Standards of quality and safety for substances of human origin intended for human application (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD)

SUBJECT MATTER

1. Following a vote in the European Parliament on 24 April 2024 and adoption by the Council of the European Union on 27 May 2024, the European Union (EU) have repealed the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2004/23/EC (BTC Directives). They have also adopted a new Regulation on standards of quality and safety for substances of human origin intended for human application, SoHO Regulation (2024/1938). The SoHO Regulation makes changes to reflect scientific, technical, and medical advances in transfusion and transplantation. This adoption follows an initial proposal from the European Commission, published in July 2022.

2. The EU's existing BTC Directives set a range of safety and quality standards, including:
   - standards for all steps in the transfusion process for human blood and blood components from donation, collection, testing, processing, storage to distribution;
   - standards for all the steps in the transplantation process for tissues and cells from donation, procurement, testing, processing, preservation, storage to distribution.
   - traceability and technical requirements for blood, tissues and cells; and
   - notification requirements in the event of a serious adverse event or reaction which may impact the safety and quality of blood, blood components, tissues and cells.

3. The EU's existing BTC Directives apply directly in Northern Ireland (NI) under the terms of the Windsor Framework due to NI's unique access to the EU Single Market. Equivalent safety and quality standards also apply in Great Britain (GB) by the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 and the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020.

4. The changes that the EU has adopted in its SoHO Regulation are intended to future-proof SoHO legislation, brings into scope legislation applicable to SoHO and acknowledge new technologies and emerging risks, while continuing to provide high safety and quality standards for SoHO therapies. The Regulation provides improved protection for donors and recipients (as well as for children born following medically assisted reproduction), supports the continuity of supply and strengthens the existing legal framework while also increasing flexibility in order to keep up with scientific and technical developments. It also creates conditions for safe, effective and accessible innovation, improves harmonisation across Member States, facilitating cross-border exchange of SoHO and improving patient access to therapies and improves crisis preparedness and resilience to safeguard access to therapies.

5. The new Regulation allows for the maintenance or introduction of more stringent measures at a national level. The measures should be compatible with Union law and be proportionate to the risk to human health.

6. The Regulation also continues to set out requirements for bodies carrying out specific SoHO activities (including processes for authorisation) and competent authority supervision.

7. As per the previous BTC Directives, the SoHO Regulation will continue to apply to blood, blood components, tissues and cells (including haematopoietic stem cells from peripheral blood, from umbilical-cord blood or from bone marrow, reproductive cells and tissues, embryos, foetal tissues and cells and adult and embryonic stem cells).

8. The new Regulation will also bring into scope all SoHO intended for human application and used to manufacture products regulated by other specific Union legislation, with the exception of solid organs intended for transplantation (as their donation and transplantation are significantly different, determined, inter alia, by the effect of ischemia in the organs, and so remain regulated separately under Directive 2010/53/EU) and human breast milk (HBM) used exclusively for feeding one's own child. The purpose of which is to provide harmonised preparation and consistent treatment for substances intended for human application, and improve the safety, effectiveness and accessibility of SoHO.

9. Compared with the previous BTC Directives, this therefore brings into scope of the Regulation of SoHO substances such as intestinal microbiota (IM), HBM (in non-exempt cases) and blood preparations that are not used for transfusion (e.g., serum eye drops, fibrin glue, platelet rich plasma). The Regulation will also apply to any future substances or products not yet used for human application that may be developed following scientific advances or other developments where it comes within the definition of SoHO. There is the potential for other SoHO to be brought into scope. For example, exosomes could come within scope, but this is still to be determined by the SoHO Coordination Board (SCB).

