HM Government

The Blood Safety and Quality Provisional Common Framework

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by Command of Her Majesty

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The Blood Safety and Quality Provisional Common Framework

OUTLINE

SECTION 1: WHAT WE ARE TALKING ABOUT

1. Policy Area

Blood Safety and Quality

1.1 The Joint Ministerial Committee (EU Negotiations) agreed that officials should work together to develop arrangements for Common Frameworks (see Appendix I). This Framework relates to blood safety policy. It encompasses elements of the Blood Directive (Directive 2002/98/EC) and the implementing acts which relate to the safety and quality of blood and blood components. This Framework sets out arrangements for co-operation between officials in the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health).

1.2 The Blood Directive aims to establish minimum safety and quality standards for human blood and its components to ensure a high level of health protection. It covers blood collection (including donation) and testing, as well as the processing, storage and distribution of blood when it is used in transfusions. The EU Directives that intersect with devolved competence in this policy area are listed in the section below.

1.3 In accordance with the retained EU law that implements the Blood Directive, the UKG, SG, WG and NI Department of Health are obliged to ensure that safety and quality standards are maintained.

1.4 **To note:** The safety and quality of blood products is regulated under separate legislation and is covered by Medicines policy. More information about this can be found in section 2.

2. Scope

2.1 **Intersection with devolved competence:** This policy area (blood safety and quality) was previously governed by harmonised EU Directives (set out below). The EU Directives are implemented in domestic legislation applicable across the whole of the UK. Enforcement of the implementing legislation is delegated to the UK-wide regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

2.2 As the Transition Period has ended, the different governments have wider scope to use their powers to make changes to blood safety and quality regulation.

2.3 This Framework will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.

2.4 **EU Legislation:** EU legislation is currently implemented on a UK-wide basis. The main piece of EU legislation that intersects with devolved competence in this policy area is Directive 2002/98/EC ("the Blood Directive"). The Blood Directive sets the safety and quality standards in relation to blood and blood components.

2.5 The implementing directives that intersect with devolved competence (for Northern Ireland, Scotland and Wales) in this policy area are:

- **Commission Directive 2004/33/EC** as regards certain technical requirements for blood and blood components;
- **Commission Directive 2005/61/EC** as regards traceability requirements and notification responsibilities in case of serious adverse reactions and events;
- **Commission Directive 2005/62/EC** as regards European Union standards and specifications relating to the quality system for blood establishments;
- **Commission Directive 2009/135/EC** which allows for temporary exemptions from the requirements set out in Commission Directive 2004/33/EC in light of a risk of shortage of blood and blood components caused by the Influenza A (H1N1) pandemic; and
- **Commission Directives 2011/38/EU, 2014/110/EU and 2016/1214** which make amendments to the implementing directives referred to above.

2.6 **Broadly the retained EU law in this area:**

- sets the standard for the safety and quality of blood and blood components;
- sets the technical requirements for blood and blood donation and the traceability requirements and notification responsibilities in case of serious adverse events or reactions (SAERs);
- sets out Community standards and specifications relating to the quality system for hospital blood banks and facilities; and
- addresses quality system standards and specifications for blood establishments and sets some further specific technical requirements.

2.7 **Transfer of Commission Powers:** The safety and quality of blood is an area of devolved competence. Statutory instruments made in 2019 under powers in the European Union (Withdrawal) Act 2018 transferred to the UKG, SG, WG and the NI Department of Health power to make regulations on matters previously included in implementing Directives made by the European Commission. This includes powers to update technical requirements, for example, requirements to ensure traceability in line with scientific and technical developments. These powers are limited to authorities in Great Britain by statutory instrument made in order to implement the Ireland/Northern Ireland Protocol, as the 2018 Act confers the necessary powers on the NI Department.

2.8 **Competence**: Legislative competence for the safety and quality of blood and blood components is devolved to Northern Ireland, Scotland and Wales. Therefore, the Framework has been made on a UK-wide basis with the agreement of the UKG, SG, WG and NI Department of Health. This will facilitate the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for blood and blood components. The UKG, SG, WG and NIE have agreed with the principles that will govern the development of the Framework.

2.9 **Extent:** This Framework is UK-wide (covering England, Northern Ireland, Scotland and Wales), but does not cover the Crown Dependencies or Overseas Territories.

2.10 **Scope within rules for different parts of the UK to do things differently:** Maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for blood to continue to be shared across the UK. This Framework agreement sets out a process by which a government can suggest future changes to the standards and how such a proposal will be collectively considered before one or more governments introduces a change. It will allow for necessary divergence by one or more governments as required, in order to respond to needs such as location-dependent public health concerns.

2.11 **Out of Scope:** Blood products or plasma derivatives are covered by human medicines regulations. The manufacture of plasma-derived blood products is subject to pharmaceutical legislation as they are classified as medicines, while the donation, collection and testing of plasma is regulated by the same legislation as blood and blood components. Donated plasma, a component of blood, can be used to manufacture medicinal products like immunoglobulins, albumins and non-recombinant clotting factors (e.g. Factor VIII).

2.12 **Interdependencies include:**

- **The Common Framework for the safety and quality of organs, tissues and cells:** as there are joint UK-wide groups that advise Ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation.
- **Medicines Regulation**: UK plasma can be used for fractionation in order to produce some plasma-derived medicines, so there are also some interdependencies between the requirements of the Blood Safety and Quality Regulations 2005, which continue to govern the collection of plasma, and the Human Medicines Regulations 2012, which govern the manufacture of medicinal products from plasma.
- **Medical devices legislation:** as reagents (medical devices) are used in the collection and processing of blood and blood components.

3. Definitions

3.1 **Blood components:** A therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods.

3.2 **Blood products:** Any therapeutic product derived from human blood or plasma, this includes plasma derivatives manufactured from pooled plasma donations in plasma fractionation centres (such as albumin, coagulation factors and immunoglobulins). Plasma derivatives are covered by the Medicines Act and, like any other drug, must be prescribed by a licensed practitioner.

