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The UK and devolved governments published provisional common frameworks on **blood safety and quality** and **organs, tissues and cells** in January 2022.

Common frameworks are agreements between the governments on how to work together and manage divergence in areas previously governed at EU level.

The governments are publishing common frameworks in provisional form for scrutiny. In early 2022, the Senedd's **Health and Social Care Committee** scrutinised both provisional common frameworks and made recommendations about them to the Welsh Government.

Once all parliaments have completed scrutiny, the governments intend to respond to recommendations and agree final versions of the frameworks.

This briefing provides an overview of both provisional common frameworks.

Contents

Summary

When the UK was a member of the EU, EU law set harmonised minimum standards on blood safety and quality and for organs, tissues and cells for human use. National authorities were able set more stringent standards. Now that the Brexit transition period has ended, the UK, Scottish and Welsh Governments can **diverge from retained EU law**. The Welsh Government has powers to carry out some functions formerly exercised at an EU level.

The common frameworks set out how the UK and devolved governments will work together and manage divergence in this new context. The governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other. The governments will seek to agree whether they will follow the same rules or diverge. The frameworks state that they will allow for 'necessary' divergence, but offer limited guidance on what this means.

Under the Northern Ireland Protocol in the UK-EU Withdrawal Agreement, Northern Ireland will continue to align with EU law on blood, organs, tissues and cells. Both frameworks provide for the governments to consider the implications of changes to the law in Great Britain (England, Wales and Scotland) for alignment with Northern Ireland, and for implications of changes to EU law applying in Northern Ireland for alignment with Great Britain.

Both frameworks set out a dispute resolution process. If the governments do not agree on whether to take the same approach or diverge, they will seek to resolve the disagreement at the lowest possible level. They may then escalate the disagreement to senior officials and to Ministers.

As part of their principles for establishing common frameworks, the UK and devolved governments agreed that frameworks should 'ensure compliance with international obligations' and enable 'entering into and implementing new trade agreements and international treaties'. Some common frameworks set out arrangements for devolved governments to engage in collaboration at the international level. However, neither of these frameworks do this.

Neither framework requires the governments to update parliaments and stakeholders on how it is working, or to involve parliaments and stakeholders in review and amendment. The four governments have agreed in principle to report regularly to parliaments on common frameworks. The Welsh Government has also agreed unilaterally to report to the Senedd on common frameworks and to consult the Senedd and stakeholders during review and amendment.

1. Background

Legislation in scope

EU-derived legislation

EU Directives set standards for blood, organs, tissues and cells for human use. The Directives are transposed into domestic law by regulations.

EU Directives on blood sets out harmonised minimum standards on blood safety and quality. National authorities may set more stringent standards. **Directive 2002/98/EC (the Blood Directive)** sets out requirements for blood safety and quality, on donation, collection, testing, processing, storage and distribution. In addition:

- **Directive 2004/33/EC** sets technical requirements for blood and blood components;
- **Directive 2005/61/EC** sets requirements for traceability and notification in case of serious adverse events and reactions;
- **Directive 2005/62/EC** sets standards for blood banks; and
- **Directives 2009/135/EC, 2011/38/EU, 2014/110/EU** and **2016/1214** set out some additional requirements.

EU Directives on Organs, Tissues and Cells also set out harmonised minimum standards. **Directive 2010/53/EU (the Organs Directive)** and **Directive (2004/23/EC) (the Tissues and Cells Directive)** set safety and quality standards for organs, tissues and cells. In addition:

- **Directive 2012/25/EU** sets information procedures for the exchange of organs for transplantation between EU countries;
- **Directive 2006/17/EC (amended by Directive 2012/39/EU)** sets technical requirements for donation, procurement and testing of tissues and cells;
- **Directive 2006/86/EC (amended by Directive 2015/565)** sets requirements for traceability, notification of serious adverse events and reactions, and processing of tissues and cells;
- **Directive 2015/566** sets procedures for verifying the safety and quality of imported tissues and cells; and
- **Decisions 2010/453/EC** and **Decision (2015) 4460** set some additional requirements.