10. Subject to the processes set out in Schedule 6B of the Northern Ireland Act 1998 and Article 13(3a) of the Windsor Framework, the new SoHO Regulation will apply in NI in accordance with Article 13(3) of the Windsor Framework. As set out in further detail in the impact assessment, the UK Government's assessment is that while the Regulation creates some new operational requirements for entities carrying out SoHO activities in NI and for competent authorities, this is unlikely to prevent the movement of SoHO from GB to NI. This is predominantly because of the high standards that are applied across the UK, and the UK's role in contributing to the European-wide standards that are the basis of EU regulation in this area. The Government is also committed to ensuring the smooth flow of substances of human origin between Great Britain and Northern Ireland and, if needed, will take action to support GB-NI movement. In addition, the Regulation provides derogations which would allow for movement and application of SoHO, where specific conditions are met. The UK Government will also continue to work closely with the EU, through the processes established under the Windsor Framework, as new implementing acts or guidelines are adopted further to the Regulation. An explanatory memorandum (EM) to the UK Parliament for the draft of this proposed legislation was published on 28 September 2022. That EM provides further background and should be read in conjunction with this EM.

SCRUTINY HISTORY

11. The Commission previously published the draft proposal for the Regulation in 2022 and an EM for that draft proposal was published by the Department of Health and Social Care, on 28 September 2022 and reviewed by the relevant UK Parliamentary Scrutiny Committees.

MINISTERIAL RESPONSIBILITY

12. The Parliamentary Under Secretary of State (Minister for Public Health and Prevention) has policy responsibility for human breast milk, the EU future relationship, Windsor Framework and international trade in regard to health.

13. The Parliamentary Under Secretary of State (Minister for Patient Safety, Women's Health and Mental Health) has policy responsibility for blood, blood components, reproductive and non-reproductive tissues and cells.

14. The Minister of State for Health (Secondary Care) has policy responsibility for IM and blood preparations that are not used for transfusion.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

15. The Devolved Governments, Food Standards Agency, Food Standards Scotland and other SoHO regulators have been kept up to date with the progression of the Regulation and have been consulted in the preparation of this Explanatory Memorandum.

Blood, Tissues, and Cells

16. Blood, blood components and non-reproductive tissues and cells policy is devolved. The Scottish Parliament, Welsh Parliament and Northern Ireland Executive therefore have an interest.

17. The Blood Safety and Quality Provisional Common Framework, and the Organs, Tissues, and Cells (apart from embryos and gametes) Provisional Common Framework support 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 non-reproductive tissues and cells.

18. Reproductive tissues and cells are a reserved policy, and therefore there is not a Common Framework for this area. However, close working continues between the UK Government and the Devolved Governments on reserved and excepted matters that impact significantly on devolved responsibilities including the donation, processing and use in treatment of human reproductive cells.

19. Both provisional Common Frameworks have been jointly developed by the UK Government and Devolved Governments and have been operational since March 2020. These Common Frameworks set 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 government(s) introduce a change. Where rules in NI change, 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.

20. These provisional Common Frameworks also reflect the specific circumstances that arise as a result of the Windsor Framework and reiterate the commitment to a UK-wide approach in terms of decision making, governance, and dispute resolution. The underlying principle is that administrations 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.

Human breast milk

21. HBM is devolved and currently considered to be a food under the definitions in assimilated Regulation 178/2002 Article 2 or Regulation (EC) No 178/2002 for NI. 'Food' is defined as '*any substance or product, whether processed, partially processed, or unprocessed, intended to be, or reasonably expected to be ingested by humans'* and currently falls under the Food and Feed safety and hygiene (FFSH) Common Framework.

22. In the UK, anyone selling or supplying HBM must comply with UK general food law (under EU Regulation 178/2002) and food hygiene legislation under EU Regulation 852/2004. The National Institute for Health and Care Excellence (NICE) also provides clear guidelines for HBM in a clinical context.

23. The new Regulation will apply in NI and classify HBM as a SoHO from 2027. As set out in the FFSH Framework, the UK Government will continue to work with the Department of Health (NI) on the implementation of this Regulation.