3.3 **Memorandum of Understanding (MoU) on Devolution:** The overarching MoU which sets out the understanding of, on the one hand, the UKG , and on the other, the Scottish Ministers, the Welsh Ministers, and the Northern Ireland Executive Committee of the principles that will underlie relations between them. This is separate to the Joint Ministerial Committee (EU Negotiations) Communique of October 2017.

3.4 **Joint Ministerial Committee (EU Negotiations) (JMC(EN)) Communique October 2017**: The committee members included representatives from the UKG, SG, WG and NIE. The group was established to provide a means for the devolved governments to be fully engaged in determining the UK's approach to EU and trade related issues. On 16 October 2017, agreement was reached on the principles and definitions for the Common Frameworks for areas where EU law intersects with

devolved competence. In June 2020, NIE Ministers agreed to the principles set out in the communique, following the restoration of the NIE in January 2020.

3.5 **Concordat:** Joint non-legislative agreement that gives effect to the Common Framework.

3.6 **2019 Blood Safety and Quality EU Exit SI:** The Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2019 (as amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020).

SECTION 2: PROPOSED BREAKDOWN OF POLICY AREA AND FRAMEWORK

4. Summary of proposed approach

4.1 **Purpose and general principles[1]:** In 2018 it was agreed that a Common Framework in this area would be desirable across the UK. The JMC (EN) principles are described in the Joint Ministerial Committee's communique of 16 October 2017. The communique sets out that Common Frameworks will be established where they are necessary in order to:

- **enable the functioning of the UK internal market, while acknowledging policy divergence:** for blood this will make it easier for blood and blood components to be shared around the UK.
- ensure compliance with international obligations;
- ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
- enable the management of common resources;
- administer and provide access to justice in cases with a cross-border element;
- **safeguard the security of the UK:** for blood the sharing of serious adverse events or reactions (SAERs) information to maintain patient safety.

4.2 The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework.

[1] The principles that are relevant for blood safety and quality are in bold.

4.3 A level of commonality would be beneficial particularly for organisations that operate across UK borders and therefore, as is currently the case, close collaboration between the governments should continue.

4.4 There is currently good information sharing and collaboration across the UK. This Framework agreement should support the continuation of this.

EU Exit SIs:

4.5 Although competence in respect of blood is devolved, it was agreed that there would be UK-wide legislation regarding the safety and quality standards for blood in the event of a 'no-deal' EU exit (The 2019 Blood Safety and Quality EU Exit SIs[2]). The legislation was made to ensure that the regulatory framework for blood could operate as intended following the UK's departure from the EU, and to retain the safety and quality standards for blood. The legislation also transfers power to update certain aspects of the quality and safety regulations (such as updating safety and quality standards in response to technological advances) to either the Secretary of State for Health and Social Care on behalf of the UK (with the consent of Scottish and Welsh Ministers and the Department of Health in Northern Ireland) or, to each of the Ministers in relation to their part of the UK.

4.6 The 2019 Blood Safety and Quality EU Exit SI was amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020 (2020 Blood SI[3]) to implement the Protocol on Ireland/Northern Ireland. The 2020 Blood SI limits the regulation-making powers in the 2019 SI to Great Britain, as the EU (Withdrawal) Act 2018 now contains regulation-making powers (section 8C and paragraph 11M of Schedule 2), enabling the Secretary of State for Health and the NI Department of Health to make regulations to implement the Protocol including in response to future changes in EU law.

Non-legislative:

4.7 As the UKG, SG, WG and NI Department of Health will have the power to diverge from the UK Regulations should they choose, a concordat (Annex I) between the

[2] The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019/4
[3] The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020/1304

four nations will be put into place to formally agree the ways of working set out in this Framework.

Four governments collaborative working:

4.8 The governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and considering the UK-wide impact of such changes. They will follow the approach in this Framework to support collaborative decision making with a view to supporting continued sharing of blood and blood components across the UK.

4.9 There is a need for continued robust policy development encompassing policy and technical expertise from all four governments, including the need to fully assess the potential impacts of legislative changes on all affected stakeholders. Governments may wish to do this work individually or in collaboration before initiating a UK-wide discussion of a potential change to the standards.

Risk assessment and management:

4.10 As stated above, maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for blood and blood components to continue to be shared across the UK.

4.11 One or more governments may initiate the risk assessment process that should include discussions with the national blood services and the regulator, as appropriate. The assessment should include seeking advice from the relevant scientific advisory bodies. Final decisions at the end of the risk assessment process should require collective sign-off (e.g. legislative or operational changes) by all Ministers across the UK. While the ability to diverge is always available to any individual government, it will be important for any diverging government to consider the impact on patient safety and confidence, and compatibility with the JMC(EN) Common Frameworks principles.

4.12 Where appropriate, joint recommendations may be made to Ministers. Ministers will ultimately retain the right to take individual decisions for their government. For Ministers and officials, for areas within the scope of the Framework, a consensus/discussion to inform the other parties should first be sought.

4.13 The dispute resolution process is outlined in section 13 of this document.

Divergence:

4.14 Maintaining a compatible minimum set of quality and standards between the UKG, SG, WG and NI Department of Health will make it easier for blood and blood components to continue to be shared across the UK. The Framework sets out a process by which any government can suggest changes to the standards and how such a proposal will be collectively considered before one or more governments introduces a change. It will allow for necessary divergence by one or more governments as required, in order to respond to needs such as location-dependent health concerns.

Dispute Resolution:

4.15 All four governments will retain the ability to diverge from generally harmonised rules within their part of the UK. Where divergence is not considered acceptable by one or more governments in the UK, every effort will be made to address disagreement at the lowest level possible. Only when all opportunities for avoiding a dispute at the policy level have been sought, will the dispute resolution mechanism be engaged. Dispute resolution is anticipated to only be required in a very small number of cases and is set out in section 13 of this agreement should it be needed.

The Protocol on Ireland/ Northern Ireland:

4.16 The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

- Paragraph 22 - substances of human origin

4.17 This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.

4.18 Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in

alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.