Transfer of functions to domestic authorities

Following the end of the transition period, the regulations transposing the Directives have been preserved as retained EU law under the EU (Withdrawal) Act 2018. The UK and devolved governments can now make changes to the regulations.

To ensure that the regulations would continue to function after the end of the transition period, the UK Government made 'correcting' changes to them using powers in the EU (Withdrawal) Act. There was no public consultation on the correcting regulations. The **Scottish Parliament took evidence** on the regulations from a small number of stakeholders. The Welsh Government consented to the regulations and **notified the Senedd under Standing Order 30C.**

The blood regulations were amended in the **Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2019** and in further regulations to implement the Northern Ireland Protocol in **2020**.

The organs, tissues and cells regulations were amended in the **Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019** (and **2020**) and the **Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019** (and **2020**).

The correcting regulations transfer certain powers from the European Commission to the Welsh Ministers, and to the Secretary of State with the consent of the Welsh Ministers, including the ability to:

- make certain changes to update safety and quality requirements (for example, in response to technical developments);
- set requirements for the traceability of tissues and cells;
- make provision on serious adverse events and reactions to transplants and transfusion;
- set requirements for verifying equivalence of standards for imported tissues and cells;
- set requirements for blood and tissue establishments; and
- update organ and donor characterisation requirements (for example, in response to disease outbreaks).

The regulations also made some further changes, including to:

- remove some requirements, including obligations to make certain reports to

the Commission and Member States and to use the Single European Code to facilitate traceability of organs, tissues and cells;

- remove reciprocal obligations between UK and EU institutions, including the obligation for the Human Tissue Authority to contribute to the EU's network of competent authorities; and
- implement changes to movement of blood, organs, tissues and cells between Great Britain and Northern Ireland.

The Northern Ireland Protocol requires that EU law on the safety and quality of blood, organs, tissues and cells continue to apply in Northern Ireland (see page 8 below). The 2020 regulations implement the Protocol by limiting regulation-making powers to Ministers in Great Britain. The UK Government and Northern Ireland Executive have powers under the EU (Withdrawal) Act 2018 (as amended) to implement EU law in Northern Ireland by regulations.

International obligations

Blood, tissues and cells and organs are regulated at a national level, supported by an international system of recommendations, standards and monitoring by the World Health Organisation (WHO).

The WHO's forum, the **World Health Assembly**, adopts **resolutions** which require a majority of states to pass and which are indicative of requirements on a variety of health matters, including on the availability, safety and quality of blood products. For example, **Resolution WHA63.12** (2010) urges member states to take steps on the availability, safety and quality of blood products.

The information below explains relevant international instruments and sets out the UK's international obligations in this area, particularly with regards to the new UK-EU relationship.

Blood

The WHO monitors the regulation of blood in all countries and maintains a substantial body of guidance, standards, training and technical support to support the regulation of blood at an international level. The WHO groups its activities into the following categories:

- National blood policy and organisation;
- Blood supply;

- Blood donors;
- Blood screening;
- Blood processing;
- Supply of plasma-derived medicinal products (PDMP);
- Clinical use of blood;
- Blood transfusions; and
- WHO response.

In response to slow progress worldwide on blood availability and safety via national-level regulation, in 2020 the WHO launched its **Action framework to advance universal access to safe, effective and quality assured blood products 2020 – 2023** . The framework sets out strategic objectives to allow the WHO to better carry out its mandate on blood and increase its impact. A summary of the framework's aims is available on the **WHO's website** and in its **news story** announcing the framework.

Products of human origin

In 2017, the World Health Assembly **issued ten principles** for promoting ethical practices in the donation and management of medical products of human origin, applicable to tissues, cells and organs. It encouraged a strategic approach and a mix of governance mechanisms to implement the principles.

Obligations arising from the new UK-EU relationship

Since the UK's exit from the EU, the UK and EU have continued to cooperate in this area. However, this does not continue in all arrangements from when the UK was an EU member. More information on the changes which came into effect on the UK's exit are set out in an EU **readiness notice** on substances of human origin (blood, tissues and cells, organs).