Intestinal microbiota and blood preparations that are not used for transfusion

24. IM (also referred to as faecal microbiota transplants) and blood preparations that are not used for transfusion are currently classed as a medicinal product by the Human Medicines Regulations 2012 (HMRs) (Directive 2001/83/EC). The regulation of human medicines is transferred to NI and reserved for Wales and Scotland, but MHRA regulates UK-wide. As with HBM, IM and blood preparations that are not used for transfusion will come under the SoHO Regulation from 2027. Donor health and testing requirements would apply to IM and blood preparations that are not used for transfusion up to the point of processing even if they were then used for medicinal

products.

25. The SoHO Regulation sets out the interaction between SoHO and medicinal products and medical devices as well as their regulatory status. Where SoHO is collected to manufacture a medical device that is regulated by Regulation 2017/745/EU, medicinal product regulated by Directive 2001/83/EC, advanced therapy medicinal products (AMTP) regulated by Regulation 1394/2007 or investigational medicinal products regulated by Regulation 536/2014 – the provisions of the SoHO Regulation applicable to the SoHO activities referred to in Article 2 paragraph 1 (c)(I) to (iv) and (viii) apply.

26. Where SoHO activities referred to in Article 2 paragraph 1 (c)(vii), (ix), (x) and (xi) are carried out on SoHO up to and including distribution to a manufacturer regulated by other Union legislation (such as those referred to above) this Regulation will also apply.

27. Where SoHO (e.g., IM and blood preparations that are not used for transfusion) are used to manufacture products regulated by other Union legislation and those products are exclusively used for therapeutic use on the person from whom the SoHO was collected, the provision of the SoHO Regulation relating to the SoHO activities referred to in Article 2 paragraph 1 (c)(iii) and (iv) apply.

28. As set out in the Joint Ministerial Committee (EU Negotiations) Communique 2017, although there is not a Common Framework for these areas the UK Government will continue to work closely with the Devolved Governments, including with the Department of Health in NI.

LEGAL AND PROCEDURAL ISSUES

EU Legal Base

29. The SoHO Regulation has been adopted under Article 168(4)(a) of the Treaty on the Functioning of the European Union (power of the Parliament and the Council to adopt measures setting high standards of quality and safety for SoHO). It will be applicable to and in the UK in respect of Northern Ireland in accordance with Article 13(3) of the Windsor Framework.

Voting Procedure

30. The voting procedure for this Regulation is by qualified majority voting.

Timetable for adoption and implementation

31. On 24 April 2024, the European Parliament approved the new Regulation on standards of quality and safety for SoHO intended for human application.

32. On 27 May 2024, the Council of the European Union adopted the new Regulation on standards of quality and safety for SoHO intended for human application.

33. The Council of the European Union has now formally adopted the new Regulation; it was published in the Official Journal of the EU on 17 July 2024.

34. The Regulation will enter into force on 7 August 2024 (the twentieth day following its publication in the Official Journal) and will become applicable in the EU and NI on 7 August 2027 (three years' time), with an extra year for certain provisions.

35. The Regulation repeals and replaces the BTC Directives (Directives 2002/98/EC and 2004/23/EC) and brings into scope the regulation of SoHO to include HBM (currently regulated by Regulation 178/2002), IM and blood preparations not used for transfusion (currently regulated by Directive 2001/83/EC). These legislations are all included in Annex 2 to the Windsor Framework. This measure will therefore become applicable in NI, in accordance with Article 13(3), subject to the processes set out in Schedule 6B of the Northern Ireland Act 1998 and Article 13(3a) of the Windsor Framework.

