice is heard and used constructively:

” The patient safety commissioner’s scope is about listening to the patient, taking that holistic view and identifying what we do not already have. If it was purely about identifying what we know with regard to complaints or concerns, we already have those systems in place. We are looking for a body that can take a holistic overview and provide a nurturing and learning culture, to encourage us to look beyond what we already know [...] It is important that the patient safety commissioner has the scope to enable even a small number of individual concerns to be raised, so that the underlying issues can be identified and we can understand whether something can be put in place to avoid harm or an adverse experience for other people <sup>40</sup> .

107. Of a similar view, Dr Amit Aggarwal from the Association of the British Pharmaceutical Industry stated:

” The bill also offers an opportunity for the patient safety commissioner to give sufficient weight to anecdote. Baroness Cumberlege’s report cited the fact that anecdotal evidence was often dismissed, but the patient safety commissioner can give weight to such anecdote in a systematic, evidence-based and objective way, and therefore set priorities that are important to patients and to the public. Fundamentally, that is where I believe that the value of the role lies. I think that it provides an opportunity to fundamentally alter the landscape of patient safety for the better <sup>41</sup> .

108. The Committee also heard evidence on the Commissioner’s role and how its functions could incorporate the views of staff within healthcare services, pharmaceutical and health technology industries.

109. During evidence, the then Minister for Public Health, Women’s Health and Sport, set out that the Commissioner should be able to hear from staff in relation to patient safety concerns, and gave a commitment to review the Bill to ensure this was clear.

” It should be perfectly possible for staff to raise concerns and for the patient safety commissioner to listen to those concerns. I expect the patient safety commissioner to be an ear in the system and listening to staff would be an important part of that. We need to make clear that staff can raise their concerns. We are at stage 1 of the legislation and I am open to ideas about how we can make sure that that is clear. Essentially, however, the commissioner should be a listening ear. It would seem odd to me if they were not listening to staff <sup>42</sup> .

110. The Committee supports the primary functions of the Patient Safety Commissioner for Scotland as being to advocate for systemic improvements and to amplify the voice of patients.

111. The Committee recognises stakeholder concerns that the Commissioner will not address individual complaints, but also recognises that there are established processes in place for handling individual cases and complaints. However, given that some of the common themes from the Independent Medicines and Medical Devices Safety Review related to patients feeling they were not listened to and the length of time taken for their problems to be acknowledged, the Committee considers marketing and raising public awareness, as well as managing expectations, in relation to the role of Patient Safety Commissioner to be paramount. While recognising the independent status of the Commissioner, the Committee believes it will be important for the Patient Safety Commissioner for Scotland, once appointed, to put in place the mechanisms for addressing these considerations as an initial priority.

112. The Committee is supportive of giving the Commissioner the necessary operational freedom to determine their initial goals and priorities for the role as well as how they will accomplish their overall purpose. The Committee recognises that the remit of the Patient Safety Commissioner for Scotland is wider than its counterpart in England and, in this context, highlights the particular



importance of being very focused in terms of defining priorities that are manageable and deliverable within the constraints of available resources.

113. The Committee supports the Scottish Government's rationale for not including social care within the Commissioner's initial remit. However, the Committee calls on the Scottish Government to confirm the Commissioner would be able to investigate and make recommendations to reflect the voice of patients on issues that intersect with, or transcend, health and social care.
114. The Committee recognises the role of staff in raising patient safety concerns, and the existing processes in place to raise those concerns, for example, in relation to whistleblowing. The Committee welcomes the then Minister's commitment to clarify the Bill to provide clarity around the Patient Safety Commissioner's role in listening to staff, to the extent this supports the Commissioner's primary purpose of amplifying the patient voice, and looks forward to further detail at Stage 2.

## Principles and communication

### Statement of principles

115. Section 3 of the Bill requires the Commissioner to develop a statement of principles that will inform the way in which they carry out their functions. This statement must be made publicly available and include a principle that the Commissioner will work cooperatively with others where appropriate, while having regard to the importance of the Commissioner's independence.
116. The [policy memorandum](#) provides little detail as to how the principles should be established or what should be included:

” The first Commissioner will produce a set of principles governing their ways of working. The Commissioner can review and revise these principles at any time as the need arises, and must make the latest version of the statement publicly available. It is important to the effectiveness of the role that the Commissioner works co-operatively with other organisations such as health boards, independent providers and inspection and regulatory bodies so that information is shared and improvements can be made across the system, and the principles should reflect this.

117. Many stakeholders welcomed provision being made for a statement of principles. However, a number of stakeholders raised concerns about how these would be developed and what they would include. In its submission, the General Medical Council (GMC) noted "While the duty to prepare and publish a strategic plan carries with it a formal requirement to consult on the draft plan, there is no equivalent duty to consult on the principles<sup>43</sup>". During oral evidence, Shaun Gallagher from the GMC further expanded on this, setting out the rationale for carrying out a consultation process on the principles:

” we think that there could be an open and full consultation on the principles that the bill requires the commissioner to have, mainly to address the concerns that many people have had about a cluttered patient safety landscape, duplication and ensuring that the role fits in the most effective way and adds value <sup>44</sup> .

118. Dr Arun Chopra from the Mental Welfare Commission for Scotland argued that it was imperative the Commissioner hear the voices of under-represented groups, and they are reflected in the data collected:

” We need to ensure that we hear the voices of those groups who have struggled the most to get their points across. In the earlier evidence session, you talked about valproate, which predominantly affected women, and mesh, which again affects women. There was a consistent theme about women not having their voices heard by the profession. People from other marginalised groups, such as ethnic minorities, are not represented in the data on patient safety, and patient safety events predominantly affect marginalised groups, so it is incredibly important that we collect data about protected characteristics <sup>45</sup> .

119. Age Scotland noted the importance of the principles and welcomed the inclusive language in the Bill, but thought the Bill could go further in terms of developing the principles, calling for the advisory group (addressed [later in this report](#)) to have a role in setting the principles:

” as well as the duty to have a strategy and include in that a plan for engagement with the public and patients in particular; [...]we feel the advisory group should be explicitly involved in the creation of the principles <sup>46</sup> .

120. The Royal College of Nursing (RCN) raised separate concerns regarding the content of the principles and called for the Bill to require the principles to be linked to other relevant principles on patient safety contained in other legislation, standards or other instruments deriving from legislation:

” Our view is that the Commissioner should discharge their duties having regard to relevant principles on patient safety contained in other legislation, standards or other instruments deriving from legislation, and that this should be made explicit in the Bill[...] There is now such a well-established landscape of principles setting out how services should ensure patient safety and the provision of high-quality services, that it seems a missed opportunity not to more directly and explicitly embed the Commissioner and their role into that landscape in this Bill <sup>47</sup> .

121. In particular, the RCN recommends that the Bill should make reference to the following legislation:

- Health and Care (Staffing) (Scotland) Act 2019
- Patients’ Rights (Scotland) Act 2011
- Public Bodies Joint Working (Scotland) Act 2014
- Public Services Reform (Scotland) Act 2010



- National Health Service (Scotland) Act 1978
122. The RCN further call for amendment of the Health and Care (Staffing) (Scotland) Act 2019, due to the intrinsic link between safe staffing and patient safety:
- ” Given the fundamental link between safe staffing and patient safety, we believe the Patient Safety Commissioner will be a key stakeholder in relation to monitoring how the duties introduced by Scotland’s safe staffing legislation are being met. The Bill should therefore amend the 2019 Act to require Scottish Ministers to submit its annual report on staffing (as required by section 4 (12IM)) to the Commissioner <sup>48</sup> .