New UK-EU arrangements relate to matters covered by the framework in the following specific circumstances:

Circumstances which present a threat to health security

In the **Trade and Cooperation Agreement** (TCA), the UK and EU have agreed to cooperate on threats to health security. This includes informing one another of any life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of

spreading, across the borders of the UK and at least one Member State. Provision is made on the practical arrangements of UK-EU cooperation on health security.

Further information may be found in the Senedd Research briefing on the **common framework for public health protection and health security**.

Future cooperation in international forums

In the TCA, the UK and EU have also committed to cooperate in international forums on the prevention and detection of, preparation for, and response to emerging threats to health security.

Withdrawal Agreement

The Withdrawal Agreement, which set the terms for the UK's exit from the EU, also includes provision in this area. In particular, Article 41(1) provides that an existing good placed on the market in the UK or EU before the end of the transition period (31 December 2021) can circulate and be made available in those markets until it reaches its end user. This applies to blood, tissues, cells and organs.

The Northern Ireland Protocol provides that EU legislation on blood, tissues and cells, and organs applies to and in the UK in respect of Northern Ireland.

Domestic law and policy

Within the framework of their international commitments, the UK and devolved governments have scope to set additional rules for blood, organs, tissues and cells at domestic level. For example:

- the **Human Transplantation (Wales) Act 2013** introduces a 'deemed consent' system for organ donation. Similar legislation has been passed in England, Scotland and Northern Ireland.
- in 2020, Ministers in all parts of the UK agreed to **ease some restrictions on donating blood** for men who have sex with men.

2. The common frameworks

The two provisional common frameworks set out how the governments should work together and manage divergence in law and policy after the end of the transition period. Each framework is given effect by a Concordat formally agreed between the governments.

Both frameworks require the governments to discuss and agree approaches to law and policy, and set out processes for resolving any disputes or disagreements that arise. The **Senedd's Health and Social Care Committee has raised concerns** about the impact of this on the role of the Welsh Government, the Senedd and stakeholders in making laws for Wales. The **Welsh Government has said** that the frameworks will not affect devolved powers.

The two frameworks will be interdependent. In a letter to the House of Lords Common Frameworks Scrutiny Committee, **the UK Minister said** that two separate frameworks had been developed (rather than one) because 'there are significant differences in the underlying legislation and regulatory oversight'.

The frameworks recognise that they will also need to link up with the regulation of medicines and medical devices. This is not devolved.

3. Roles and responsibilities

The UK and devolved governments are responsible for the regulation of blood, organs, tissues and cells within their competence. EU law will continue to apply in Northern Ireland.

The frameworks both set out that regular meetings of officials from the four governments will be held to share information on relevant law and policy across the UK and consider proposed policy changes.

There are scientific advisory committees on blood, organs, tissues and cells. The **Independent Advisory Committee on the Safety of Blood, Tissues and Organs** (SaBTO) advises Ministers on policy for ensuring the safety of blood, cells, tissues and organs for transfusion and transplant. SaBTO does not appear to have any current members from organisations in Wales.

The **Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)** advises the transplant and transfusion

services and prepares service guidelines for transfusion services. The Medical Director of the Welsh Blood Service sits on this Committee. The **Wales Transplantation Advisory Group** also provides advice on transplantation policy in Wales.

In the NHS, the **blood services for each part of the UK** collect, process and supply blood to hospitals. The **UK Blood Services Forum** co-ordinates the four blood services. **NHS Blood and Transplant** is responsible for supply of organs and tissues for transplant across the UK.

The regulator that enforces blood safety and quality legislation across the UK is the **Medicines and Healthcare products Regulatory Agency (MHRA)**, which is a reserved authority. The **Human Tissue Authority** is the UK regulator for organs, tissues and cells policy. The Welsh Government is responsible for appointing one member to the Human Tissue Authority under the Human Tissue Act 2004.

4. Managing divergence: principles

These two frameworks affirm the six **principles agreed for common frameworks by the Joint Ministerial Committee (European Negotiations)** in 2017. They identify three of the principles in particular that apply to these frameworks:

- enabling the functioning of the UK internal market, while acknowledging policy divergence;
- enabling the management of common resources; and
- safeguarding the security of the UK (i.e. by supporting patient safety).

The frameworks both state that 'maintaining a compatible minimum set of safety and quality standards' will make it easier for blood, organs, tissues and cells to continue to move between different parts of the UK.