POLICY AND LEGAL IMPLICATIONS

Changes being introduced by the SoHO Regulation

36. The SoHO Regulation includes a variety of activities within the definition of "SoHO activity" including registration and testing of donors and, the collection, processing and monitoring of clinical outcomes for SoHO intended for human application. The Regulation:
    - aims to improve the quality and safety of SoHO and facilitate cross-border exchanges, including through further detailed provisions regarding oversight by competent authorities, authorisation processes and SoHO recipient and donor protections.
    - mandates (rather than encourages, as was the case under previous legislation) voluntary and unpaid SoHO donations, prohibits financial incentives for donors, and allows compensation for living donors within national legislation; and
    - includes a rapid alert system for severe incidents, requiring Member States to ensure the adequate supply of critical SoHO and review emergency plans.

37. Some measures such as Preparation Process Authorisation (PPA) are already in place for tissues and cells in the UK. The Regulation introduces administrative changes to this process in NI and the UK Government will work with the Devolved Governments and regulators to consider how to best streamline these arrangements and support stakeholders in preparing for the changes.

38. The below sets out a summary of the assessment across a range of different areas; and sets out more detailed analysis on the impacts for the different substances.

39. Once the structures that will provide further clarity on the implementation of the SoHO Regulation are in place and further detailed guidelines and acts are published, the UK Government will carry out further analysis. The Government is committed to public health and supporting the movement of SoHO from GB to NI and will review any new guidelines and acts with that in mind.

SoHO Coordination Board (SCB)

40. The Regulation establishes a SoHO Coordination Board with the aim of ensuring coherent procedures for the application of this Regulation. The Regulation establishes the new SCB that will provide the relevant best practice, clarity on the regulatory status of SoHO and promote coordination between Member States concerning the SoHO Regulation implementation and delegated and implementing acts.

41. This will enable new evidence to be considered in a timelier manner than the previous EU legislation allowed, and safety requirements to be kept up to date (e.g., to reflect scientific developments). The SCB will also be used to confirm which substances fall within the scope of the Regulation.

Provisions regarding scope

42. The new Regulation strengthens existing requirements that apply to substances within scope. Firstly, it improves protections for SoHO donors, recipients, and offspring from medically assisted reproduction, as well as supports the sufficiency of the supply of SoHO that are critical to the health of patients.

43. Secondly, it sets out the interaction between SoHO and medicinal products and medical devices as well as their regulatory status. Where SoHO is collected to manufacture a medical device that is regulated by EU 2017/745, medicinal product regulated by 2001/83/EC, advanced therapy medicinal products (AMTP) regulated by 1394/2007 or investigational medicinal product regulated by 536/2014 – the provisions of the Regulation applicable to the SoHO activities referred to in Article 2 paragraph 1 (c)(i) to (iv) and (viii) apply. The aim is to provide clarity to industry and regulators on the complex interactions between the SoHO and pharmaceutical legal frameworks.

Competent authorities

44. The Regulation stipulates that competent authorities should be designated, to fulfil all functions within the scope of the Regulation, such as perform supervisory activities and order cessation of activities where needed. If there are multiple competent authorities dealing with different substances within scope of the Regulation, a single independent SoHO national authority should be designated.

45. In NI, as per the rest of the UK, different competent authorities regulate the various substances.

    - The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for blood preparations that are not used for transfusion, IM, blood and blood components.
    - The Human Tissue Authority (HTA) is responsible for non-reproductive tissues and cells.

- The Human Fertilisation and Embryology Authority (HFEA) is responsible for reproductive tissues and cells.
- The Food Standards Agency (FSA) regulates HBM in England, Wales and NI and the Food Standards Scotland (FSS) regulates HBM in Scotland.

46. The UK Government is considering how UK-wide regulators will operate from 2027 and will provide further guidance.

47. As set out in the Regulation, there is an intention for a single national authority in NI to be appointed. An update will be provided on this in due course, following detailed guidance from the EU.

Supervisory abilities

48. The new SoHO Regulation sets out that competent authorities must put in place mechanisms to register SoHO entities (entities that have a direct impact on the quality, safety, or effectiveness of SoHO), establishments (that process, store, release, import and export SoHO) and SoHO preparations. In cases where SoHO is moved from GB to NI, the establishment must be authorised to move these substances into NI and have processes in place to ensure that the substances are of equivalent standards to those set out in the Regulation (and guidelines).

