

Eluned Morgan MS
Minister for Health and Social Services
Welsh Government

21 March 2022

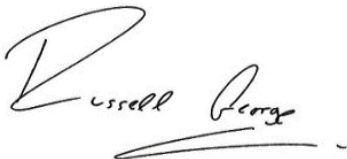
Dear Eluned

Provisional common frameworks

Thank you for your letters of 17 January 2022 regarding the Public Health Protection and Health Security; Blood Safety and Quality; and Organs, Tissues and Cells (apart from embryos and gametes) provisional common frameworks.

Our views on these provisional common frameworks are set out in the annex. I look forward to receiving your response by **Monday 9 May**.

Yours sincerely



Russell George MS
Chair, Health and Social Care Committee

cc Tracey Cooper, Chief Executive, Public Health Wales
Huw Irranca-Davies MS, Chair, Legislation, Justice and Constitution Committee, Welsh Parliament
Baroness Andrews, Chair, Common Frameworks Scrutiny Committee, House of Lords
Colm Gildernew MLA, Committee for Health, Northern Ireland Assembly
Gillian Martin MSP, Health, Social Care and Sport Committee, Scottish Parliament
William Wragg MP, Chair, Public Administration and Constitutional Affairs Committee, House of Commons

Croesewir gohebiaeth yn Gymraeg neu Saesneg. We welcome correspondence in Welsh or English.

Annex: Public Health Protection and Health Security; Blood Safety and Quality; and Organs, Tissues and Cells (apart from embryos and gametes) provisional common frameworks

Risks and benefits of the common framework approach

- 1.** The purpose of common frameworks is to establish common approaches in some areas that were previously governed by EU law, but that are within areas of competence of the devolved governments or legislatures.¹ They are a key tool for intergovernmental working and discussion on approaches to law and policy now that the UK is no longer a member of the EU.
- 2.** The Public Health Protection and Health Security (PHPHS), Blood Safety and Quality (BSQ) and Organs, Tissues and Cells (apart from embryos and gametes) (OTC) common frameworks set out how the Governments will work together and make decisions on regulatory alignment and divergence in the post-Brexit context.
- 3.** The structures provided by these common frameworks could enhance joint working and promote a shared approach to tackling common challenges. They could offer opportunities for the Welsh Government to influence and inform decisions taken by other Governments, as well as providing defined routes for engagement at an international level.
- 4.** However, the common frameworks also present potential risks, such as relinquishing regulatory freedom in favour of a common approach, making it harder for Welsh stakeholders to influence decisions, and risking blurring accountability to individual Parliaments.
- 5.** Such benefits and risks are not unique to the common frameworks that we have considered, but cut across the whole common frameworks programme. In February 2022, the Scottish Parliament Constitution, Europe, External Affairs and Culture Committee concluded that:

"[...] Common Frameworks [...] have the potential to resolve the tensions within the devolved settlement through managing regulatory divergence on a consensual basis while facilitating open trade within the UK internal market.

261. But the Committee believes there is a risk that the emphasis on managing regulatory divergence at an inter-governmental level may lead to less transparency

¹ Joint Ministerial Committee (EU Negotiations), [Communique](#), 16 October 2017

and Ministerial accountability and tension in the balance of regulations between the Executive and the Legislature".²

6. The correspondence we have received from the Welsh Government in respect of common frameworks has not always clearly articulated the risks and benefits of working through those frameworks, or how they might be managed.

Recommendation 1: The Welsh Government should explain how it will identify and manage risks associated with and arising from the PHPHS, BSQ and OTC common frameworks on an ongoing basis, including how information about such risks will be shared with Senedd committees.

Implications for making Welsh law and policy

7. The PHPHS, BSQ and OTC common frameworks require Governments to discuss and agree approaches to law and policy, and set out processes for resolving any disputes or disagreements that arise. As such, the frameworks could, in practice, limit the exercise of devolved competence.

8. This will not only affect the Welsh Government as it makes policy or prepares legislation, but will also affect the development of Senedd Bills. For example, Members who wish to table amendments to Bills passing through the Senedd, or committees that plan to introduce committee Bills, may need to consider the implications of relevant common frameworks, and potentially how to engage with these intergovernmental arrangements.