## Communication

123. Section 4 of the Bill requires the Commissioner to have regard to 'inclusive communication'. The Bill defines this as ensuring individuals who have communication difficulties can receive information and express themselves in ways that best meets their individual needs.
124. On the whole, stakeholders were supportive of this provision of the Bill and felt it would promote equity of awareness and access to the Commissioner. The Health and Social Care Alliance Scotland (the ALLIANCE) expressed a view in its written submission <sup>49</sup> that such communication needed to be in place 'at the earliest opportunity' to make sure it was fully inclusive, and that this should include information in alternative formats and languages.
125. However, the Equality and Human Rights Commission questioned the necessity of this provision in the Bill noting little difference to the provisions in the [Equality Act 2010](#):
- ” While the commitment to inclusive communication is welcome, most public bodies are already subject to Section 20 of the Equality Act 2010, which sets out the reasonable adjustment duty [...] The inclusive communication duty contained in the Bill should complement, and not duplicate or conflict with, the existing Equality Act 2010 reasonable adjustment duty. Section 4 of the Bill does not clearly define how inclusive communication differs from the reasonable adjustment duty <sup>50</sup> .

126. The Committee recognises the importance of giving the Commissioner the freedom to define and establish their own principles, following commencement of the role. However, it also recommends that the Bill should require the Commissioner to consult with stakeholders on these principles. The Committee recommends that such provisions should follow a similar process to the Commissioner's duty to consult on their strategic plan.
127. Recognising that the interventions highlighted in the Independent Medicines and Medical Devices Safety Review all affected women, the Committee calls for the principles underpinning the work of the Patient Safety Commissioner to include an explicit commitment to listening to and supporting under-represented voices.

128. The Committee also agrees with the Royal College of Nursing that the Commissioner should be required to take account of existing legislation when drafting the principles and recommends that provision for such a requirement should be made on the face of the Bill.
129. The Committee takes a view that, unless the Scottish Government can demonstrate the specific added value provided by those provisions of the Bill on inclusive communication, they should be considered superfluous given the pre-existing reasonable adjustment duty provided by the 2010 Equality Act and should therefore be removed.

## Strategic planning

130. Sections 5-7 of the Bill relate to strategic planning. Provisions in these sections require the Commissioner to develop a strategic plan that lasts no longer than four years, is publicly available and must be laid before Scottish Parliament. The Commissioner must consult the Scottish Parliament Corporate Body (SPCB) and the Patient Safety Commissioner for Scotland advisory group on the development of the plan, and it must include certain provisions as a minimum. The strategic plan must also set out how it will raise awareness of the Commissioner's role and how the public can communicate with the Commissioner.
131. Most stakeholders were content with the provisions within this section of the Bill. However, evidence to the Committee highlighted some concerns over Section 6, which sets out the consultation process for the strategic plan. In its submission, the Equality and Human Rights Commission stated:

” In the interests of accountability and openness, and of both being and being seen to be the ‘new voice ... from the perspective of the patient’ envisaged by the Cumberledge Review, we recommend that the Commissioner explicitly apply concepts of co-production to the design of its initial goals, priorities for the role and decisions on how it should work. Co-production, properly implemented, provides the framework to develop meaningful relationships and is itself a form of participation.

The Bill should include a commitment to co-production for the Commissioner, to ensure the views of those directly affected by Patient Safety considerations are centred in the design of initial goals, priorities for the role and decisions on how it should work <sup>51</sup> .

132. Irene Oldfather from the Health and Social Care Alliance Scotland (the ALLIANCE) supported a similar view in her evidence to the Committee, stating:

” My final point is that the bill mentions providing a strategic plan and ensuring that that is consulted on. Again, we suggest going a bit further by co- producing it with people who have experienced patient safety issues across the piece <sup>52</sup> .

133. The policy memorandum states that amplifying the patient voice is one of the Bill's main purposes. The Committee is of the view that the principles and the strategic plan underpinning the work of the Commissioner should be developed in consultation with those it seeks to represent, alongside other patient safety stakeholders and organisations. The Committee recommends that the Scottish Government strengthen Section 6 of the Bill to ensure proper consultation with patient safety stakeholders and organisations as part of their development. In so doing, we also ask the Scottish Government to consider to what extent co-production can be incorporated into this approach.

## Formal investigations

134. Sections 8-11 in the Bill relate to formal investigations. The Bill gives the Commissioner the power to undertake formal investigations into healthcare safety issues.
135. The Bill states that a formal investigation begins as soon as the terms of reference become publicly available and that the terms of reference must:
- describe the issue to be investigated
  - identify anyone who the Commissioner expects to address a recommendation to in the final report
  - state whether the Commissioner will require access to information about individuals during the course of their investigation, the reasons why such access is needed and if the information will need to be provided in an anonymised way or not.

The Commissioner will be required to consult with the advisory group on the draft terms of reference and once launched, must bring the investigation to the attention of anyone who may be required to provide information, or who may have a recommendation directed at them in the report resulting from the investigation.

136. The Bill states that once a formal investigation is concluded, the Commissioner must produce a report and lay a copy before the Scottish Parliament. The report must set out its findings, the reasons behind them and any recommendations. The Commissioner must also give a copy of the report to anyone to whom a recommendation is addressed.
137. According to the draft Bill, where a report contains a recommendation which is aimed at them, a person or organisation is required to respond to that recommendation, within the timescale specified in the report. This response should be in a written format and include detail on what that person or organisation has done, or proposes to do, to address the recommendation(s) of the Commissioner, or if they do not intend to implement a recommendation, the reasons for not doing so. The Commissioner may publish the response (either in full or in part) or publicise any failure to respond to a recommendation.
138. A number of organisations expressed general support for these provisions, on the

understanding that they would be required to respond to a Commissioner's report but that the content of their response would in no way be restricted and they would not be bound to accept or implement individual recommendations. NHS Grampian suggested one potential scenario might be that an organisation would provide a response giving a commitment to implement a recommendation "as far as they are able"<sup>53</sup>.

139. However, the Committee heard concerns from patient representatives that organisations would not be compelled to accept or implement a recommendation. Based on his own experience, Fraser Morton argued that if not compelled to make changes, organisations may not apply the necessary learning to prevent other such incidents from happening in the future:

” I have a thick pile of action plans from deaths similar to Lucas’s, which public bodies have failed to learn from<sup>54</sup>.

140. Mr Morton further argued that, for recommendations to be taken seriously, further powers to escalate or sanction are required. In this context, he highlighted the powers of the Health and Safety Executive to "make enforcement orders, issue fines or take your liberty away in a serious incident"<sup>55</sup>. He further noted that while sections 14 of the Bill makes provision for escalation to the Court of Session, in the event of a failure to supply required information, there is no corresponding provision for such an escalation process if an organisation fails to implement a Commissioner's recommendation<sup>56</sup>. The question of sanctions is addressed in more detail [later in this report](#).

141. Stakeholders also raised additional concerns relating to formal investigations, including:

- the potentially significant resources required to undertake investigatory work compared with the level of resource set out in the financial memorandum accompanying the Bill (addressed in more detail [later in this report](#)),
- potential duplication of functions, associated working relationships, and crossover with investigations by other bodies (addressed [earlier in this report](#)), and
- lack of provision in the Bill for an ongoing role of the Commissioner in monitoring implementation of its recommendations.