- As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.

- Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

4.19 Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

The UK and EU Trade and Cooperation Agreement (TCA):

4.20 The area of policy covered by this Common Framework does not fall directly within the provisions of the Trade and Cooperation Agreement, although both the Common Framework and that agreement will impact significantly on devolved and reserved responsibilities.

5. Detailed overview of proposed framework: legislation (primary or secondary)

5.1 N/A – no legislation to support the framework is considered necessary.

6. Detailed overview of proposed framework: non-legislative arrangements

6.1 A concordat between UKG, SG, WG and NI Department of Health provides the basis for managing and maintaining the collaborative ways of working set out in this framework. Adopting a non-legislative approach maintains the existing good working relationships between the governments and allows for flexibility to adapt where change is needed.

6.2 The underlying principle is that the governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and allowing sufficient scope for UK-wide discussion and decision making.

6.3 If one or more government wishes to diverge from the UK-wide standards for safety and quality, it is agreed that this should be done after consultation with the other governments and after consideration of the impact on the existing standards of safety and quality for blood and blood components.

7. Detailed overview of areas where no further action is thought to be needed

7.1 Not applicable.

OPERATIONAL DETAIL

SECTION 3: PROPOSED OPERATIONAL ELEMENTS OF FRAMEWORK

8. Decision making

8.1 Individual governments will be able to make decisions (at Ministerial level in relation to proposals for legislative change or other significant policy issues) on the safety and quality standards for blood and blood components. This includes, but is not limited to, the following:

- standards and requirements relating to a quality system for blood establishments;
- information to be provided to donors;
- information to be obtained from donors;
- blood quality and safety requirements;
- storage, transport and distribution requirements;
- quality and safety requirements;
- traceability requirements;
- deferral criteria for donors of blood and blood components. Deferral is defined in the Blood Safety and Quality Regulations 2005 and refers to the suspension (either permanent or temporary) of the eligibility of an individual to donate blood or blood components;
- requirements applicable to autologous transfusions; and
- the procedure for notifying serious adverse reactions and events.

8.2 If a government wants to make a change to the blood safety and quality legislation, they will:

- notify all governments setting out details of the proposal and invite comments;
- arrange a meeting with policy officials to discuss the detail of the proposals, if an government requests this;
- seek to agree a way forward on the issue; and
- depending on the issue, seek input from the following:
    - advice from an advisory body or the regulator; and
    - consultation with stakeholders.

8.3 Officials will share information, advice and views so that each government can advise Ministers on the proposal and its impacts and seek Ministerial decisions.

8.4 If agreement is not reached on a way forward, to assess a proposal or on the factual information within the advice to Ministers, any government can escalate the issue so that it can be discussed at senior official level. If an agreement is not reached at senior official level and all alternatives have been exhausted, the proposal can be escalated to be discussed at Ministerial level.

9. Roles and responsibilities of each party to the framework

9.1 The following sets out the role and responsibilities of officials and Ministers in this Framework.

Officials:

9.2 Regular meetings will be arranged by the Blood Safety team to take place around the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) meetings. This will provide an opportunity to discuss blood policy, share updates and consider the short-term and long-term impact of any developments. Advice will be shared with Ministers with the rationale for the approach taken (e.g. a UK/GB-wide approach), or why divergent policies may be necessary.

9.3 Specific ad-hoc meetings and day-to-day discussions on the policy covered by this Framework will continue. Advice will be put to Ministers outlining the rationale for the approach taken within this policy area (e.g. a UK/GB-wide approach), or why divergent policies may be arranged if/when a proposal arises. Officials across governments will convene to discuss policy issues as appropriate and keep colleagues regularly informed of any ramifications the policy may have on governments.

9.4 If officials do not agree when making decisions, issues discussed at a working level can be escalated to senior officials in line with the Framework's dispute avoidance and resolution mechanism (Appendix II).

Senior Officials:

9.5 Senior officials (e.g. Deputy Directors and Directors) will provide strategic direction on the policy governed by this Framework. They may review an issue as per a Framework's dispute avoidance and resolution mechanism if officials are not able to agree an approach, in another attempt to reach agreement. Senior officials should convene to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis.

Ministers:

9.6 Ministers may receive advice from their officials either concurrently across governments as issues arise or in the course of business as usual work for individual governments. If work is remitted to senior officials and an issue remains unresolved, the issue may be escalated to Ministers. Where Ministers are considering issues as part of the Framework's dispute avoidance and resolution mechanism this could be via several media, including inter-ministerial meetings or by correspondence.

Senior Ministers:

9.7 Terminology distinguishing Ministerial hierarchy is not universal across governments. Where there is a distinction, it is likely that advice presented to a Minister who is not a Senior Minister, will be copied to a Senior Minister who may provide an additional steer if needed. In some circumstances, the Senior Minister will also be the most appropriate Minister to make a decision and therefore the distinction between Senior Minister and Minister will not be relevant. In the case of UKG, a Senior Minister would be a Secretary of State (SofS).

Information sharing:

9.8 Each government will aim to provide each other with a full and open (as possible) access to scientific, technical and policy information including statistics and research and, where appropriate, representations from third parties.

10. Roles and responsibilities of existing or new bodies

10.1 The current scientific advisory bodies are:

- **Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)**

The purpose of JPAC is:

- To ensure that all relevant aspects dealing with the safety of blood and tissues in the UK are covered, and that the professional advice emanating from JPAC is communicated appropriately and in a timely fashion.
- To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services, taking account of the Blood Safety and Quality Regulations (2005), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and future UK legislation affecting the blood and tissue services. For example, the Tissue Donor Selection Guidelines - Deceased Donors.
- To be an Advisory Committee to the United Kingdom Blood Transfusion Services, normally by reporting to the Medical Directors of the individual Services who are themselves individually accountable to the Chief Executives/ Directors of the Services. Decisions on policy and implementation would be vested in the individual Chief Executives/Directors and their Service boards and, where appropriate, their respective Health Departments.

