Respondent 1

ANON-XZ49-NTV8-F

Publish response

NHSBT Public Affairs

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - significant Impact

No

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

This piece of EU Regulation is updating regulations and guidance in an area that already exists. The use of SoHO requires legal requirements to be met.

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - not applying eu act

Unsure

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - tell us why

To not comply/deal with EU regulations and products would be for the NI Assembly to decide.

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. - Any other matters

Yes

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. - Tell us why

NHSBT provides a blood and transplantation service to the NHS, looking after blood donation services in England and transplant services across the UK. This includes managing the donation, storage and transplantation of blood and blood components, organs, tissues, bone marrow and stem cells, and researching new treatments and processes.

NHSBT does trade in Europe and has supplies in common with EU countries.

NHSBT will ensure it meets all relevant regulatory and legal requirements.

Respondent 2

ID ANON-XZ49-NTVA-R

Publish response

Human Tissue Authority

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - significant Impact

No

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

The new Regulation on Standards of Quality and Safety for Substances of Human Origin (SoHO) Intended for Human Application (2024/1938) replaces existing Directives 2002/98/EC (relating to blood and blood components) and 2004/23/EC (relating to tissues and cells). Our response to this survey focuses on areas within the HTA's remit, specifically, non-reproductive tissues and cells intended to be used in human application. Based on our current understanding and noting that implementation of the Regulation is in the early stages, we do not currently believe that there is likely to be a significant impact on everyday life for most people within the communities in Northern Ireland (NI) in a way that is liable to persist.

However, as a caveat to the "No" designation above, we do believe that implementation could have an impact on some specialist, technical services that work with or use tissues and cells in human application and would have to adapt to a revised regulatory framework. Examples of specialist, technical services include establishments that collect, process and store tissues and cells within NI, such as stem cells and bone products. It also includes those that receive cardiovascular, ocular and bone products from suppliers for use in human application, including specialist hospital departments and dental practices.

The Regulation expands the scope of activities and materials for which quality and safety standards apply. It provides an open definition of SoHO and aims to use technical guidance to set specific standards, allowing the Regulation to keep pace with scientific and technical developments. We understand that the Regulation seeks to increase protections for donors and recipients, introduce clinical monitoring to support innovation, monitor SoHO supply and facilitate working across member states.

It is important to note that while the Regulation introduces different regulatory frameworks for NI and Great Britain (GB), it builds on quality and safety requirements that are aligned and currently exist in both the UK and EEA. The existence of the current aligned framework means the impact of a new framework is envisaged to be less than it would otherwise have been.

The HTA is aware that the UK Government (UKG) 2024 Explanatory Memorandum (https://www.niassembly.gov.uk/globalassets/committee-blocks/windsor-framework-democratic-scrutiny-committee/inquiries/uk-government-explanatory-memor committed to ensuring the smooth flow of SoHO between GB and NI, taking action where required. Competent Authorities (CAs) such as the HTA will work with key players, such as UKG, to review standards and requirements in light of the new Regulation. This review of standards would be aided by existing frameworks, including the Blood Safety and Quality Provisional Common Framework, and the Organs, Tissues, and Cells Provisional Common Frameworks. These frameworks support good working relations, open communication and maintain compatible minimum standards of safety and quality for blood and non-reproductive cells within the UK.

The Regulation allows a three-year transition period (due to end in August 2027). During this period, we understand that the EEA will establish a SoHO Coordination Board (SCB) to support implementation of the Regulation. Implementation Acts (as outlined in the Regulation) and technical guidance are also expected to provide specific details about the standards and requirements of the Regulation, and enable a full impact assessment. Based on this information, new policies and processes will be developed by CAs during the transition period to aid implementation. This includes the development of guidance to support establishments that fall under the Regulation to implement relevant changes.

In summary, given what is known about the Regulations, we anticipate there will be some impact on some specialist, technical services involved in the use of human tissue and derived products for human application. We envisage that change will be addressed through a suitably managed regulatory change process.

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - not applying eu act

Unsure

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

If the Regulation did not apply to Northern Ireland (NI) this would introduce a difference in regulatory requirements between NI and the Republic of Ireland. In this scenario, this would result in an impact on some specialist, technical services that

would have to adapt to a revised regulatory framework. As outlined in our response to question one, there are currently relatively equivalent standards between UK and EU quality and safety requirements concerning SoHO.

As outlined in the UK Government's (UKG) 2024 Explanatory Memorandum (https://www.niassembly.gov.uk/globalassets/committee-blocks/windsor-framework-democratic-scrutiny-committee/inquiries/uk-government-explanatory-memor the extent of any impact of the Regulation in Northern Ireland will depend on the position adopted by the UK Government in relation to SoHO, and whether this affects the movement of SoHO between GB and NI. The memorandum also sets out that it will take action as needed to support the continued supply of GB-originating SoHO to NI.

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. - any other matters

Yes

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. – tell us why

An initial assessment of the SoHO Regulation indicates that there will be resource and financial implications for competent authorities as well as those who are subject to the Regulation. Implementing the Regulation would require systems, processes and pieces of guidance to be amended or developed.

For example, while the HTA has an established process in place for approving preparations, it may need to be adapted. This is due to the Regulation introducing new requirements, including the need for clinical outcome monitoring plans. The relevant systems, skills, and guidance would need to be developed under these requirements. Other examples would include formalising SoHO emergency plans, identifying and registering entities and establishments that fall under the Regulation, and producing guidance for new donor protections.