9. It could also make it more difficult for stakeholders in Wales to influence the development of Welsh law and policy.

10. When the Governments agreed principles for common frameworks, they agreed that they should "maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules."³ We regard this as an important principle.

11. In its report in February, the Scottish Parliament Constitution, Europe, External Affairs and Culture Committee recommended that:

"...there should be a similar agreement between the Scottish Government and Scottish Parliament that, as a minimum, there should be no dilution of public consultation or of parliamentary scrutiny."⁴

² Scottish Parliament Constitution, Europe, External Affairs and Culture Committee, *UK Internal Market inquiry*, 22 February 2022, p.42

³ Joint Ministerial Committee (EU Negotiations), *Communique*, 16 October 2017

⁴ Scottish Parliament Constitution, Europe, External Affairs and Culture Committee, *UK Internal Market inquiry*, 22 February 2022, p.36

12. Thought should be given to whether such an agreement between the Senedd and the Welsh Government would be helpful.

Recommendation 2: The Welsh Government should set out how it will ensure that the PHPHS, BSQ and OTC frameworks will maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as was afforded by current EU rules.

Recommendation 3: The Welsh Government should seek intergovernmental agreement that the PHPHS, BSQ and OTC common frameworks will lead to no dilution of public consultation or of parliamentary scrutiny in policymaking or the legislative process.

Recommendation 4: The Welsh Government should explain how it will ensure that these common frameworks will not limit the role of the Welsh Government, the Senedd, or stakeholders in Wales when making law and policy for Wales. This should include how the Welsh Government will facilitate the engagement of committees or Members of the Senedd with the common frameworks if required, to ensure that frameworks do not represent a barrier to the operation of the Senedd's legislative procedures.

Transparency

13. We recognise that the process of reaching four-Government agreement on common frameworks is necessarily iterative and can be complex. It was helpful that initial draft versions of the BSQ and OTC provisional common frameworks were published in early 2021. However, it is far from ideal that the final provisional frameworks were not published for scrutiny until the end of 2021, especially as they have already been in operation since the end of the transition period on 31 December 2020.

14. The frameworks will, rightly, remain under review. This is especially important in the context of learning from the response to the COVID-19 pandemic.

15. However, the frameworks themselves include limited information about ongoing reporting to Parliaments and stakeholders, engagement with stakeholders, or scrutiny of changes proposed during review and amendment processes. We explore each of these issues below.

Reporting on the operation of frameworks

16. In November 2021, the House of Lords Common Framework Scrutiny Committee noted its disappointment that the PHPHS framework did not include a commitment to ongoing engagement with Parliament. It stated that:

"Transparency in this area should include regular statements to legislatures on the functioning of this framework. We recognise that there are a number of initial

reviews of the framework scheduled and instead would suggest coinciding the planned three-yearly reviews with such engagement.

We recommend that the framework should be updated to include a commitment to update each of the 4 UK legislatures on the ongoing functioning of this framework after the conclusion of the three-yearly reviews.”⁵

17. It made similar comments in December 2021 in respect of the BSQ and OTC frameworks.⁶

18. In a letter to the Fifth Senedd’s External Affairs and Additional Legislation Committee in January 2020, the then Counsel General and Brexit Minister committed to “lay a report before the Senedd at least annually, which provides an assessment of the functioning of each Common Framework”.⁷ We welcome this commitment from the Welsh Government.

19. In November 2021, the Counsel General told the Senedd’s Legislation, Justice and Constitution Committee that the four Governments had “committed to future reporting on the frameworks as part of the process for the oversight of the frameworks within the Intergovernmental Relations Review”, and that this would assist Senedd committees in monitoring frameworks in the longer term.⁸

20. In January 2021, in response to questions about how the Senedd and stakeholders would be updated on the continuing operation of the frameworks, including any changes, the Minister for Health and Social Services told us that:

*“The **expectation** is that reports on frameworks will be public documents once they are signed off by portfolio Ministers and will be made available to the relevant committees in the four nations as well as relevant stakeholders.”⁹ [emphasis added]*