142. In its written response, the General Medical Council highlighted concerns around the lack of an ongoing monitoring role for the Commissioner after receiving an initial response to one of their investigation reports:

” We support the proposed power for the PSC to require ‘persons’ to respond to a recommendation within a report produced by the PSC – as set out in Article 11. However, one interpretation of the legislation is that it only permits the PSC to obtain a one-off response from the ‘person’ in question and does not appear to permit the PSC to obtain further responses. We would suggest that the PSC also have a role in monitoring the implementation of recommendations – beyond soliciting initial responses to their publication in a report – and therefore, this power may need to be broadened to accommodate this<sup>57</sup>.

143. The Law Society of Scotland expressed concerns related to circumstances where the Commissioner hears concerns regarding individuals involved in criminality or who have impaired fitness to practice. It states that in the Bill "It is[...] not clear how the relationship between the Commissioner and the Crown Office and Procurator Fiscal Service (COPFS) would operate <sup>58</sup> ", and that in its view "There is also a risk that that the PCS may represent a route to sanctions without the burden and standard of proof which come with criminal proceedings <sup>59</sup> ".
144. Stakeholders have also questioned how whistleblowing information from healthcare providers would be considered by the Commissioner. In her written response, the Scottish Public Services Ombudsman (SPSO), who fulfils the role of the Independent National Whistleblowing Officer, also calls for improved clarity on investigations in this respect, in particular in relation to responsibility for such investigations:
- ” The legislation around investigatory function would also benefit from redrafting. As currently proposed, the legislation appears to misunderstand the close relationship between individual impact and systemic failing that exist in the delivery of health care. An alternative option would have been to provide SPSO with the ability to undertake own initiative investigations. That is a significant policy decision and, at this stage, SPSO would recommend that the section in the Bill on investigations is either taken out in total or redrafted with a clearer focus <sup>60</sup> .

145. Given the situations that gave rise to the Independent Medicines and Medical Devices Safety Review, whereby patients were routinely not believed and dismissed, and no actions were taken to address patient safety concerns, the Committee considers it vital that the Commissioner has the necessary capabilities to follow-up on the implementation of its recommendations. The Committee recommends that the relevant sections of the Bill be amended to give the Commissioner the necessary powers to undertake such follow-up, whether that is with the 'person' the recommendation is addressed to, or with a regulatory or patient safety partner.

## Gathering and use of information

146. Sections 12-15 in the Bill relate to the gathering and use of information.
147. Sections 12 and 13 both allow the Commissioner to access information. Section 12 allows the commissioner to require a healthcare provider to supply any information that is relevant to the work of the Commissioner but this does not include information about individuals. Although Section 13 allows the Commissioner to require anyone (not just healthcare providers) to supply information, including information about individuals, this power only covers information relevant to an issue under investigation, rather than the work of the Commissioner more generally and can only be used if the Commissioner is satisfied it is proportionate. Neither section 12 nor 13 require anyone to provide information that they would be entitled to refuse to provide in proceedings in a court in Scotland.

148. Many stakeholders welcomed the powers to require information detailed within these sections of the Bill. During evidence, Dr Chris Williams from the Royal College of General Practitioners noted:

” I am especially pleased about the power to compel evidence to be produced; that, in particular, will make a big difference <sup>61</sup> .

149. The Scottish Public Services Ombudsman raised a concern about Section 12 and whether it would apply to private companies:

” Section 12 compels some organisations to provide evidence. This is limited to healthcare providers and it is not clear whether it would extend to private companies who may be providing devices or medicines. Given it was concern about medicine and devices that led to the creation of the role, this may be a significant limitation <sup>62</sup> .

150. Section 14 sets out action the Commissioner may take where a person has refused to supply information, failed to supply information without a reasonable excuse, or the Commissioner suspects the person has deliberately altered the information in question. The Commissioner may:

- publicise the person’s refusal, or failure, to supply the information.
- report the matter to the Court of Session

The Court of Session may then:

- make any order for enforcement that it considers appropriate.
- deal with the matter as if it were a contempt of court.

151. Section 15 provides for breaches of confidentiality around information shared with the Commissioner. The [explanatory notes](#) state:

” the Commissioner (including any former Commissioners), the Commissioner’s staff (or past staff), a member of the advisory group established under section 16 and an agent (or former agent) of the Commissioner [...] would be guilty of an offence if they disclose information which has been obtained in the course of the Commissioner’s activities, and which is not at the time of disclosure, and has not previously been, in the public domain.

This offence would not apply to the sharing of information with a person’s consent, or in instances where sharing that information was necessary for the Commissioner to carry out their functions. It would also not apply to disclosures for court proceedings or the investigation of a crime, or in cases where it was intended to help Healthcare Improvement Scotland, the Scottish Public Services Ombudsman or the Patient Safety Commissioner for England carry out their statutory functions. In cases where the offence does apply, if found guilty, this could result in a fine up to the statutory maximum<sup>vii</sup> if tried by a sheriff, or an unlimited fine if tried by a jury.

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vii Defined in schedule 1 of the Interpretation and Legislative Reform (Scotland) Act 2010 as the prescribed sum under section 225(8) of the Criminal Procedure (Scotland) Act 1995 (currently £10,000).



152. In her written response, the Scottish Public Services Ombudsman suggested that the provision in Section 15(2) which permits the disclosure of information for the purpose of assisting certain persons in exercising their statutory functions may need further examination:

” Given the breadth of the potential remit, greater thought may need to be given to better set out the relationship between the PSC and the broader landscape. This may extend to requirements to co-operate and consult in some areas and to information sharing in others. To give just one example, the list of organisations in section 15(2) is fairly narrow and doesn't extend to the Health and Safety Executive<sup>63</sup> .

153. The General Medical Council (GMC) and the Nursing and Midwifery Council were also of the view that this section should be extended to include professional regulators. Shaun Gallagher from the GMC told the Committee:

” There is also a need to strengthen the powers in relation to information sharing [...] We think that there is a need to allow information to be shared with professional regulators—maybe not all the time, but certainly where appropriate; for example, where there is a concern that would be suitable for us to follow through on and investigate<sup>64</sup> .

## Data

154. Dr Anna Lamont from NHS National Services Scotland highlighted the potential for the Commissioner to improve consistency and data gathering processes across a complex patient safety landscape in Scotland and the rest of the UK:

” At the moment, local authorities, health boards and patients have multiple ways of recording data—in fact, if incidents take place in boards, there are different systems to report them locally and nationally, which do not talk to each other or collaborate. There is an opportunity here to prioritise that collaboration and bring that data together. It is about working with existing safety organisations<sup>65</sup> .

155. Dr Lamont further highlighted the additional benefits the Commissioner could bring to the data that is collected and analysed to allow patient trends to be recognised and addressed alongside existing data sets:

” At the moment, many of the systems focus on reporting from professionals. There is an opportunity here for parallel mechanisms that amplify the patient voice. Where there are small signals within individual nations, they can be brought together to recognise the concern. That is applicable in Scotland. Many of the examples that I have from the NHS National Services Scotland incident reporting centre are very small—two, three, four or five events that have happened across the UK, which lead to investigations about concerns, then to collaborations with manufacturers, then to checking and changing the process, and then to future patient safety. With the patient safety commissioner we have the opportunity to mirror that system for patient voices<sup>66</sup> .