Respondent 3

ANON-XZ49-NTV9-G

Publish response

Human Fertilisation and Embryology Authority

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - significant Impact

No

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

The Human Fertilisation and Embryology Authority (HFEA) is the UK wide regulator of fertility treatment and embryo research and as such, we can only address this question specifically in relation to the fertility sector. We are not concerned that the 2024 SoHO Regulations will affect everyday life of NI communities, including fertility patients (for example, we are not concerned that patients' ability to import donor sperm for treatment will be affected). It's possible that the Regulations will have other effects (for example, additional requirements for HFEA licensed fertility clinics).

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - not applying eu act

No

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

As set out above, we are the regulator of fertility treatment and embryo research and we can only address this question specifically in relation to the fertility sector. We would not be concerned that (should the 2024 SoHO Regulations not be applied) everyday life would be affected for fertility patients as the sector is already well-

regulated in the UK with similar standards as those proposed by the 2024 Regulations. However, it is possible that should the 2024 SoHO Regulations be applied only in the EU and not in NI, import and export between NI and the EU would be more complex. This may affect, for example, fertility patients wishing import donor sperm into NI from the EU.

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. - any other matters

Yes

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. – tell us why

Submission of data to the EU SoHO platform. Whilst the whole of the EU is subject to GDPR requirements, the stricter duties of confidentiality in the Human Fertilisation and Embryology Act 1990 (as amended) ('the HFE Act') is only relevant to HFEA licensed centres in the UK. Depending on what data is required, if Northern Ireland centres were required to submit data to the EU SoHO Platform (either directly or through the HFEA), it is possible that this could be a criminal offence under the HFE Act, s33A. At this stage we do not know exactly what data will need to be provided to the EU SoHO Platform and it seems this has yet to be finalised (eg, Article 14).

Regulation would apply different standards in Northern Ireland than in Great Britain, and regulation for Northern Ireland will become more complex as a result. As a UK-wide regulator we will need to continuously monitor developments in EU guidance and UK guidance and, for Northern Ireland, assess the extent of any divergence and how clinics can practically resolve discrepancies or divergences, should they arise. There may be a lack of clarity with respect to the position in NI should direct legislative or regulatory conflicts arise between GB and EU interpretations.

This will also be a more complex exercise for the small fertility sector in Northern Ireland where there will be regulatory overlap (since both UK and EU guidance applies) and the licensed clinics in Northern Ireland will need assess how to resolve any conflicts.

Respondent 4

ANON-XZ49-NTVF-W

Publish response

Medicines and Healthcare products Regulatory Agency

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - significant Impact

Unsure

Does it appear likely that the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

MHRA is responsible for ensuring compliance with the UK Blood Safety and Quality Regulations 2005. These regulations implement Directive 2002/98/EC of the European Parliament and Council of 27 January 2003 setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. They also implement Commission Directive 2004/33/EC which contains certain technical requirements relating to blood standards. These regulations apply to Hospital Blood Banks and Blood Establishments in the UK. There are six Hospital Blood Banks and one NHS Blood Establishments in NI.

The European Council reports on the new EU SoHO Regulation:

“In addition to improving quality and safety, the regulation aims to increase harmonisation and facilitate cross-border exchanges and access to SoHO, including by:

• setting up an EU-level SoHO coordination board supporting member states in the implementation of the regulation
• introducing common EU-wide procedures for the authorisation and assessment of SoHO preparations
• requiring member states to designate a SoHO national authority and other competent authorities to authorise SoHO preparations and ensure independent and transparent oversight of SoHO-related activities

• setting out additional authorisation and inspection requirements for establishments that both process and store, release, import or export substances of human origin
• establishing a new common IT platform, the EU SoHO platform, to register and exchange information on related activities”

The new EU SoHO Regulation continues to support an established regime to ensure the quality and safety of blood and blood components for transfusion or to be presented as a starting material for the manufacture of a medicinal product (blood preparations that are not used for transfusion).

The new EU SoHO Regulation now captures the collection of intestinal microbiota, to be presented as a starting material for the manufacture of a medicinal product.

MHRA has not granted any licences in NI for the manufacture of intestinal microbiota medicinal products.

The UK Government will be working with Devolved Governments and stakeholders to review the EU SoHO Regulation over the next twelve months.

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? - not applying eu act

Unsure

Does it appear likely that NOT APPLYING the EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist? – tell us why

The collection of blood and blood components for transfusion or to be presented as a starting material for the manufacture of a medicinal product continue to follow the European Directorate for the Quality of Medicines & HealthCare Good Practice Guidelines for standards and specifications for implementing the quality system in blood establishments. This is to ensure the quality and safety of blood and blood components.

The collection of intestinal microbiota, to be presented as a starting material for the manufacture of a medicinal product will have to follow the European Directorate for the Quality of Medicines & HealthCare Good Practice Guide to the quality and safety of tissues and cells for human application which includes intestinal microbiota. This is to ensure the quality and safety of the material collected.

The UK Government will be working with Devolved Governments and stakeholders to review the EU SoHO Regulation over the next twelve months.

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. - any other matters

Unsure

Are there any other matters regarding the EU act that you wish to draw to the Committee's attention? Please note, any information provided should be of an evidential nature rather than a commentary. – tell us why

The UK Government will be working with Devolved Governments and stakeholders to review the EU SoHO Regulation over the next twelve months.