21. The Counsel General repeated this ‘expectation’ in oral evidence to the Legislation, Justice and Constitution Committee on 31 January 2022.¹⁰ In a letter to that Committee in March 2022, he stated

⁵ [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 23 November 2021

⁶ [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 14 December 2021

⁷ [Letter from the Counsel General and Brexit Minister to the External Affairs and Additional Legislation Committee](#), 23 January 2020

⁸ [Letter from the Counsel General and Minister for the Constitution to the Legislation, Justice and Constitution Committee](#), 19 November 2021

⁹ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022

¹⁰ Legislation, Justice and Constitution Committee, RoP [paragraph 54], 31 January 2022

that the “exact format of the annual reporting mechanism is currently being worked through at an official level”.¹¹

22. We appreciate that the frameworks and associated reporting are intergovernmental arrangements, and that the Welsh Government may not be able unilaterally to guarantee that these joint reports will be published. Nevertheless, we are concerned that full agreement has not yet been reached on this important point of transparency, and that a commitment to publishing reports is not included in the frameworks.

Recommendation 5: In line with the recommendations made by the House of Lords Common Framework Scrutiny Committee, the Welsh Government should secure intergovernmental agreement to update the PHPHS, BSQ and OTC common frameworks to include a commitment to update legislatures on the ongoing functioning of the frameworks after the conclusion of each review.

If this commitment is not included in the frameworks, the Welsh Government should confirm that joint reports on the frameworks will nevertheless be published in line with its stated expectation.

If intergovernmental agreement on this point cannot be secured, the Welsh Government should explain the reasons why intergovernmental reports will not be published, and confirm that it will nevertheless publish unilateral annual reports in line with its previous commitment.

Stakeholder engagement

23. The PHPHS, BSQ and OTC frameworks offer limited commitments on stakeholder engagement. All three frameworks provide that the parties may use third parties to provide advice in certain circumstances. The BSQ and OTC frameworks also include commitments to communicate changes to the frameworks to stakeholders.

24. We note that following scrutiny of the BSQ and OTC frameworks, the House of Lords Common Framework Scrutiny Committee stated:

“While we note the commitment to communicate changes in the frameworks to stakeholders, we regret the absence of a commitment to more meaningful ongoing stakeholder engagement. In our Committee’s March 2021 report, we concluded that frameworks were weakened by the lack of stakeholder consultation and recommended that future reviews of frameworks should include an open and well-publicised stakeholder consultation process that reaches beyond the small number

¹¹ Letter from the Counsel General and Minister for the Constitution to the Legislation, Justice and Constitution Committee, 2 March 2022

of stakeholders previously consulted. We believe that this is necessary in these frameworks as it is with other frameworks.”¹²

25. The House of Lords Committee recommended that the frameworks should be updated to “include an ongoing commitment to stakeholder engagement” including an open consultation process as part of the first two-year review.¹³ In respect of the PHPHS framework, it similarly recommended that the first three-year review should include an open consultation process with stakeholders.¹⁴

26. In this context, we welcome the Welsh Government’s commitment to engage with “relevant stakeholders during the review or amendment process as appropriate”.¹⁵

27. We agree with our colleagues in the House of Lords that there must be ongoing, open and meaningful engagement with stakeholders on the operation of these frameworks. We believe that this should be provided for within the frameworks themselves.

Recommendation 6: In line with the recommendations made by the House of Lords Common Framework Scrutiny Committee, the Welsh Government should secure intergovernmental agreement to update the PHPHS, BSQ and OTC common frameworks to include:

Provision that the first review of each framework should include an open consultation process with stakeholders.

Commitment to ongoing stakeholder engagement.

Should either of these outcomes not be secured, the Welsh Government should explain the reasons why not, and outline what will be done instead to ensure that there is ongoing, open and meaningful engagement with stakeholders across the UK.

Scrutiny of changes during review and amendment

28. The PHPHS, BSQ and OTC frameworks do not offer a role for parliamentary scrutiny of changes proposed during review and amendment processes.