156. Dr Arun Chopra from the Mental Welfare Commission spoke of his experience of working with the Patient Safety Commissioner for England and the data emerging from this cooperation so far:

” Last week, I was speaking to the Patient Safety Commissioner for England , Henrietta Hughes, and I asked her what were the top things that she was hearing in the area of mental health, in which I work. She was immediately able to give me a response about the suicidality that is related to people using particular medicines for skin conditions, post-serotonergic difficulties—which people get when they have been on an antidepressant for too long—and electroconvulsive therapy or ECT. Those are the signals that her team and she are picking up from emails and phone call conversations. That work adds value to the existing mechanisms that we have <sup>67</sup> .

157. While Dr Chris Williams expressed some concern about how long it would take to develop expertise around data collection, he acknowledged the benefit of the Commissioner having an "ability to tap into different sources of data, to open and commission investigations, and to compel people to provide information" <sup>68</sup> .

158. In her written response, the Scottish Public Services Ombudsman expressed further concerns about potential inequality of treatment of different cases and concerns that might arise from the varying levels of resource and capacity different patients and patient groups might have to engage with multiple organisations. She suggested strengthening provisions in the Bill related to information sharing and co-operation could address this potential risk:

” As establishing the PSC creates a new point for feedback and data gathering, this creates the risk that trend data about what concerns are being raised is accidentally inflated by the same issue entering the system at multiple, discrete points [...] the failure to put in place provisions to allow for a sufficient level of information sharing and co-operation across agencies risks amplifying the concerns raised by those most able to engage with multiple agencies <sup>69</sup> .

159. Dr Gary Duncan, chief of staff to the Patient Safety Commissioner for England noted that additional capacity and capability would be needed within their existing set up to strengthen this data analysis:

” [...] without a data analytics function, the novel insights that a commissioner could have would be limited. There are things that good-quality policy and strategy professionals can do with the data that exists, but we are keen to do something a little more sophisticated. That would require that high-level strategic function and data analytics capability within our team to identify, gather and analyse data to produce novel insights <sup>70</sup> .

160. Resources in relation to the Commissioner's role are considered [later in the report](#).

161. The Committee takes the view that powers given to the Patient Safety Commissioner for Scotland under Section 12 of the Bill to compel organisations to provide evidence must include private companies who provide devices or medicines. It considers there is a lack of clarity in the Bill as introduced as to whether these powers will apply to private companies and believes this needs to be clarified at Stage 2 to ensure that they do.

162. The Committee has heard strong evidence in support of extending the list of



organisations authorised to receive confidential information for the purpose of assisting them in exercising their statutory functions to include:

- professional regulators, and
- the Health and Safety Executive

It therefore calls on the Scottish Government to give consideration at Stage 2 to amendments to Section 15(2)(d) of the Bill that would give effect to this recommendation.

163. The Committee notes evidence from the Patient Safety Commissioner for England that having in place sufficient and suitable data analytics capability will be crucial to the Patient Safety Commissioner fulfilling their role effectively. It therefore calls on the Scottish Government, in advance of Stage 2, to address what level of resource will be required to put this capability in place.

## Sanctions

164. As part of those sections relating to the gathering and use of information, the Bill makes provision for the Commissioner to be able to publicise an organisation's failure to provide information and to report matters to the Court of Session. Section 15 of the Bill also sets out provisions relating to the imposition of sanctions for breaches of confidentiality.
165. During evidence, opinion was divided on whether the Commissioner had appropriate enforcement powers and whether they should be able to impose further sanctions during fulfilment of their duties.
166. In its written submission, the Professional Standards Authority for Health and Social Care made the case for a light-touch approach to sanctions, as set out in the Bill:
- ” In line with the principles set out in our guidance on regulatory policy-making, Right-touch regulation<sup>viii</sup>, we advocate using the minimum regulatory force required to achieve the desired outcome. Transparency can be a powerful tool, and for this type of role could be enough to effect change where needed<sup>71</sup>.
167. Dr Amit Aggarwal from the Association of the British Pharmaceutical Industry spoke of the power of 'naming and shaming' as a sanction during his evidence, noting "the commissioner's powers to publicly name and shame are pretty strong. I do not see a common scenario in which an organisation would choose to ignore that completely"<sup>72</sup>.
168. Healthcare organisations and regulators expressed the view that more punitive sanctions should be discouraged on the basis that this would risk exacerbating blame cultures, increasing the burden of bureaucracy, damaging staff morale and leading to reduced participation.

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viii <https://professionalstandards.org.uk/what-we-do/improving-regulation/right-touch-regulation>

169. Evidence to the Committee highlighted that there is often a culture of fear among staff of being referred to their regulator. Some of the written submissions expressed related fears that the Commissioner would become another means by which to ‘berate and punish staff’. Opposing the use of more punitive sanctions, Bill Wright from Haemophilia Scotland spoke about the adverse impact on patients when the system encourages a blame culture and treats patients’ complaints as a threat.

170. Speaking about her experiences since taking up her role on 12 September 2022, Dr Henrietta Hughes, the Patient Safety Commissioner for England stated:

” Using powers, fines or enforcement feels like quite a punitive thing to do. I am keen to encourage, support, suggest and influence in that much more positive space [...]having a just culture and a positive and encouraging way of doing things is more effective than deploying powers in the first instance <sup>73</sup> .

171. In relation to formal investigations, Fraser Morton expressed a contrary view that, based on his experiences, powers for further escalation or sanction, above those currently in the Bill, are required to ensure the Commissioner’s recommendations are taken seriously <sup>74</sup> .

172. During evidence, the then Minister for Public Health, Women’s Health and Sport spoke about the powers of the Commissioner and the need for a learning and improvement culture around patient safety in Scotland:

” [...]it is a role that is really about encouraging a culture of openness and inquiry, and it is absolutely in the system’s best interests to adopt that culture. That is how we will give the best patient care. If we do not learn when mistakes happen or when safety issues arise, mistakes will be repeated, which is not in the interests of patients or the system. Therefore, I think that there will be enough power <sup>75</sup> .

173. The Committee acknowledges views on the importance of sanctions, but also believes that the overarching priority of the Patient Safety Commissioner must be to avoid creating or exacerbating blame cultures and to foster a culture of openness, learning and collaboration. The Committee therefore concludes that the powers set out in the Bill strike an appropriate balance in this regard.

## Advisory group

174. Section 16 of the Bill requires the Commissioner to establish and maintain an advisory group to provide advice and information in relation to the Commissioner’s functions. The [policy memorandum](#) states:

- ” As well as patient representation, the advisory group will allow the Commissioner to obtain specialist and professional guidance that is not able to be provided by their core staff. The membership of the advisory group should consist of 50% patients and representatives of patients. While the advisory group will give the Commissioner advice on matters relating to their work, for example from a clinical, legal, ethical and patient point of view, the Commissioner should also engage with stakeholders, patients and members of the public in other ways, such as through stakeholder workshops and public consultation exercises.
175. Many stakeholders welcomed that the advisory group will consist of 50% patient representation. However, there were concerns as to how membership would be defined and stakeholders called for greater clarity on group membership and how it will operate in practice.
176. Age Scotland expressed concerns around how the advisory group would be fully representative and reflect diversity across Scotland:
- ” We would welcome inclusion of more specific language about the make up of the advisory group for Office of the Patient Safety Commissioner – including to ensure that the patients involved are diverse and reflect the background and experience of patients across Scotland <sup>76</sup> .
177. Irene Oldfather from the Health and Social Care Alliance Scotland (the ALLIANCE) suggested how the language in the Bill might be strengthened in terms of representation, and highlighted how those with protected characteristics should be involved, something which was also noted by other stakeholders in written evidence to the Committee:
- ” Section 16(4)(c) mentions “persons who appear to the Commissioner to be representative”. We felt that that wording is a little bit woolly and could be strengthened. The approach should be not about appearing to be representative but about demonstrating that—it should be about having people who demonstrate a commitment. We wonder whether the committee might consider making an amendment to the bill in those terms. We would welcome having people with protected characteristics—in particular, women—being represented on the advisory panel. Women have told us that they felt that they were not being listened to in the system, so it is important that sufficient protection is given to ensure that there is a strong voice for them on the advisory group <sup>77</sup> .
178. The ALLIANCE argued in its written submission that participation in the group should be meaningful and that it must be ensured that members are supported, and properly remunerated, to be able to fully engage. They suggested that this support:
- ” should include resource for accessible and inclusive communication, including any assistive technology or communication support costs required to enable lived experience representatives to take part in and contribute to the advisory group in an equitable way. We suggest that learning can be taken from established groups such as the People Led Policy Panel to ensure the provision of adequate support for all members of the advisory group <sup>78</sup> .