10.2 **Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO):** Provides policy advice to Ministers in the four governments of the UK on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation.

10.3 Both of the groups above are independent from the UKG, SG, WG and NIE and provide advice for the whole of the UK.

10.4 **UK Blood Services Forum:** The UK Blood Transfusion Services have a body to coordinate co-operation-the UK Blood Forum. The Forum comprises the chief executives and medical directors of the four Services. JPAC are accountable to the medical directors who themselves are accountable to their chief executives. Both the UK Blood Forum and JPAC ensure consistency in professional matters.

10.5 **Official level Blood Safety and Quality meetings:** All parties will continue to regularly share information with one another in relation to the scope of this agreement. This is in order to: maintain public health and patient safety; allow for effective collaborative working and consideration of the Framework Principles, while acknowledging policy divergence.

10.6 Official level blood safety and quality meetings will continue to discuss:

- the impact of decisions on other governments, including any impacts on cross-cutting issues;
- prospective policy changes;
- emerging issues and intelligence etc.

10.7 As mentioned in section 9, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Officials or Senior Officials will then report to the relevant Ministers if necessary to provide an update or to escalate an issue.

10.8 The official level meetings will be arranged by the DHSC Blood Safety team and will include colleagues from the devolved governments.

11. Monitoring and enforcement

11.1 Official level Blood Safety and Quality meetings with policy teams across the four nations will take place around SaBTO meetings, to monitor the Framework, where not monitoring in the course of routine business. The purpose of monitoring is to assess:

- inter-governmental co-operation and collaboration as a result of the Framework;
- whether parties are implementing and complying with the Framework;
- whether divergence has taken place in contravention of the Common Framework principles;
- whether divergence has taken place in contravention of the principles of the intergovernmental relations review; and
- whether divergence has taken place that impacts on the policy area covered by the Framework.

11.2 The outcome of this monitoring will be used to inform joint decision-making going forward and the next review and amendment process. If there is an unresolved disagreement, the dispute avoidance and resolution mechanism should be used.

12. Review and amendment

12.1 **Process**:

- The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.
- There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.
- The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by the non-legislative agreement.
- Third parties can be used by any party to the Framework to provide advice at any stage in the process. These include other government departments or bodies as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.
- At the outset of the review stage, parties to the Framework must agree timelines for the process, including the possible amendment stage.
- If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

12.2 **Review Stage:**

- An initial review will take place one year after the Framework comes into effect; it will be used to determine if the arrangements are functional.
- Following the initial review, a periodic review of the Framework will take place every two years and will be in line with official or, if required, ministerial-level meetings.

- The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.
- During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.

- An exceptional review of the Framework is triggered by a 'significant issue':
  - A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the Framework.
  - The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.
  - The same significant issue cannot be discussed within six months of the closing of that issue.
- The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be 2 years until the next periodic review and at least 6 months until the same significant issue can trigger an exceptional review).

12.3 **Amendment Stage:**

- Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the Framework or all.
- If an amendment is deemed necessary during either type of review, the existing Framework will remain in place until a final amendment has been agreed.
- All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.

- If parties cannot agree whether or how a Framework should be amended this may become a disagreement and as such could be raised through the Framework's dispute avoidance and resolution mechanism.

12.4 Changes to the Framework and concordat will be communicated to stakeholders via the current communication channels.

13. Dispute resolution

13.1 The goal of the dispute avoidance and resolution mechanism is to avoid escalation to formal processes through the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties of this Framework becomes a 'dispute' when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.

13.2 This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the Common Frameworks principles (as defined by the appropriate intergovernmental structures). In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