¹² [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 14 December 2021

¹³ [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 14 December 2021

¹⁴ [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 23 November 2021

¹⁵ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022; Letter from the Minister for Health and Social Services (PHPHS common frameworks), 17 January 2022

29. In the Minister for Health and Social Services' letter to us on 17 January 2022 she suggested that Senedd committees will be notified if changes are made:

*"If changes are made to the frameworks then these will be notified to Senedd committees in order for them to carry out the level of scrutiny they deem appropriate and necessary."*¹⁶

30. The Counsel General told the Senedd's Legislation, Justice and Constitution Committee on 31 January 2022 that the Welsh Government was open to considering recommendations made by the Senedd or stakeholders as part of the process of reviewing the frameworks.¹⁷ In a letter to that Committee on 2 March 2022, he confirmed that the Welsh Government would notify the Senedd and stakeholders when a common framework is reviewed, and consider their recommendations before the review process concludes.¹⁸

31. We welcome this commitment. While scrutiny of any changes that have been made is clearly important, it would doubtless be more effective to ensure that the Senedd and other Parliaments are able to scrutinise any proposed changes before they are made. It would also be helpful for us to be notified in sufficient time in advance of any planned review to enable us to take an informed decision about whether any detailed work is required to help inform the development of any proposed changes.

32. To avoid duplication, it would also be helpful for such notification to include information about how and when stakeholders will be engaged in any particular review, and how and when any consultation responses will be made public.

Recommendation 7: The Welsh Government should confirm that it will notify Senedd committees in advance of reviews of the PHPHS, BSQ and OTC common frameworks and ensure that committees have an opportunity to scrutinise any proposed changes. Notifications should include information about the proposed approach to consultation with stakeholders.

Dispute resolution

33. We welcome the Minister for Health and Social Services' commitment to notify the relevant Senedd committee(s) of any disputes raised under the three common frameworks. We recognise that the dispute resolution process set out in the frameworks comprises a number of stages, with only those disputes that cannot be resolved at official level to be escalated to Ministers.

¹⁶ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022

¹⁷ Legislation, Justice and Constitution Committee, RoP [paragraph 52], 31 January 2022

¹⁸ Letter from the Counsel General and Minister for the Constitution to the Legislation, Justice and Constitution Committee, 2 March 2022

Recommendation 8: To ensure proportionality, the Welsh Government need only notify Senedd committees of disputes arising under the common frameworks that are escalated to Ministerial level.

34. We note that the frameworks do not specify any timelines or time limits for dispute resolution. The BSQ and OTC frameworks state that when disputes arise, the making of legislation may be postponed until all four Governments are in agreement on how to proceed.

35. It is possible, therefore, that the resolution of disputes could result in delay to Welsh Government legislation or policy decisions, with knock on implications for the time available for scrutiny, implementation or spending.

Recommendation 9: The Welsh Government should set out its views on whether any time limits should be specified within the dispute resolution process.

36. The common frameworks were published before the Intergovernmental Relations Review was completed, but note that they would be updated to reflect the Review's outcomes.

37. We note that the Review has now been completed, and that it includes a revised inter-ministerial dispute resolution process through which disputes over common frameworks can be escalated.¹⁹

Recommendation 10: The Welsh Government should confirm that, before they are finalised, the PHPHS, BSQ and OTC common frameworks will be updated to reflect the new inter-ministerial dispute resolution process set out in the review of intergovernmental relations published in January 2022.

Provisional PHPHS common framework

Background

38. The provisional PHPHS common framework sets out how the UK Government, devolved governments and public health agencies will work together on public health protection and health security outside the EU.

UK Health Protection Committee: transparency of operation

39. The PHPHS framework states that the UK Health Protection Committee (UK HPC) has agreed a shared work programme. It also explains that the UK HPC is replacing the EU Health Security Committee (EU HSC) in the domestic context. We note that the EU HSC publishes information about

¹⁹ UK Government, *Policy paper: review of intergovernmental relations*, 13 January 2022

its work, including its rules of procedure, membership, background documents, and reports on its activity.²⁰

40. We believe that there should be similar transparency about the work and operation of the UK HPC.

Recommendation 11: The Welsh Government should seek intergovernmental agreement that the UK Health Protection Committee should publish and provide regular updates on its shared work programme. This should include the publication of reports of its meetings.