Irene Oldfather followed this up in oral evidence:

” We believe that, in order to give the position the gravity and impetus that it needs, people should be paid for the work that they do. Just because they have lived experience should not mean that they get only expenses <sup>79</sup> .

179. The [financial memorandum](#) sets out indicative costs associated with reimbursing the time and expenses of patient representatives who are not in employment. It notes that these payments are at the discretion of the Commissioner, and overall costs may vary depending on group membership and in the event of virtual meetings.

180. In relation to organisational and professional membership of the advisory group, stakeholders made the following suggestions:

- NHS National Services Scotland felt that while NHSScotland employees should not be permitted to sit as part of the advisory group, experienced current or former NHS colleagues should be permitted to represent the voice of people from a healthcare background <sup>80</sup> .
- Valproate Scotland felt that any current employee of a healthcare provider or supplier should not be permitted to sit as part of the advisory group <sup>81</sup> .
- The Association of Anaesthetists felt that both patient and healthcare professionals, who are experts in safety matters, should be appointed to the advisory group <sup>82</sup> .
- Community Pharmacy Scotland <sup>83</sup> and the National Pharmacy Association <sup>84</sup> felt that a community pharmacist should be appointed to the advisory group, arguing that community pharmacy plays a key role in patient care and the overall delivery of patient safety.
- The Equality and Human Rights Commission felt that someone with expertise in regulation in Scotland, the UK, or international contexts, should be appointed to the advisory group <sup>85</sup> .

181. A number of stakeholders also highlighted the benefit of collaboration among patient safety commissioners across the UK, a sentiment very much welcomed by Dr Henrietta Hughes in her evidence to the Committee. In its written submission, the Professional Standards Authority for Health and Social Care went further, suggesting:

” [...] the four UK Commissioners should come together to form what we called a Consortium. The Consortium would help the Commissioners coordinate their work, identify trends on a large scale, and provide a UK-wide picture of safety in health and care <sup>86</sup> .

182. The Committee agrees with Irene Oldfather that the wording in Section 16(4)(c) of the Bill requires further review and should be amended to specify that individuals appointed to the advisory group 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.

183. The Committee also agrees that all advisory group members should be properly supported and remunerated to be able to contribute effectively to the group's work. It concludes that all patient representatives on the advisory group should be entitled to such reimbursement, regardless of their employment status. The Committee further recommends that calculating the rate of travel expenses payable to patient representatives must take due account of the particular circumstances of those travelling from remote and rural areas and potentially higher travel costs they may face.

## Miscellaneous provisions

184. Section 17 of the Bill permits the Commissioner to lay before the Parliament any report prepared by the Commissioner if the Commissioner considers it appropriate to do so. This is aside from the investigation reports the Commissioner has a duty to lay before the Scottish Parliament under Section 10 of the Bill.
185. Section 18 of the Bill makes provision to protect the Commissioner against actions of defamation. Any statement made to the Commissioner, or a member of the Commissioner's staff, and any which appear in the Commissioner's report on an investigation have absolute privilege. Absolute privilege confers complete protection against accusations of defamation. Any other statement<sup>ix</sup> made by the Commissioner or any of its staff, in connection with the Commissioner's functions, have qualified privilege. Qualified privilege would provide protection where it can be shown no malice or intent to injure was intended.
186. Section 19 of the Bill requires the Commissioner to comply with any direction given by the Scottish Parliament Corporate Body (SPCB) in terms of: the location of the Commissioner's office and the sharing of staff, premises, resources or services with other public bodies. Any such direction is to be published by the SPCB.

187. The Committee is content with sections 17, 18 and 19 of the Bill and, in particular, welcomes that section 18 will enable the Commissioner to carry out their work effectively, without fear of being subject to actions of defamation.

## Final provisions

188. Section 20 introduces schedule 2 which amends enactments relating to public authorities in order to bring the Commissioner within their provisions.

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<sup>ix</sup> Definition of a 'statement' is set out in section 36(b) of the [Defamation and Malicious Publication \(Scotland\) Act 2021](#).

189. Section 21 provides definitions of the following terms:

- Commissioner
- forensic medical examination<sup>x</sup>
- health care
- Parliamentary corporation, and
- patient<sup>xi</sup>.

190. In her written submission, the Scottish Public Services Ombudsman raises concerns around the lack of definition of 'safety' used in the Bill and calls for this to be added to the Bill to ensure clarity:

” I have been unable to find a clear definition of “safety” as opposed to concern or experience. Adding such a definition may be a way to focus the Commissioner's area of interest in a way that would be helpful for users and make their role in the landscape much clearer<sup>87</sup> .

191. Sections 22 - 25 of the Bill relate to ancillary provision, regulatory making powers, commencement and short title.

192. The Committee is for the most part content with the provisions set out in Sections 20 to 25 but believes there would be benefit in including a definition of 'patient safety' on the face of the Bill. It calls on the Scottish Government to address this directly in responding to this report.

193. The Committee is also content with the ancillary provisions set out in Schedule 2 of the Bill.

## Delegated powers

194. The Delegated Powers and Law Reform (DPLR) Committee considered the Bill at Stage 1 at its meeting on 15 November 2022. The [Committee reported](#) that it did not need to draw the attention of the Parliament to the delegated powers related to the following three provisions:

- Section 22 - Ancillary provision
- Section 24(2) - Commencement
- Paragraph 21(2), Schedule 1 - Accounts and audit

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<sup>x</sup> Forensic medical examination is defined in the Forensic Medical Services (Victims of Sexual Offences) (Scotland) Act 2021.

<sup>xi</sup> Patient is to be construed in accordance with the National Health Service (Scotland) Act 1978


195. The Committee notes the conclusion of the Delegated Powers and Law Reform Committee that it is content with the delegated powers provisions contained in the Bill.



# Role of the Parliament

196. Schedule 1 of the Bill provides that the Commissioner will be an appointment by HM The King on the nomination of the Scottish Parliament. The Scottish Parliamentary Corporate Body (SPCB) will be responsible for recruiting the Commissioner and providing the resources for the Commissioner and the staff and operations of the office. The SPCB will also determine the length of the term of office of the Commissioner, up to a maximum of eight years. The Bill prevents a serving or past Commissioner from being reappointed to the office.
197. The Commissioner will be responsible to the Parliament, both in terms of reporting on discharge of their powers and functions and the operations of the Code of Practice, as well as for the administrative operation of their office and use of resources. The Commissioner will be responsible for recruiting and appointing the staff of their office, subject to the terms and conditions agreed by the SPCB.