13.3 The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

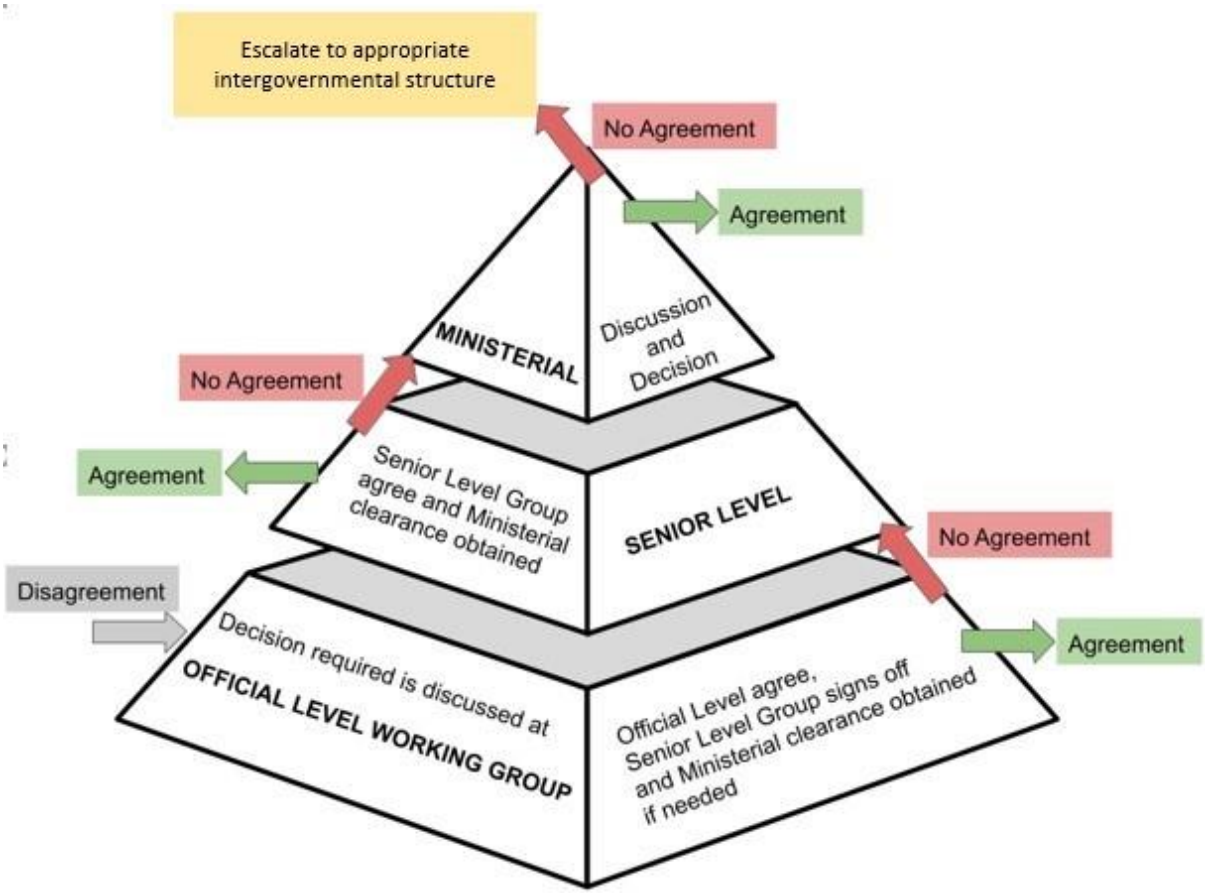


Figure 1: The levels of escalation for disagreements and disputes.

13.3.1 **Official level:** Following the approach set out in sections 8 and 9 and Appendix II of this Common Framework and within the spirit of the Concordat, the four governments will seek every opportunity to resolve differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions. Regular official level meetings will continue to provide an opportunity to discuss blood safety and quality policy, share updates and consider the short-term and long-term impact of any developments. Policy leads (e.g. Team Leaders) will provide strategic direction on the policy governed by this Framework and take key operational decisions.

13.3.2 Where officials become aware of proposals, potential issues or areas of disagreement via any means, the first step will be to seek to resolve this amongst policy leads without escalation. This will usually be resolved via discussion with policy colleagues in each government, to determine the source of the disagreement, to examine evidence, to establish whether it is a significant concern and to work through possible solutions to the satisfaction of all parties. It is expected that most disagreements would be resolved at this point.

13.3.3 **Senior Official level:** Where it has not been possible to resolve any disagreement at official level, this will initially be referred to Senior Officials for resolution. At this stage Senior Officials can decide whether it would be appropriate to arrange a meeting with counterparts across governments. Alternatively, or after such a meeting, Senior Officials may determine that the issue cannot be resolved at this stage, at which point the involvement of Ministers will be required.

13.3.4 **Ministerial level:** Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Blood Safety and Quality Common Framework, the making of legislation may need to be postponed until all four governments are in agreement on how to proceed. The parties may conclude, having considered potential impacts on patient safety, the JMC (EN) principles and the finalised principles for Intergovernmental Relations, that divergence is appropriate.

13.3.5 **Resolve through appropriate intergovernmental structure:** As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated under the appropriate intergovernmental structures

Timescales for escalation

13.4 When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated more quickly.

Evidence gathering

13.5 At each stage, further evidence may be requested from the preceding forum before the disagreement is discussed.

Third parties

13.6 JPAC and SaBTO may be used to provide scientific or technical advice to the UKG, SG, WG and NI Department of Health.

SECTION 4: PRACTICAL NEXT STEPS AND RELATED ISSUES

14. Implementation

14.1 This Framework will take effect once agreed by all parties and approved by Ministers. The Common Framework will only be put in place once there is final ministerial sign off from all four governments

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communique - October 2017

JOINT MINISTERIAL COMMITTEE (EU NEGOTIATIONS) COMMUNIQUE October 2017

The fifth Joint Ministerial Committee (EU Negotiations) met today in 70 Whitehall. The meeting was chaired by the Rt Hon Damian Green MP, First Secretary of State and Minister for the Cabinet Office.

The attending Ministers were:

From the UK Government: the First Secretary of State and Minister for the Cabinet Office, Rt Hon Damian Green MP; the Secretary of State for Exiting the EU, Rt Hon David Davis MP; the Secretary of State for Wales, Rt Hon Alun Cairns MP; the Secretary of State for Scotland, Rt Hon David Mundell MP; and, Parliamentary Under Secretary of State for Northern Ireland, Lord Bourne of Aberystwyth.

From the Welsh Government: Cabinet Secretary for Finance and Local Government, Mark Drakeford AM.

From the Scottish Government: the Minister for UK Negotiations on Scotland's Place in Europe, Michael Russell MSP.

In the absence of Ministers from the Northern Ireland Executive, a senior civil servant from the Northern Ireland Civil Service was in attendance.

The Chair opened the meeting by summarising the bilateral engagement and political developments that had taken place since JMC(EN) last met. The Secretary of State for Exiting the EU provided an update on the previous rounds of negotiations with the EU and the Committee discussed forthcoming priorities and the future relationship with the EU. The Committee discussed the establishment of common frameworks.

Ministers noted the positive progress being made on consideration of common frameworks and agreed the principles that will underpin that work (attached).

Common Frameworks: Definition and Principles

Definition

As the UK leaves the European Union, the Government of the United Kingdom and the devolved administrations agree to work together to establish common approaches in some areas that are currently governed by EU law, but that are otherwise within areas of competence of the devolved administrations or legislatures. A framework will set out a common UK, or GB, approach and how it will be operated and governed. This may consist of common goals, minimum or maximum standards, harmonisation, limits on action, or mutual recognition, depending on the policy area and the objectives being pursued. Frameworks may be implemented by legislation, by executive action, by memorandums of understanding, or by other means depending on the context in which the framework is intended to operate.

Context

The following principles apply to common frameworks in areas where EU law currently intersects with devolved competence. There will also be close working between the UK Government and the devolved administrations on reserved and excepted matters that impact significantly on devolved responsibilities.

Discussions will be either multilateral or bilateral between the UK Government and the devolved administrations. It will be the aim of all parties to agree where there is a need for common frameworks and the content of them.

The outcomes from these discussions on common frameworks will be without prejudice to the UK's negotiations and future relationship with the EU.