Resources and capacity

41. The PHPHS framework states that the parties have agreed that the implementation of the shared work programme will be delivered within their existing resources, and will not be contingent on allocation of new resources by any party.

42. Public Health Scotland gave evidence to the Scottish Parliament's Health, Social Care and Sport Committee on 21 December 2021, during which it raised concerns about its ability to deliver its responsibilities under the work programme within its existing resources, particularly within the context of the ongoing response to the COVID-19 pandemic:

"In the programme that has been set by the Health Protection Committee, Scotland has been identified as the lead in three areas—review of disease notifications, analysis of the four-nations working groups and a look at the evolving science of genomics with regard to collaborations, co-operation and sharing of data sets and information. Those are big pieces of work.

I can speak only for Public Health Scotland, but I have to say that we would be extremely hard-pressed to contribute meaningfully to those pieces of work and reviews."²¹

43. In the Minister for Health and Social Services' letter to us of 17 January 2022, she acknowledged that the UK HPC and Four Nation Health Protection Oversight Group (HPOG) work programme, which underpins the PHPHS common framework, would "require resources to ensure that Wales can make a full and ongoing contribution and an assessment of the resources required is currently

²⁰ See European Commission, [Health Security Committee](#) and [Health Security Committee reports on COVID-19 outbreak](#) [accessed February 2022]

²¹ Scottish Parliament Health, Social Care and Sport Committee, [Official Report](#), 21 December 2021

underway".²² On 12 January 2022, Public Health Wales told us that resourcing for Wales' representation on the UK HPC and the HPOG would be met from existing budgets.²³

Recommendation 12: The Welsh Government and Public Health Wales should confirm whether they have any concerns about the potential resource or capacity implications associated with the work programmes of the UK Health Protection Committee or the Health Protection Oversight Group. This should include setting out the outcome of the assessment of resources referred to by the Minister for Health and Social Services in her letter of 17 January 2022, and, if the work programme is to be resourced from within existing budgets, details of where the funding and staff resource allocated to the work programme has been transferred from.

Recommendation 13: The Welsh Government and Public Health Wales should ensure that the work programmes published by the UK Health Protection Committee and the Health Protection Oversight Group include details of which bodies will be responsible for carrying out which activities, and how such activities will be resourced.

Representation and secretariat

44. The framework provides that the rotating chair of the UK HPC will be supported by a secretariat provided by the UK Department of Health and Social Care, whereas the rotating chair of the HPOG will be supported by a secretariat from the UK Health Security Agency (UKHSA). In each case, the framework provides that each nation may also designate a secretariat to support the group's progress alongside the permanent representative.

45. Therefore, while the chairs of the UK HPC and the HPOG will rotate between the four nations, the secretariats will be provided primarily by UK bodies.

Recommendation 14: The Welsh Government and Public Health Wales should explain why there will not be a joint secretariat established for the UK Health Protection Committee or the Four Nation Health Protection Oversight Group. They should also indicate whether they intend to designate any supporting secretariat for either group.

International obligations

46. The framework recognises that public health protection policy aims to protect populations living across geographical regions and international boundaries. It states that it takes an "all hazards" approach to cross-border health protection and health security. As such, it takes into account

²² Letter from the Minister for Health and Social Services (PHPHS common framework), 17 January 2022

²³ Letter from Public Health Wales, 12 January 2022

international obligations in these areas, such as the WHO's International Health Regulations (IHR) and UK-EU requirements agreed in the Trade and Cooperation Agreement (TCA).

47. In her letter of 17 January 2022, the Minister for Health and Social Services advised that the framework would enable the four Governments to formulate common stances and approaches where appropriate, and to strengthen coordination in other areas. This could include developing UK-wide approaches to public health issues that could be communicated to international partners, including the WHO, the European Centre for Disease Control (ECDC) and EU Member states.

Recommendation 15: The Welsh Government should ensure that information about international activity within the scope of the PHPHS common framework is included in its regular reports to the Senedd on the operation of the common frameworks. This should include:

Recent activity carried out by the Welsh Government or Public Health Wales.

Details of common stances agreed with other parties to the framework for the purpose of international engagement.

Information about upcoming international developments or obligations that would be within the scope of the framework.