They also say that the frameworks will also allow for 'necessary divergence' to 'respond to needs such as location-dependent public health concerns.'

5. Managing divergence: practice

Making decisions

The frameworks both set out 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.

If any government proposes to make a change to the relevant EU-derived legislation (see section 1 above), it should notify the other governments. The governments should arrange a meeting with policy officials to discuss the proposal if any government requests this

One or more of the governments may initiate a risk assessment for a policy proposal. Depending on the issue, they may seek advice from scientific advisory committees, the regulator, the national blood or transplant services, or stakeholders.

Officials from the governments will seek to reach a consensus for a common recommendation to ministers. The recommendation could either be for a harmonised approach to policy or legislation across the UK/GB or for divergent approaches.

Stakeholders discussed the risk assessment and decision-making process in evidence to the House of Lords Common Frameworks Scrutiny Committee in May 2021. A **representative of the MHRA said**:

> .... although the MHRA is mentioned, it is not called out specifically enough and the focus is more at the policy level of making changes rather than what the implications may be at the operational level. This is key for our work and key for the availability and ease of movement and so on.

The representative said that he had suggested to the UK Government that the roles of the MHRA and the Human Tissue Authority should be made clearer.

Responding to urgent situations

The Concordats to each framework briefly address how they might work in urgent situations (for example, in response to an emerging disease). They state that "there may be a need for their separate responsibilities to be tackled with uniformity" and "[w]here all agree that consistency is needed, consultation on a common approach shall be undertaken".

The frameworks do not provide any assessment of how this might affect the response to an urgent situation.

UK Government's review of retained EU law

The **UK Government has set out plans** to introduce a Retained EU Law Bill to make it easier to change or repeal retained EU law (REUL) and to remove the special status it has in UK law. This could lead to existing standards being removed or changed in domestic law.

The **UK Government has said** that it will not seek to make changes to retained EU law within Common Frameworks "without following the ministerially-agreed processes in each framework".

Interaction with the UK Internal Market Act 2020

The frameworks recognise that part of their purpose is to ensure the functioning of the UK internal market.

The **UK Internal Market Act 2020** sets out principles of mutual recognition and non-discrimination for goods. In essence, it aims to allow goods permitted or imported into any one part of the UK to be sold in any other part.

Section 10 of the Act allows the UK Government to create exclusions from the mutual recognition principle for goods to give effect to an agreement reached through a common framework. The UK and devolved governments have now **agreed a process for doing this.** The **Welsh Government has said** it will notify the Senedd when it seeks an exclusion.

Regulatory requirements justified for the protection of public health are excluded from the market access principles. Sales made for the purpose of performing a public function (such as NHS procurement) are also excluded. Because of this, the movement of blood, organs, tissues and cells may not always be in scope of the market access principles...

The **Welsh Government has confirmed** that "there is an intersect between these frameworks and the UK Internal Market Act". However, neither framework gives any assessment of whether changes to the relevant legislation could fall within the scope of the Act.

Managing international obligations

In 2017, the **Joint Ministerial Committee (European Negotiations) agreed** frameworks would be established where necessary for:

- entering into and implementing new trade agreements and international treaties; and
- ensuring compliance with international obligations.

The organs, tissues and cells framework states that these principles do not apply to it. The blood safety and quality framework recognises both principles apply but provides no detailed consideration of their application.

In the principles for working together in both frameworks, a commitment is included to maintain open communication and to share information at the earliest opportunity on UK/EU/international issues.

The only international obligations mentioned relate to the UK-EU relationship. No mention is made of other types of international instruments, such as World Health Organisation standards or recommendations.

Both frameworks state that they do not "directly fall within the provisions" of the UK-EU Trade and Co-operation Agreement, while recognising that the agreement will 'impact significantly on devolved and reserved responsibilities."

Both frameworks recognise post-Brexit arrangements for Northern Ireland, including its economic and social links with Ireland, and their shared land border. A commitment is included to adhere to the Belfast (Good Friday) Agreement.