## Resources

198. The Public Finance and Administration (FPA) Committee issued a [call for views on the estimated financial implications of the Bill](#) as set out in its accompanying [financial memorandum](#) (FM). This ran from the 28 October 2022 until 6 Jan 2023 and did not receive any responses.
199. The Convener of the FPA Committee wrote to the Convener of this Committee in relation to the Bill on [31 January 2023](#). In this letter, the FPA Committee highlighted concerns expressed by the SPCB on [10 January 2023](#), as part of the FPA Committee's scrutiny of the SPCB Budget for 2023-24. These concerns related to the funding of officeholders, in particular the increasing number of commissioners and their associated costs.
200. The FPA Committee's report on the SPCB Budget for 2023-24 stated:  
  
 The Committee expresses concern regarding the potential for a significant increase in the number of officeholders with their associated costs. In 2023-24 the percentage increase in funding needed to meet those costs appears to be significantly higher than that made available to other areas of the public sector  
88
201. The FPA Committee report notes that Officeholders' bids for 2023-24 amount to a total higher than was forecast in the SPCB's budget for 2022-23. Evidence to the Committee showed that additional resourcing was required for the Ethical Standards Commissioner due to external audit recommendations, and an increase in workload caused by the number and complexity of complaints the Commissioner received. Similarly, the SPCB provided more detail on the restructuring of the Scottish Human Rights Commission, again noting additional resource was needed  
89
202. Other SPCB supported officeholders have faced resourcing issues as a result of changes or expansion to their role and powers over time, or as a result of growing demand for activity:



- The introduction of the Scottish Welfare Fund has impacted on the resource requirements of the Scottish Public Services Ombudsman <sup>90</sup>
  - The provisions of the Children and Young People (Scotland) Act 2014 has had significant resource implications for the Office of the Children and Young People's Commissioner in Scotland <sup>91</sup> .
203. Part 4 of Schedule 1 sets out provisions to allow the Commissioner to appoint staff and to determine their terms and conditions, subject to the consent and approval of the SPCB. Part 5 requires the Commissioner to prepare a budget before the start of each financial year and to seek the approval of the SPCB. The [explanatory notes](#) state that the Commissioner may seek to revise the budget during the year by submitting revised proposals to the SPCB for approval.
204. While taking evidence about this Bill, this Committee heard concerns from a number of witnesses who questioned the extent to which the Commissioner is adequately resourced to perform the functions set out in the Bill.
205. Current proposals in the Bill are for the Commissioner to be supported by three policy staff and one administrator, with estimated running costs of £644,065 per year. The Scottish Parliament Information Centre briefing on the Bill <sup>92</sup> compares the resourcing of Commissions and Commissioners appointed by the SPCB and reports the funding set out in the FM would indicate that, in financial terms, the Commissioner would be one of the smaller Parliamentary Commissioners.
206. Stakeholders have highlighted potential resource concerns given the broad scope of the role and what might be considered as relatively modest resources set out in the financial memorandum. In her written submission, the Scottish Public Services Ombudsman stated:
- ” ...the resources given to the office mean the Commissioner would, in my view, be unable in practice to dedicate the staff resource required to undertake investigatory work on anything other than an exceptional basis. It is also important to note that the work undertaken prior to an investigation when deciding what to investigate and the scope of that investigation, can be significant and the current proposed resources may even struggle with those early stages. I could also not find a specific line in the budget for the public health campaign type work that may be required to meet the function of promoting safety practices to the public. Generally, there seems to be a potentially significant mismatch between the budget as set out and the remit and ambition for the office in the legislation <sup>93</sup> .
207. Simon Watson from Healthcare Improvement Scotland argued that the issue of resourcing is closely linked to the proposed investigatory remit of the Commissioner for Scotland, highlighting "the question about the investigatory remit and its breadth as possibly one of the more significant factors in how big the resource needs to be". Similarly, the General Medical Council expressed concerns around funding limitations and the impact this could have on the Commissioner's capacity to undertake investigations:

” With regard to funding, given that the level of this will dictate how many investigations the PSC can undertake, and to reiterate the point we make above, it will be important for the PSC to communicate its threshold for action, and how many investigations (and over what timeframe) it can undertake each year, from the outset <sup>94</sup> .

208. In their written response, Parkinson's UK Scotland has also called for "flexibility if it transpired that additional staffing were to be needed for a specific investigation or inquiry" <sup>95</sup> .

209. Addressing the connection between the size and scope of the PSC's remit and the level of resource allocated to the role, the then Minister for Public Health, Women's Health and Sport reiterated the collaborative role the Commissioner is expected to adopt by working with existing patient safety bodies, organisations and regulators and emphasised the importance of the Commissioner not replicating those functions. In relation to investigations, the Minister stated:

” I do not think that it will be the norm for the patient safety commissioner to have to carry out inquiries themselves, so I do not think that there will be duplication of effort. I would still expect bodies such as HIS or the ombudsman to carry out inquiries when issues are raised with them. However, I would expect the commissioner to be looking at the evidence that those organisations find and pull it together, in order to help patients navigate that complex landscape and to pick up on systemic issues given that opportunities to identify those have been missed in the past <sup>96</sup> .

In relation to individual complaints, the Minister noted that the role of the Commissioner is not to resolve individual complaints and instead:

” we are proposing that the Commissioner has substantial information gathering and investigative powers for situations where they wish to look further into an issue that other organisations such as Healthcare Improvement Scotland and the Scottish Public Services Ombudsman are not better placed to take on <sup>97</sup> .

In relation to data, the Minister stated:

” There will have to be a robust capacity for data analysis, but I am not going to write the job descriptions for the various job roles in the team now. I should say, though, that there is a lot of data analysis expertise already in the system, and that will have to complement the work that is being done, but I get what was said last week about being able to crunch the data and develop fresh insights <sup>98</sup> .

210. NHS National Services Scotland argued in its written submission that funding for the Commissioner should not detract from other patient safety organisations and should be reviewed following initial set up of the Commissioner:

” The commissioner should be appropriately funded to carry out their role and to be independent of but accountable to the public, NHSS and Scottish Government. However this should not be at the detriment of funding or supporting other patient safety organisations such as HIS. Additionally, there needs to be a balance between funds available for patient safety oversight and the resources needed to improve patient safety at service delivery level. As funding is tight, it might be wise to build in a review period of between 1 and 3 years after establishment to check if the funding is sufficient/ appropriate <sup>99</sup> .

211. During evidence, the Patient Safety Commissioner for England, Dr Henrietta Hughes, spoke about her experience in setting up her office and functions, arguing there would be a need to demonstrate agility initially but a requirement for additional resource in subsequent years:

” Having a small set-up team is really important in order to be agile and to be able to design and develop the functions of the office. However, it is also important to have a longer-term plan for the scope of the role and for the expansion of the team to meet the needs of patients, because it could be a bit of a distraction when setting up the functions to also be saying, “These are the types of roles that I need in the team”. Therefore, beginning with the end in mind would be a really good step in that situation <sup>100</sup> .

212. Dr Hughes also set out resource constraints that she has so far encountered as part of her role:

” Given the volume of people who have contacted us and the size of my team, it has been beyond us to follow up as much as we would like to do and to support all the different patients and patient groups. That is really tough, because, when somebody has already been to lots of organisations and been told, “Nothing to see here”, and then they come to the patient safety commissioner and we say, “We would love to help but, with such a small team, we are not able to do it”, it is challenging to maintain a good relationship with those patients. It is only because of the incredible generosity of the patients who have contacted us that we have been able to do that. I am keen that we help many more patients and patient groups. I am looking forward to going out over the next year and doing public engagement events at which we can meet a wider group. However, a lot of concerns that have been put on ice over the years are still unresolved and they are coming to me and my office <sup>101</sup> .