Relations between UK and EU agencies

48. In December 2021, the UKHSA signed a Memorandum of Understanding (MoU) with the ECDC.²⁴

49. However, we note that Public Health Scotland told the Scottish Parliament's Health, Social Care and Sport Committee that it had some concerns about the extent of devolved engagement in the process of agreeing the MoU:

"We are not quite there yet, because the current technical committee has 15 representatives from the UK Health Security Agency but only one from Wales, two from Northern Ireland and three from Scotland. Some work is therefore needed to make sure that we are adequately represented in those technical discussions."²⁵

50. The TCA provides that UK access to the EU's Early Warning and Response System (EWRS) for communicable diseases can be granted on request. However, it is not clear from the framework documents and MoU whether this has been secured.

²⁴ UK Government, [Press release: UKHSA signs memorandum of understanding with ECDC](#), 2 December 2021

²⁵ Scottish Parliament Health, Social Care and Sport Committee, [Official Report](#), 21 December 2021

Recommendation 16: The Welsh Government and Public Health Wales should explain how they engaged in the process of developing and agreeing the Memorandum of Understanding with the European Centre for Disease Control, and how Wales will engage with the ECDC through the PHPHS common framework.

Recommendation 17: The Welsh Government should confirm whether UK access to the EU's Early Warning and Response System (EWRS) has been secured, and, if not, whether access will be requested through the PHPHS common framework.

Provisional BSQ and OTC common frameworks

Background

51. The provisional BSQ and OTC common frameworks set out how the UK Government and devolved governments will work together and manage divergence in these policy areas outside the EU.

Review of retained EU law

52. The UK Government has set out its intention to legislate to enable retained EU law to be amended more easily.²⁶

53. In her letter of 17 January 2022, the Minister for Health and Social Services stated that any proposed amendment or repeal of retained EU law would be undertaken through a "separate process" to the frameworks.²⁷

54. However, the UK Government has subsequently said that it is:

"...committed to the proper use of Common Frameworks and will not seek to make changes to retained EU law within Common Frameworks without following the ministerially-agreed processes in each framework".²⁸

55. Managing divergence between different parts of the UK in areas covered by retained EU law is a core purpose of the common frameworks programme. It is therefore important that any amendment or repeal of retained EU law in common framework areas be taken through the relevant common frameworks, not a "separate process".

²⁶ UK Government, *The benefits of Brexit: how the UK is taking advantage of leaving the EU*, January 2022

²⁷ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022

²⁸ UK Government, *The benefits of Brexit: how the UK is taking advantage of leaving the EU*, January 2022, p.33

Recommendation 18: The Welsh Government should confirm that any proposed amendments or repeals of retained EU law within the scope of the BSQ or OTC common frameworks will be undertaken through the common frameworks and not by a separate process.

Recommendation 19: The Welsh Government should commit to notifying the Senedd, including the relevant committee(s), of any proposals to amend or repeal retained EU law within the scope of the BSQ or OTC frameworks that would affect Wales or Welsh patients.

UK Internal Market Act 2020

56. Part of the purpose of the BSQ and OTC frameworks is to ensure the smooth functioning of the UK internal market.

57. The UK Internal Market Act 2020 (the 2020 Act) sets out new market access principles in law. In essence, the principles aim to allow goods permitted or imported into any one part of the UK to be sold or supplied in any other part, with some exceptions. The UK and devolved Governments have agreed a process for considering UK Internal Market Act exclusions in common framework areas.²⁹

58. The Welsh Government's view is that the 2020 Act implicitly diminishes the powers of the Senedd and the Welsh Government.³⁰

59. In her letter of 17 January 2022, the Minister for Health and Social Services confirmed that these common frameworks do intersect with the 2020 Act, and referred to the agreed process for agreeing exclusions.³¹ However, neither of the common frameworks includes any reference to the 2020 Act or to the exclusion process.

60. In December 2021, the House of Lords Common Frameworks Scrutiny Committee highlighted that the UK Government had previously acknowledged the interaction between the 2020 Act and the frameworks. That Committee felt that even though it was "unlikely for there to be conflicts between these frameworks and the Act, we believe an approach that is prepared for that eventuality should be preferred". It recommended, therefore, that the "frameworks should be updated to reference its interaction with the UK Internal Market Act 2020 and acknowledge the process for agreeing exemptions from that Act".³² We agree with our colleagues in the House of Lords.