Managing divergence between Great Britain and Northern Ireland

Changes to EU law on the safety and quality of blood, organs, tissues and cells must be applied in Northern Ireland under the Northern Ireland Protocol (see section 1 above).

This could create divergence between the law in Northern Ireland and the rest of the UK over time. The European Commission published an **evaluation of EU legislation on blood, tissues and cells in 2019** and **proposed a new Regulation** in July 2022.. The **Welsh Government has said** it will "consider, with the other governments in the UK, the implications of any changes".

The frameworks set out that:

- when the UK, Scottish and Welsh Governments make decisions on changing rules in Great Britain, the Northern Ireland Executive will participate fully in discussions and the views of Northern Ireland Ministers will be taken into account; and
- when rules in Northern Ireland change in alignment with EU rules, all four governments will consider the changes and determine 'any impacts or subsequent actions arising'.

The frameworks both state that officials in Northern Ireland will "continue to be involved in policy development and discussions to resolve disputes where required." If Northern Ireland Executive Ministers feel that concerns have not been addressed properly, they can raise a dispute through the framework.

In evidence to the **Common Frameworks Scrutiny Committee**, stakeholders agreed that they were not aware of "significant appetite" for policy divergence.

6. Resolving disputes

The frameworks both set out a process for the resolution of disputes. They state that the process will only be used when "divergence would impact negatively on the ability to meet the common frameworks principles". Otherwise, the governments may agree to disagree.

If policy officials do not agree on whether to recommend that the governments should take a common approach or diverge, the disagreement may be escalated to senior officials and then to portfolio Ministers. Officials, regulators, JPAC and SaBTO may be asked to provide technical advice at each stage in the dispute resolution process.

The frameworks recognise that this process could delay the making of legislation and indicate that timescales for escalation will be guided by the urgency of the proposal.

If the dispute cannot be resolved by portfolio Ministers, it may be escalated to "the ministerial committee outlined in the MoU on Devolution". In January 2022, the **governments agreed** a new inter-ministerial dispute resolution process as part of the Intergovernmental Relations Review. The **Counsel General said** this was a "groundbreaking step".

The framework does not provide for disputes to be notified to parliaments or stakeholders. However, the **Welsh Government has committed** to notify the Senedd of disputes.

7. Monitoring, review and revision

The frameworks both state that officials will monitor their operation at regular meetings, including to assess whether they are being implemented properly and whether any divergence has taken place in contravention of the framework principles.

The governments will review the frameworks for the first time one year after they have come into operation, and every two years after that.

There will also be a review if a 'significant issue' arises that has a 'fundamental impact' on the framework's operation. The same significant issue cannot be discussed within six months of the conclusion of the discussion.

Following a review, the governments may agree to open a discussion of amendments. Amendments to the frameworks must be agreed unanimously. If there is no agreement, the dispute resolution process may be used.

8. Transparency and accountability

In correspondence with the House of Lords Common Frameworks Scrutiny Committee, **the UK Government said** that blood services in each part of the UK, the MHRA, SaBTO, and JPAC had been consulted on the draft provisional blood safety and quality framework.

For the organs, tissues and cells framework, NHS Blood and Transplant, SaBTO, JPAC, the Human Tissue Authority (HTA), the Welsh Transplantation Advisory Group, the Cardiff and Vale University Health Board, the Welsh Renal Clinical Network, and Health and Social Care Northern Ireland (HSCNI) were consulted.

The UK Government states that stakeholders agreed with the rationale and scope of the framework, but "highlighted the impact of the Ireland/Northern Ireland Protocol".

The frameworks both state that third parties (including external stakeholders) may be asked to provide input into the review and amendment process. However, no

process is set out for parliaments to monitor the operation of the frameworks or to contribute to review and amendment. The frameworks state that changes will be communicated to stakeholders 'via the current communication channels'. In March 2022, **the Counsel General agreed** in correspondence with the LJC Committee to notify the Senedd and stakeholders when a common framework is reviewed, and consider their recommendations before the review process concludes.

There is no commitment for reports on the operation of the framework to be produced or published. The **Welsh Government has committed unilaterally** to report annually to the Senedd on frameworks. In November 2021, the **Counsel General also said** that the governments had agreed to future reporting to parliaments on common frameworks.