49. Some entities will already be licensed under the BTC Directives, including for the movement of blood, blood components, tissues, and cells from GB to NI, as similar provisions were in place under Directives 2002/98 and 2004/23 and no immediate action may be required. It is estimated that there is a limited number of entities not already licensed, that will need a licence/authorisation under the new Regulation.

50. The UK Government and competent authorities will work with industry to minimise the impact of any new requirements and process authorisations swiftly. Some entities, such as hospitals, may also be eligible for support under existing international projects, such as the ReaderShip project, that aims to assist hospitals in complying with the new legislation. The project focuses on efficient management and coordination elements, including efficient management of registration, ensuring traceability and vigilance, collecting activity data, and ensuring quality management of SoHO in the hospital.

51. On the movement of SoHO between GB and NI, the UK has high quality and safety standards in place and, while in some cases entities (e.g., for IM, HBM and blood preparations not used in transfusions) which are not yet authorised may experience new requirements, we do not anticipate that these will significantly affect the movement of SoHO. Further analysis can be found below.

52. The UK Government will continue to monitor further EU guidance and implementing acts and will take action, if needed, to support the continued flow of SoHO between GB and NI. Although unlikely to be required, the Regulation also provides for a derogation that would allow for SoHO to be moved from Great Britain to Northern Ireland without a prior authorisation in health emergency situations.

53. For some substances, to facilitate the movement of SoHO, the UK Government and regulators will need to update guidance or make other changes as a result of the new Regulation. For instance, the HFEA will need to update the NI Standard Licence Conditions.

54. Regarding inspection processes more generally, certain SoHO entities/establishments (e.g., blood) across the UK are already subject to inspections, and the new Regulation (which includes registration) may result in a reduction in inspections from every two years to at least every four years.

Obligations on SoHO entities and establishments

55. SoHO entities will need to comply with a range of provisions, such as the need to have a responsible person for ensuring that SoHO activities carried out by the SoHO entity comply with the relevant regulatory requirements. Many of these provisions also already apply in some form under the BTC Directives, although they would now also apply to other substances such as HBM, blood preparations that are not used for transfusion and IM. In some instances, SoHO entities will be required to report data to the EU SoHO Platform, although this would typically be done by the competent authority. The UK Government will issue guidance and liaise with relevant SoHO entities in due course.

56. For some substances, the processes set out in the Regulation are generally already in place, and therefore do not require significant changes to SoHO activities in NI. For example, in the UK there is already a regulatory requirement for blood, blood components, tissues and cells for establishments to report serious adverse reactions or events to the competent authority.

57. For HBM, under the current regulations for HBM banks the local authorities and district councils (LAs/DCs) have the enforcement powers. There is a reporting system to the central competent authority and the LA's/DC update this on quarterly basis to report any findings or breaches in legislation. There may be additional information about SoHO activities that need to be collected and submitted.

58. The HMRs set out obligations on the recording or reporting of suspected adverse reactions as well as changes to risk. However, additional information may also need to be collected and submitted for IM and blood preparations that are not used for transfusion.

59. The UK Government and competent authorities will publish further guidance to support SoHO establishments and entities in implementing the changes.

60. Examples of entities that are in scope of these definitions:
    - Blood: blood establishments, hospital blood banks, and blood facilities that collect, test, and supply human blood or blood components intended for transfusion.

- Non-reproductive tissues and cells: tissue banks or hospital units where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken.
- Reproductive tissues and cells: tissue establishments and fertility clinics.
- HBM: human breast milk banks and commercial suppliers. The NHS is the main public health provider of HBM in the UK, supported by human milk banks (e.g., the Hearts Milk Bank).
- IM: certain hospital sites and in some cases pharmacies.
- Blood preparations that are not used for transfusion: hospital sites.