213. Dr Gary Duncan, chief of staff to the Patient Safety Commissioner for England, further added “We would need expanded resources if we wanted to take on further work. <sup>102</sup> ”

214. Throughout consideration of this Bill, the Committee has heard evidence of the need for the Bill to set out more clearly how it will be ensured that the Patient Safety Commissioner for Scotland does not duplicate investigatory work by other bodies. The Committee welcomes clarification provided by the then Minister regarding the collaborative role the Commissioner is expected to adopt by working with existing organisations, thereby limiting the requirement for the

Commissioner to undertake its own investigations. The Committee recommends that the Bill is strengthened to set out more clearly this collaborative approach and, related to this, the parameters of Commissioner investigations. It should also attribute responsibility for determining which organisation is best placed to undertake an investigation in any given circumstance.

215. The Committee recognises that resource requirements of the role will be likely to change over time. Further, given the potential scope of the role, the Committee recognises stakeholder concerns that the financial memorandum may underestimate the resources which may be needed to support the delivery of the Patient Safety Commissioner for Scotland's functions.
216. The Committee acknowledges the concerns of the Finance and Public Administration Committee, as expressed in its letter of 31 January 2023, regarding the increasing number of parliamentary commissioners and their associated costs.
217. The Committee recommends that budget allocations to the Scottish Parliamentary Corporate Body (SPCB) should make adequate provision to meet the importance and scale of the Patient Safety Commissioner's functions.
218. The Committee calls on the Scottish Government to 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.
219. The Committee recommends the SPCB and Scottish Government review the resourcing provision for the Office of the Commissioner at the end of Financial Year 2025/26 (the estimated first full financial year where only running costs will be incurred). If this review indicates that further resource is required in subsequent years, the Committee calls on the Scottish Government to provide a written guarantee that any such requirement will be fully covered by a transfer of funds from the Scottish Government to the SPCB.
220. The Committee also calls for the Commissioner to report on any resourcing pressures anticipated future requirements for increased budget, as part of the annual reporting process to the Parliament.

## Review and evaluation

221. The IMMDS Review examined three main patient safety concerns and uncovered common themes, including:
  - patients were not listened to when things went wrong
  - they did not receive support from healthcare organisations, and
  - their problems were not acknowledged by the healthcare system for a long time.

An independent Patient Safety Commissioner, was recommended to "be the golden thread, tying the disjointed system together in the interests of those who matter most <sup>103</sup> ".

222. The purpose of this Bill is to establish a new Parliamentary Commissioner who will identify, promote and improve patient safety in Scotland by amplifying the patient voice. Some stakeholders expressed a view that the role and function of the Commissioner should be formally evaluated once implemented, often noting that quality assurance was a particularly important dimension. In connection with this point, Charlie Bethune from Valproate Scotland stressed:

” [...] the key thing about the appointment is that the patient groups have to have confidence in the person, both at the appointment stage and afterwards <sup>104</sup> .

223. The Scottish Women's Convention noted in their submission that women often report lacking confidence in the system and concluded, given the sensitive nature of the common themes identified, and in direct reference to the role of Patient Safety Commissioner:

” [...] women have explained that those in positions of power should be regularly evaluated to ensure propriety

- “The politicians are just doing their own thing half the time... we need to hold them accountable.”
- “It’s an MSPs job to make sure we have the services and support that we need, but we have this gap... this huge gap, where we’ve had to just do it ourselves <sup>105</sup> .”

224. The Equality and Human Rights Commission cited its research into the "impact of existing social covenants and charters <sup>106</sup> " which explored what made them successful in terms of achieving positive change. From this research, it found that success depends upon holding someone to account for delivery and reporting on outcomes and concludes:

” We recommend that the Commissioner be required to make explicit an independent process for complaints about the Patient Safety Commissioner.

We recommend that the Commissioner be required to establish reporting requirements that will assess evidence of impact of the Commissioner and provide a driver for continuous improvement <sup>107</sup> .

225. In its submission, NHS Lothian called for greater clarity around the evaluation framework to review the Commissioner, voicing concerns around the complex patient safety landscape and potential effectiveness of the role within that setting:

” This includes the adding value/not duplicating and working with a range of partners. How will the Commissioner work with HIS and is it envisaged there will be an overlap or differences in responsibilities? Will there be a hierarchy established between HIS, MWC and the commissioner? <sup>108</sup>

226. Irene Oldfather from the Health and Social Care Alliance Scotland (the ALLIANCE),

outlined a process of self-evaluation that could be built into the role of the advisory group supporting the Commissioner, and the scrutiny role of the Scottish Parliament:

” I think that there should be an opportunity, one or two years into the role, for the commissioner to be able to review it and say, “This bit is working really well, but I could do with more scrutiny powers in relation to that bit.” I hope that a very co-operative and constructive relationship could develop with Parliament through annual reports and so on, which could produce an on-going audit, monitor and review. That is really important, because things change and people have different approaches to a role.

I mentioned the advisory group earlier, which is really important. We need to ensure that that is a constant sounding board and can audit, monitor and support the commissioner, working very much in partnership with Parliament [...] A very constructive relationship could potentially be built there, but we need to ensure that there is some sort of opportunity for audit, monitor and review within the system <sup>109</sup> .

227. On the subject of evaluation, the then Minister for Public Health, Women's Health and Sport emphasised the importance of ensuring the Commissioner's independence. The Minister highlighted the scrutiny role of Parliament in terms of ensuring accountability while also confirming the Scottish Government's intention that the Commissioner would undertake a process of self-evaluation:

” That will be part of the dialogue when that person is in post. We will undoubtedly be interested to hear what the commissioner thinks that their priorities are and how they intend to measure the outcomes and demonstrate robustly to Parliament and to other interested parties that they are doing the job that we intended them to do <sup>110</sup> .

228. The Committee recognises the need for robust monitoring and evaluation to ensure that patients' voices are heard and that there is public confidence in the Patient Safety Commissioner for Scotland and the wider system for reviewing and addressing patient safety issues. The Committee notes provisions in Part 5 of Schedule 1 which require the Commissioner to prepare and publish a report on their activities in respect of each financial year. The Committee recommends that these provisions should be strengthened to require the Commissioner to undertake ongoing monitoring and evaluation of their work and incorporate the outcome of this process into their annual report.

229. Given the high-profile nature of this role, the anticipated level of public expectation around it, and the Committee's consideration in this report on enforcement, the Committee seeks reassurance from the Scottish Government that the legislation would be reviewed if the Scottish Parliament finds, during its scrutiny, that the Commissioner does not have sufficient powers to fulfil their functions effectively, or their remit requires amendment.

230. The Committee has heard evidence emphasising the importance of providing recourse to an independent process that will enable the Patient Safety Commissioner to be held to account for their conduct. The Committee believes it

will be important, either by means of a code of conduct or some other mechanism, to develop such a process in the course of establishing the role of Patient Safety Commissioner for Scotland.



# Recommendations

231. The Health, Social Care and Sport Committee draws its conclusions and recommendations on the Bill to the attention of the Parliament and recommends that the general principles of the Bill be agreed to.