²⁹ UK Government, *Guidance: process for considering UK Internal Market Act exclusions in common framework areas*, 10 December 2021

³⁰ Welsh Government, *Written Statement: legal challenge to the UK Internal Market Act 2020*, 18 January 2021

³¹ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022

³² *Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health*, 14 December 2021

Recommendation 20: The Welsh Government should explain the impact of the UK Internal Market Act 2020 on the movement of blood, organs, tissues and cells, including any risks to the practical effect of Welsh legislation and policy, and whether it is considering requesting any exclusions from the Act.

Recommendation 21: In line with the recommendation made by the House of Lords Common Framework Scrutiny Committee, the Welsh Government should secure intergovernmental agreement to update the BSQ and OTC common frameworks to refer to their interaction with the UK Internal Market Act 2020 and acknowledge the process for agreeing exemptions from that Act.

Northern Ireland Protocol and divergence from the EU

61. Under the Northern Ireland Protocol, any changes to EU law on the safety and quality of blood, organs, tissues and cells must be applied in Northern Ireland.

62. The frameworks provide information about how Governments will consider the implications of changes to law and policy in Northern Ireland and Great Britain for divergence, but offers limited detail about how this will work in practice.

63. In December 2021, the House of Lords Common Framework Scrutiny Committee welcomed the updated language in the frameworks relating to the Northern Ireland Protocol, describing it as “a great improvement”. But that Committee felt that there was still a need for the frameworks to include additional detail to tailor the commitment to the specific processes of these frameworks, as:

*“The current language does not make clear at what point in the EU legislative process measures that will be implemented in Northern Ireland through the Protocol will be submitted for the risk assessment process”.*³³

Recommendation 22: In line with the recommendation made by the House of Lords Common Framework Scrutiny Committee, the Welsh Government should secure intergovernmental agreement to update the BSQ and OTC common frameworks to include additional detail on when changes introduced in Northern Ireland through the Protocol on Ireland/Northern Ireland will be considered in these frameworks.

64. The Minister for Health and Social Services told us in January 2022 that she was aware that the European Commission planned to revise the EU Directives on the safety of blood, tissues and cells early in 2022.³⁴ She stated that the Welsh Government would, with the other Governments in the UK, consider what implications such changes might have. She added:

³³ [Letter from the Chair of the House of Lords Common Framework Scrutiny Committee to the Minister of State for Health](#), 14 December 2021

³⁴ European Commission, [Revision of the EU legislation on blood, tissues and cells](#) [accessed February 2022]

"We would not propose to make any unilateral changes in Wales, preferring to take a joint approach with the rest of the UK in respond to any changes in the EU, providing that the detail of any such joint approach is appropriate for Wales".³⁵

Recommendation 23: The Welsh Government should explain how it will assess the risks and benefits for Wales of keeping pace with changes in Northern Ireland and the EU, as opposed to maintaining the status quo in Great Britain, and what position it will take in intergovernmental discussions on these matters.

International obligations

65. Part of the purpose of common frameworks is to ensure compliance with international obligations.

66. In respect of blood, organs, tissues and cells, Wales must comply with WHO standards and with new UK-EU obligations contained in the Withdrawal Agreement and TCA.

67. The frameworks mention that Governments will share information on UK, EU and international issues, but do not go into detail. However, in her letter to us on 17 January 2022, the Minister for Health and Social Services told us that:

"These frameworks do not specifically cover international obligations – and so do not alter current obligations with which organisations are already familiar".³⁶

Recommendation 24: The Welsh Government should secure intergovernmental agreement to update the BSQ and OTC common frameworks to include detail of how Governments in the UK will work together on international and UK-EU obligations relating to blood, organs, tissues and cells. This should include how Wales will be represented in relevant discussions at the WHO and at UK-EU forums.

³⁵ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022

³⁶ Letter from the Minister for Health and Social Services (BSQ and OTC common frameworks), 17 January 2022