61. In some instances, these operators may not yet be registered according to the requirements of SoHO Regulation. For instance, HBM banks are currently registered as a Food Business Operator (FBO) and would have different requirements. The Government will issue more guidance for organisations/suppliers on the registration processes and requirements in due course.

Technical guidelines

62. The Regulation utilises the expertise of the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the European Centre for Disease Prevention and Control (ECDC) to provide technical guidelines to ensure the safety and quality of SoHO and protection of donors, recipients, and offspring. The EDQM is a pan-European (rather than EU) organisation, and the UK is represented. EDQM is also expected to be consulted on the guidelines produced by ECDC. The Commission may also adopt implementing acts concerning technical requirements.

63. The UK Government will continue to engage with the European Commission on information-sharing under the engagement channels agreed in the Windsor Framework.

Donor and recipient protection

64. The Regulation sets out provisions to protect donors and recipients, including regarding informed consent and the mitigation or elimination of health risks. It mandates that donation is voluntary, whereas the previous BTC Directives only encouraged this, particularly for cells and tissues (Article 12(1) of the Tissues and Cells Directive).

65. Payment for HBM at milk banks is not given. Donor Expressed Breast Milk (DEBM) is supplied to Neo-natal Units (NNUs) and Paediatric Wards and is donated on a voluntary basis and purchased by health providers. However, some individuals providing milk to commercial operators can be financially reimbursed depending on various factors including quality and quantity.

66. IM donors may also be reimbursed for their time. While some activities are therefore already in line with the new Regulation, the Regulation would lead to some changes to donation in commercial settings.

67. The UK Government and regulators will support bodies carrying out SoHO activity to implement the changes regarding the donation process.

68. For blood, blood components, tissues and cells, the UK (including in respect of Northern Ireland) already meets the EDQM requirements regarding the testing of pathogens, toxins, or genetic conditions, and will continue to monitor and engage with the EU on any further guidelines and implementing acts.

69. HBM banks currently already test HBM for certain pathogens, toxins, and chemical contaminants such as heavy metals to ensure compliance with food safety and hygiene legislation. However, genetic conditions fall outside the scope of the Food Safety and Hygiene Regulations. The UK Government will work with the relevant stakeholders to ensure food and feed safety. Food businesses work closely with LAs/DCs to demonstrate they are using Hazard Analysis and Critical Control Points (HACCP) based principles to comply with all elements of Food Hygiene Regulations (EC Regulation 852/2004). HACCP is a systematic approach to food safety management that aims to prevent, reduce, or eliminate potential hazards in the food production process.

70. The EDQM guidelines, which are followed across the UK, include chapters on IM (in the Tissues and Cells Guide) and blood preparations that are not used for transfusion (in the Blood Guide). For IM, there are currently voluntary guidelines in place which set out donor screening must be robust and ensure their faeces are safe to donate. Screening also needs to be repeated periodically to ensure ongoing safety.

71. Blood preparations that are not used for transfusion but meet the definition of a medicinal product and are used for a clinical indication will be classed as a blood product and will be subject to standards of quality and safety under the Blood Safety and Quality Regulations (BSQR) and the HMRs. It would therefore, meet the current EU testing requirements.

72. The UK Government will review its approach to donor and recipient protection following the publication of the EDQM and ECDC guidelines for HBM, blood preparations that are not used for transfusion and IM that may not currently meet all these requirements, as well as reviewing any new standards for blood, tissues, and cells.

73. The UK Government is committed to patient access and ensuring that SoHO can move between GB and NI. Issues related to the safety and quality of SoHO (as defined in this Regulation) will continue to be considered on a UK-wide basis, as this Regulation evolves and the systems, processes and forums set out in the Regulation are established.