# Annex A: NHS board clinical governance mechanisms

NHS boards have several mechanisms to ensure patient safety, including:

- Clinical Governance Committees responsible for oversight of the clinical governance within the board and assuring management that arrangements are working.
- An internal complaints system, whereby the information from complaints is used by boards to improve services. This follows a model complaints handling procedure established by the Scottish Public Services Ombudsman.
- Monitoring key data and incidents to aid learning and quality improvement. This includes the recording of adverse events and incidents reported under the duty of candour.
- All NHS boards should also have a whistleblowing policy and a 'Whistleblowing Champion'.

## Annex B: Relevant legislation

The below legislation introduced the following duties on NHS boards:

- In 1999, amendment of the [National Health Service \(Scotland\) Act 1978](#) introduced a statutory duty for NHS boards to have arrangements for the purpose of monitoring and improving the quality of care.
- [The Patient Rights \(Scotland\) Act 2011](#) introduced a duty on NHS boards to investigate and respond to complaints, identify improvement actions and share learning.
- [The Health \(Tobacco, Nicotine etc. and Care\) \(Scotland\) Act 2016](#) introduced a statutory organisational duty of candour.
- [The Duty of Candour Procedure \(Scotland\) Regulations 2018](#) sets out how organisations should tell those affected that an unintended or unexpected incident appears to have caused harm or death.

# Annex C: Organisations relating to patient safety in Scotland

## Healthcare Improvement Scotland (HIS)

HIS is NHS Scotland's main quality improvement body. The key roles of HIS include: setting standards for care, inspecting and auditing services, advising on managing adverse events, operating the Scottish Patient Safety Programme and the regulation of independent hospitals and clinics. HIS does not describe itself as a 'regulator' and does not deal with individual complaints and cases.

## The Mental Welfare Commission (MWC)

The MWC is responsible for monitoring the implementation of the Mental Health (Care and Treatment) (Scotland) Act 2003 and the welfare parts of the Adults with Incapacity (Scotland) Act 2000. Independent of Government and the NHS, the MWC visits patients, can undertake investigations of care and services, issue reports and recommendations, as well as providing advice and good practice guidance to patients and professionals.

## National Services Scotland (NSS)

NSS is home to the NHS Incident Reporting and Investigation Centre (IRIC) which is a specialist safety and risk management unit with responsibility for medical devices. IRIC operates a national adverse incident reporting system and a safety alert system.

## Scottish Public Services Ombudsman (SPSO)

Patients who have been through NHS complaints procedures, but are unhappy with the outcome, can refer their case to the SPSO. The SPSO also fulfils the role of the Independent National Whistleblowing Officer (INWO).

## Professional regulators

Most healthcare professions require registration with a regulatory body, such as the General Medical Council (GMC) or the Nursing and Midwifery Council (NMC), to practise. It is a criminal offence to practise without being on the relevant register for that profession. These bodies determine the necessary standards, can undertake investigations into the practise or conduct of a registrant and determine their fitness to practise, and can remove people from the register if there are problems with their conduct or competence. This regulation is intended to protect the public and ensure high quality care<sup>xii</sup>.

## Medicines and Healthcare Regulatory products Authority (MHRA)

The MHRA monitors the quality of products and responds when there are safety concerns. The regulation of medicines and medical devices is reserved to the UK Parliament.

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<sup>xii</sup> The regulation of the majority of healthcare professional groups is reserved to the UK Parliament. However, the regulation of new groups of healthcare professionals and those regulated since the Scotland Act 1998 is devolved to the Scottish Parliament. See the Scottish Government website for more information on the regulation of healthcare professional groups. [Regulation - Health workforce - gov.scot \(www.gov.scot\)](https://www.gov.scot/topics/health/workforce-regulation).

## Annex D: Oral and written evidence

232. The Committee took oral evidence on the Bill at the following committee meetings-

233. 4th Committee meeting, 2023 (Session 6) Tuesday 31 January 2023

- [Agenda](#)
- [Minutes](#)
- [Official Report](#)

234. 5th Committee meeting, 2023 (Session 6) Tuesday 7 February 2023

- [Agenda](#)
- [Minutes](#)
- [Official Report](#)

235. 6th Committee meeting, 2023 (Session 6) Tuesday 21 February 2023

- [Agenda](#)
- [Minutes](#)
- [Official Report](#)

236. 9th Committee meeting, 2023 (Session 6) Tuesday 14 March 2023

- [Agenda](#)
- [Minutes](#)
- [Official Report](#)

237. The Committee took written evidence on the Bill-

Responses submitted to the Committee's call for views are published on [Citizen Space](#).

Additional written evidence, where publishable, is available on the [Health, Social Care and Sport Committee webpage](#).

- 1 [First Do No Harm \(immdsreview.org.uk\)](https://immdsreview.org.uk)
- 2 [Contacting the Patient Safety Commissioner for England - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- 3 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 4 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 5 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 6 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 7 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 8 [Response 350550124 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 9 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 10 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 11 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 12 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 13 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 14 [Policy Memorandum \(parliament.scot\)](https://parliament.scot)
- 15 [Response 968213637 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 16 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 17 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 18 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 19 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 20 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 21 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 22 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 23 [Response 721918469 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 24 [Response 869749661 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 25 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 26 [Response 641021724 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)

- 27 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 28 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 29 [Response 952745431 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 30 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 31 [Response 356348899 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 32 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 33 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 34 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 35 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#) .
- 36 [Response 657983787 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 37 [Response 398567529 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 38 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 39 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 40 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 41 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 42 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 43 [Response 910196608 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 44 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 45 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 46 [Response 948353646 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 47 [Response 356348899 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 48 [Response 356348899 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 49 [Response 657983787 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)



- 50 [Response 11050656 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 51 [Response 11050656 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 52 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 53 [Response 793568752 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 54 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 55 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 56 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 57 [Response 910196608 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 58 [Response 384451283 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 59 [Response 384451283 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 60 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 61 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 62 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 63 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 64 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
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- 69 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 70 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 71 [Response 641021724 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 72 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)

- 73 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 74 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 75 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 76 [Response 948353646 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 77 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 78 [Response 657983787 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 79 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 80 [Response 968213637 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 81 [Response 253682068 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 82 [Response 357913980 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 83 [Response 989552443 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 84 [Response 571065467 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 85 [Response 11050656 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 86 [Response 641021724 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 87 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 88 [Budget Scrutiny 2023-24: A report on the Finance and Public Administration Committee's budget scrutiny for the year 2023-24.](#)
- 89 [Budget Scrutiny 2023-24: A report on the Finance and Public Administration Committee's budget scrutiny for the year 2023-24.](#)
- 90 [Session 4 Local Government and Regeneration Committee, Official Report, 3 February 2016, Col 22, and Cols 31-32](#)
- 91 [Session 4 Education and Culture Committee, written submission from the Children and Young People's Commissioner for Scotland](#)
- 92 [Scottish Parliament Information Centre \(SPICe\) Briefing: Patient Safety Commissioner for Scotland Bill](#)

- 93 [Response 613547420 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 94 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 95 [Response 952745431 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 96 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 97 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 98 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)
- 99 [Response 968213637 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 100 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 101 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 102 [Health, Social Care and Sport Committee, Official Report 21 February 2023](#)
- 103 [First Do No Harm \(immdsreview.org.uk\)](#)
- 104 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 105 [Response 973787436 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 106 [Response 11050656 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 107 [Response 11050656 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 108 [Response 635949600 to Patient Safety Commissioner for Scotland Bill - Scottish Parliament - Citizen Space](#)
- 109 [Health, Social Care and Sport Committee, Official Report 7 February 2023](#)
- 110 [Health, Social Care and Sport Committee, Official Report 14 March 2023](#)