Principles

1. Common frameworks will be established where they are necessary in order to:

    - enable the functioning of the UK internal market, while acknowledging policy divergence;
    - ensure compliance with international obligations;
    - ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
    - enable the management of common resources;
    - administer and provide access to justice in cases with a cross-border element;
    - safeguard the security of the UK.

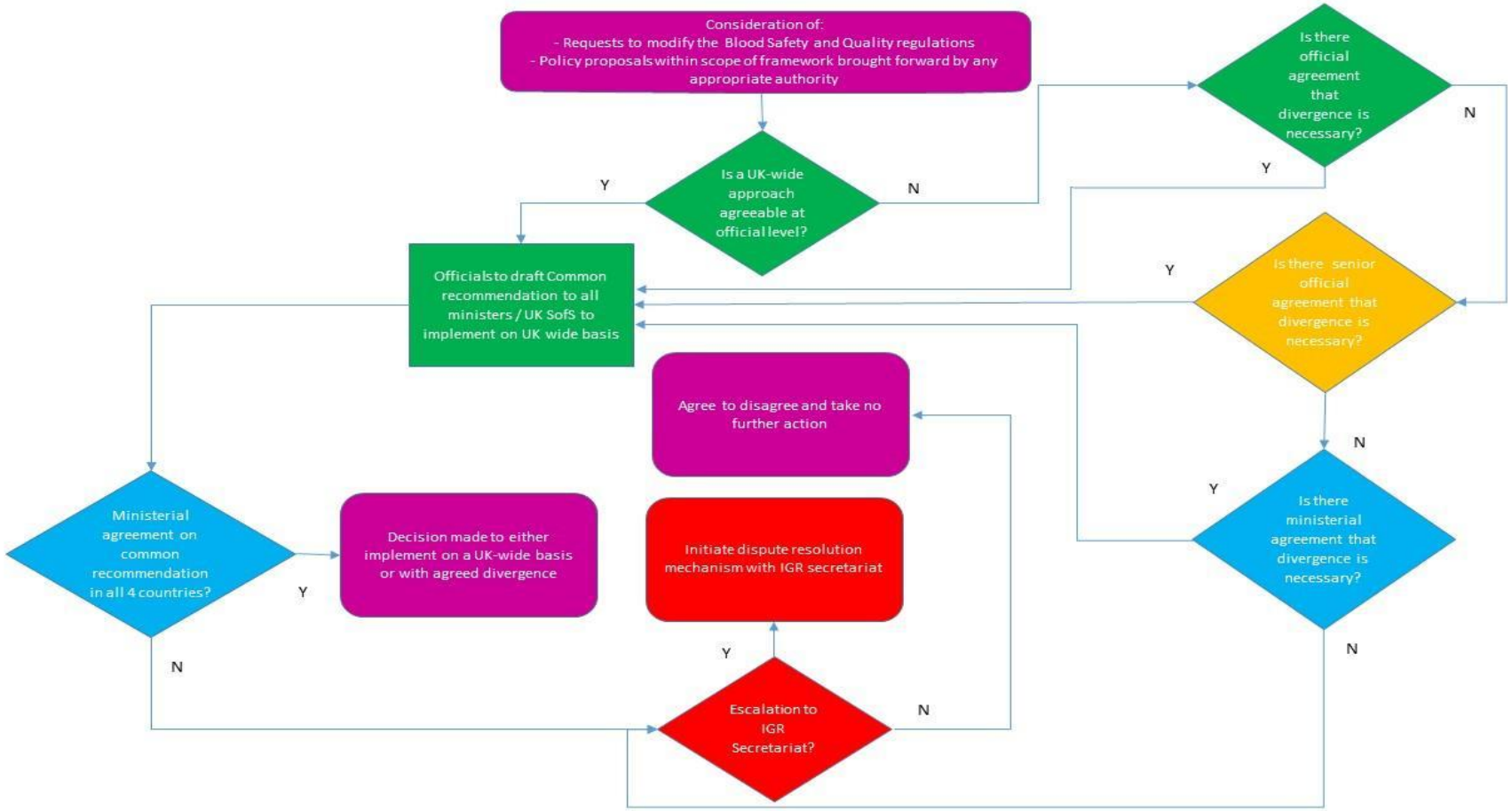
2. Frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:

    - be based on established conventions and practices, including that the competence of the devolved institutions will not normally be adjusted without their consent;
    - maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules;
    - lead to a significant increase in decision-making powers for the devolved administrations.

3. Frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK that shares a land frontier with the EU. They will also adhere to the Belfast Agreement.

APPENDIX II: Joint Decision-making Dispute Avoidance and Dispute Resolution Process

Key							
	Inputs/Outputs		Senior Officials		Officials		Secretary of State (SofS)/ Portfolio Ministers		The ministerial committee outlined in the MoU on Devolution



Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
1. In accordance with section 9 of the Framework Outline Agreement policy colleagues will meet regularly. Requests to modify legislation and policy proposals within scope of the framework may be brought forward by the appropriate authority. 2. Scientific advice and wider risk management issues are considered to reach a consensus for a common recommendation to Ministers. 3. All four governments submit the same common recommendations to Ministers for a decision (either for common approaches across the UK or divergent approaches). Where agreement cannot be reached at official level issues are referred to senior officials for consideration. 4. Ministers review recommendation seeking decisions. Officials will be asking Ministers to agree to the recommended approach. 5. Ministers reach agreed decision on common recommendations.	1. **Further discussions at official and senior official level.** 2. **Dispute avoidance initiated:** ● Pause work progressing implementation of Ministerial decision until differences are resolved. ● Senior officials from all four governments meet to consider ministerial views and determine whether there is any additional information available to support an agreed approach revert to consider any alternative approach. ● Officials submit risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four governments. 3. **Recommendations made to Ministers in the four governments:** ● Officials submit further/revised common recommendations, informing Ministers of the approaches being recommended across all four governments.	**1. Further discussion of issues.** **2. Dispute avoidance initiated:** Escalation to highest level, dispute resolution process initiated ● Pause work progressing implementation of SofS / Cab Sec / Perm Sec* level decision until differences are resolved. ● Officials submit further/revised common recommendations, informing the appropriate intergovernmental structures of the approaches being recommended across all four governments. ● The appropriate intergovernmental structures consider common recommendations and SofS / Cab Sec / Perm Sec views and consider any additional information available to support decision making. ● If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge and why agreement has not been reached to date. If the approach being recommended is agreed across the UK, proceed to a ministerial decision. ● The appropriate intergovernmental structures consider the common recommendation individually and provide a response to SofS / Min / Perm Sec private offices. **3. SofS / Min / Perm Sec reach agreed decision on common recommendation.**

Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
	● If recommended approach differs across the UK, officials provide explanation and a summary rationale setting out why it is appropriate to diverge. ● If the approach being recommended is NOT agreed by Ministers and officials from the four governments meet again. **4. Ministers receive risk management common recommendation seeking decision.** ● Each Minister considers the common recommendation individually and provides a response. ● If the approach being recommended is NOT agreed across the UK, officials meet to discuss the issues. **5. Ministers reach agreed decision on common recommendations.** ● If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK: ○ Private Offices inform officials in their own	● Private offices inform officials in their own respective government of the decision. ● Policy officials in all four governments share information on SofS / Min / Perm Sec decisions.

Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
	respective governments of the decision to implement agreed approach. ○ Policy officials in all four governments share information on the Ministers' decisions.	

SofS / Cab Sec / Perm Sec= Secretary of State/ Cabinet Secretary /Permanent Secretary

SofS / Min / Perm Sec= Secretary of State/ Ministers /Permanent Secretary

ANNEX I

Concordat on blood (and blood components) safety and quality

Introduction

1. This Concordat is an agreement between the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health in the area of blood safety and quality. It gives effect to the Blood Safety and Quality Common Framework. It also sets out the continuation of good working relations, open communication; the maintenance of a compatible minimum set of high standards of safety and quality for blood and blood components; a dispute avoidance and resolution mechanism; and a review and amendment mechanism.

2. This agreement is a political commitment and is not intended to be legally binding or enforceable. It is in accordance with the overarching Memorandum of Understanding (MoU) on Devolution[4] and the Common Frameworks principles agreed at the Joint Ministerial Committee (EU Negotiations) (JMC(EN)) on 16 October 2017[5].

Scope

3. This agreement covers the subject matter of the EU Blood Directive (2002/98/EC) and implementing acts. The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 retain the UK's safety and quality standards for blood and blood components and amends the regulations to ensure that they will operate as intended following the UK's departure from the EU. The 2019 Blood Safety and Quality EU Exit SI was amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020.

Principles for working together

4. This agreement will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.

5. The parties affirm their mutual commitment to work together on the application of retained EU law in relation to blood safety and quality policy and their respective responsibilities. This cooperation is intended to give all parties the assurance that working relationships will be conducted in a manner that is both collaborative and helpful, aiming, where possible and appropriate, to achieve agreement on policy. In addition, all parties agree that regular contact will continue to discuss ongoing business of mutual interest.

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4 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/316157/MoU_between_the_UK_and_the_Devolved_Administrations.pdf

5 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652285/Joint_Ministerial_Committee_communique.pdf

6. This Concordat is intended to provide the basis for the management and maintenance of a compatible minimum set of safety and quality standards by setting out governance arrangements and a dispute resolution process. All parties to the Concordat agree that a Common Framework approach, that recognises the Common Frameworks principles agreed at JMC(EN) in 2017 and the finalised principles for intergovernmental relations, is highly desirable across the UK. The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework.

7. Open communications will be maintained and information shared, to the extent permitted by law, at the earliest opportunity. This may include but is not confined to policy issues, stakeholder views, preparations for and outcome of consultations and research, media interest and lines to take, and emerging issues and intelligence (UK/EU/international).

8. The parties acknowledge that there may be a need for their separate responsibilities to be tackled with uniformity. For example, events could transpire that would require urgent action (such as, but not limited to, responding to emerging diseases). Each party shall consider promptly and thoroughly any concerns raised by the others. Where all agree that consistency is needed, consultation on a common approach shall be undertaken.

9. The parties shall inform each other at the earliest opportunity of any new policy proposals, before they are made public, to allow full consideration and a common approach to be reached wherever possible. Each party will also appraise the others of the ongoing development of such proposals. Where this will not be possible, each party will inform the others as soon as possible.

10. The parties to this agreement commit to resolving any issues at the lowest possible level and recognise that agreement to disagree can be an acceptable outcome, provided the JMC(EN) Common Frameworks principles remain upheld.

11. Where common recommendations may be made, Ministers will retain the right to take individual decisions for their government. For those areas within the scope of the Blood Safety and Quality Common Framework, the opportunity for consistency of approach across governments will be sought in the first instance. The ability for divergence must be retained, while taking account of its impact on patient safety and confidence, and the functioning of the UK internal market. Every effort will be made at working level to resolve any disagreements in difference of approach. Where a consensus cannot be reached by these arrangements (whether that is agreement to a UK-wide approach or to accept divergence) the dispute avoidance and resolution mechanism would come into play.

Dispute avoidance and resolution

12. The goal of the dispute avoidance and resolution mechanism is to avoid escalation to formal processes through the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties to this Framework becomes a ‘dispute’ when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.