74. The UK is a leader in transfusion, transplantation, pharmaceuticals, and food safety. The changes in the Regulation that apply in NI will not come at the expense of public health, patient safety, and access, as the Regulation allows more stringent protective measures to be implemented. Therefore, overall, we do not anticipate that changes to

the safety and quality standards set out in this Regulation will significantly impact the movement of SoHO from GB to NI.

Continuity of supply

75. The Regulation sets out that Member States must ensure continuity of supply, and mandates the drafting of a national emergency plan, with SoHO entities drafting their own in line with the national plan. We already have UK-level plans for the continuity of supply. The UK Government will continue to work with NI on continuity of supply and will support with the drafting of the emergency plan.

76. The provisions to harmonise rules and procedures across Member States should make processes clearer for UK (GB or NI) SoHO establishments and entities to import SoHO from the EU and should not substantively increase the complexity of importing from the EU.

77. We expect to be informed of all relevant new guidance and acts in good time.

Other impacts and analysis on specific types of SoHO

78. In line with the Government's commitment to ensuring NI businesses have unfettered access to the rest of the UK internal market, the measures set out in the SoHO Regulation will in no way impede the movement of qualifying Northern Ireland goods from Northern Ireland to Great Britain. Such goods will also continue to benefit from the market access principles set out in the United Kingdom Internal Market Act 2020. Accordingly, so long as those goods comply with the relevant standards and regulations, they can be supplied anywhere in the UK internal market.

79. The movement of SoHO from GB to NI facilitates its use in life-changing and life-saving treatments. Our assessment is that tissues and cells are the most commonly GB-NI moved substances, and we currently have equivalent standards in these areas. We will continue to engage with the European Commission on any updates to these standards/requirements and will keep this under close review. Given the importance of SoHO, the UK Government will take action as needed to support the continued supply of GB-originating SoHO to NI.

80. Blood and blood components are regulated in NI by the MHRA. NI is largely self-sufficient in the supply of blood and blood components, with NHS Blood and Transplant providing a contingency supply when/if needed. There is limited anticipated impact on these movements between GB and NI and the UK competent authority will work closely with the relevant seven hospital blood banks and one blood establishment in NI on implementation of the SoHO Regulation to ensure patient safety and supply.

81. Reproductive tissues and cells (gametes and embryos for human application) are regulated by the HFEA. NI imports a low volume of reproductive tissues and cells from sites in Great Britain every year. In 2023, NI only received an estimated 14 eggs, 23 embryos, 62 sperm straws and 6 sperm vials from England. NI also sent less than

5 sperm straws to Scotland, 32 embryos and 7 sperm ampoules to England. As set out in paragraph 67, the UK and the EU currently have equivalent standards for these materials, but the SoHO Regulation introduces changes in NI. As above, the Government will monitor this closely and is committed to supporting the movement of GB-originating tissues and cells to NI.

82. The new EU Regulation specifies that any promotion and public activities in support of the donation of SoHO do not refer to compensation. However, UK-wide legislation currently allows donor advertisements to refer to donor compensation. The UK Government will take the necessary steps to ensure that vital tissues and cells can continue to be moved to NI. The HFEA will provide guidance to recruitment centres that intend to supply NI to support continued movement of the relevant substances.

83. Non-reproductive tissues and cells (for human application) are regulated by the HTA and include a wide range of products such as stem cells, ocular tissues, skin and bone marrow. Approximately 11 establishments in NI are currently licensed to move non-reproductive tissues and cells from GB to NI and, to a much lesser extent, from the EU to NI. In 2023 NI sourced approximately 400 non-reproductive tissues and cells from GB, compared with approximately 20 from inside the European Economic Area.

84. HBM was not previously in scope of the BTC Directives and is considered a food under current legislation (Regulation (EC) 178/2002) and regulated by the Food Standards Agency. NICE guidance currently applies for HBM in a clinical context. With the introduction of the new SoHO Regulation, entities producing HBM in NI for reasons other than a personal context will be subject to the new EU SoHO Regulation. Although the current unregulated market for HBM in the UK appears to be small (there is a limited number of buyers/sellers/platforms), there is also a lack of data on the quantity of HBM supplied by the NHS from regulated milk banks.