13. This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the JMC (EN) Common Frameworks principles. In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

14. The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

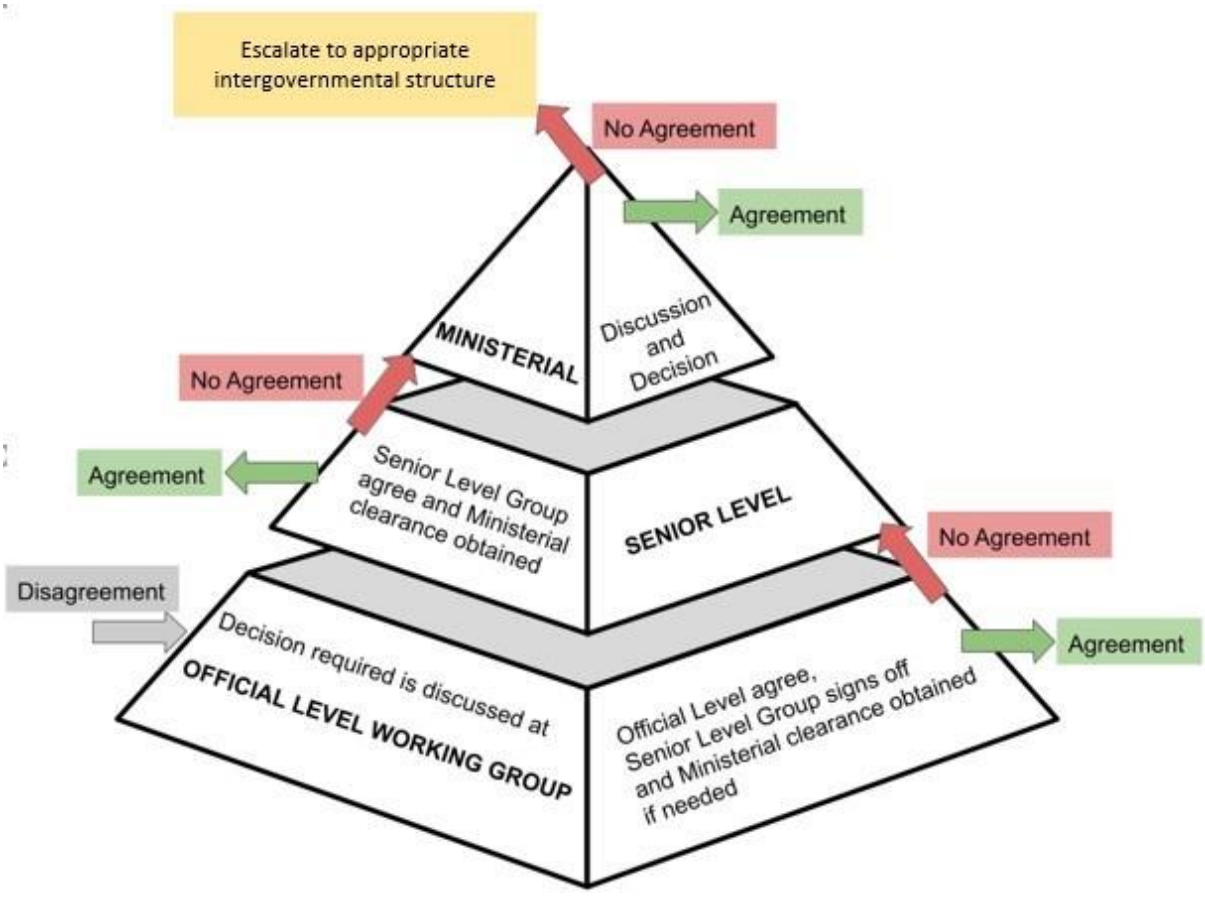

Figure 1: The levels of escalation for disagreements and disputes.

15. Following the approach set out in section 8 and 9 and Appendix II of the Blood Safety and Quality Common Framework and within the spirit of this Concordat, the all governments will seek every opportunity to resolve

differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions.

16. Where it has not been possible to resolve any disagreement in approach at official level, this will initially be referred to Senior Officials for resolution.

17. Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Blood Safety and Quality Common Framework. The parties may conclude, having considered potential impacts on patient safety and the JMC principles and reflecting the appropriate intergovernmental structures, that divergence is appropriate.

18. As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated to the appropriate intergovernmental structures for resolution under the dispute resolution process set out in the appropriate intergovernmental structures.

Timescales for escalation

19. When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated quicker.

Evidence gathering

20. At each stage further evidence may be requested from officials at the preceding level, or from stakeholders (listed below), before the disagreement is discussed.

Third parties

21. During policy development and dispute resolution, Medicines and Healthcare products Regulatory Agency (MHRA), the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) may be used to provide scientific or technical advice on the most appropriate ways to ensure the safety of blood for transfusion.

Official level meetings

22. **Official level blood safety and quality meetings:** All parties will continue to regularly share information with one another in relation to the scope of this agreement and will continue to discuss:

    - the impact of decisions on other governments, including any impacts on cross-cutting issues;

    - prospective policy changes;

- emerging issues and intelligence etc.

23. As previously mentioned, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Senior Officials will then report to the relevant Ministers as necessary, to provide an update or to escalate an issue.

Review and amendment mechanism

Process

24. The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.

25. There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.

26. The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by this non-legislative agreement.

27. Third parties can be used by any party to the Framework to provide advice at any stage in the process. These include other government departments or bodies, as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.

28. At the outset of the review stage, parties to the Framework must agree timelines for the process, including the possible amendment stage.

29. If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

Review stage

30. An initial review will take place one year after the Framework comes into effect, it will be used to determine if the arrangements are functional.

31. Following the initial review, a periodic review of the Framework will take place every two years.

    - The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.

    - During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.

32. An exceptional review of the Framework is triggered by a 'significant issue':

- A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the Framework.

- The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.

- The same significant issue cannot be discussed within six months of the closing of that issue.

33. The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be two years until the next periodic review and at least six months until the same significant issue can trigger an exceptional review).

Amendment stage

34. Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the Framework or all.

35. If an amendment is deemed necessary during either type of review, the existing Framework will remain in place until a final amendment has been agreed.

36. All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.

37. If parties cannot agree whether or how a Framework should be amended this may become a disagreement and as such could be raised through the Framework's dispute avoidance and resolution mechanism.

38. Changes to the Framework and Concordat will be communicated to stakeholders via the current communication channels.

The Protocol on Ireland/ Northern Ireland

39. The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

    - *Paragraph 22 - substances of human origin.*

40. This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.

41. Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.

    - As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.

    - Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

42. Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

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