85. There is only one self-regulated commercial supplier in the UK, but individuals may also supply on unregulated platforms as well. In NI there is currently one NHS Trust human breast milk bank, Western Trust Milk Bank, that supplies HBM to Health and Social Care in NI and the Republic of Ireland. The current regulator is the Food Standards Agency (FSA). As part of the Common Frameworks process, the UK Government intends to work with Devolved Governments to review the EU standards and requirements for HBM and discuss the GB approach in light of the changes introduced by the SoHO Regulation.

86. Currently there is relatively limited demand for IM (regulated by MHRA) and limited movement. Of the four registered organisations, only the University of Birmingham has supplied NI. While this concerns a small volume of movement between GB and NI, these products are important to treat recurrent *Clostridioides difficile* (C. diff) infections and ulcerative colitis. It is expected that demand for IM will increase following technological advancements in this area. There are some differences in the current standards for IM and those set out in the SoHO Regulation, for example the donation procedures. The UK Government will review its legislation and guidance in

this area and work with the relevant stakeholders to ensure that GBIM can continue to move between GB and NI as needed.

87. A number of blood components are not used for transfusion but for other therapeutic purposes (e.g., serum eye drops; fibrin glue or platelet rich plasma) and are not included in the scope of the BTC Directive but will be in scope of the SoHO Regulation, and these are regulated by MHRA. At the moment the only blood preparation that is not used for transfusion (and not plasma for medicine) is platelet rich plasma. MHRA is not aware of any manufacture of this under a manufacturing licence. As with IM, the donation process will differ, and demand is likely to increase in light of scientific and technological advancements. The Government will continue to review new standards and work with relevant stakeholders to implement these.

88. The UK Government will engage closely with the EU, regulators, and affected stakeholders on changes to standards and requirements that apply. As noted, the UK maintains high standards in these areas and contributes to the pan-European body that the EU will continue to draw upon for technical and good practice guidelines. NI also will continue to have access to information through EU-UK structures/forums set up as a result of the Windsor Framework.

CONSULTATION

89. The EU held (targeted and public) stakeholder consultations during the impact assessment phase for the revision of the legislative framework on blood, blood components, tissues, and cells. UK regulators and stakeholders for blood, blood components, tissues and cells fed into these consultations.

90. Under the Windsor Framework, EU-UK engagement arrangements are in place, including structures to consider and identify solutions to any emerging issues of implementation or regulatory divergence. Officials have engaged to understand technical detail around implementation and will continue to do so. Officials will also continue to engage with the EDQM, a pan-European advisory body of which the UK is a member.

91. Policy officials are continuing to engage with Devolved Governments via the regular Common Framework meetings, operational and policy meetings and day-to-day policy discussions. These fora provide opportunities to discuss SoHO policy, share updates and consider the short-term and long-term impact of any developments.

92. Officials have also continued to engage with the following stakeholders during the development of the Regulation:
    - the Human Fertilisation and Embryology Authority (HFEA).
    - The Human Tissue Authority (HTA).
    - The Medicines and Healthcare products Regulatory Agency (MHRA).
    - NHS Blood and Transplant (NHSBT).
    - The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).
    - The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).

- Food Standards Agency (FSA); and
- Food Standards Scotland

93. At this stage, no public consultation is planned on this Regulation by the UK Government. External, targeted stakeholder consultation will take place with the UK Regulators for this sector, and other interested stakeholders, including those listed in paragraph 68.

FINANCIAL IMPLICATIONS

94. There will be financial implications for:
    - SoHO establishments and entities.
    - the MHRA as the NI competent authority (and UK-wide regulator) for blood, blood components, IM and blood preparations not used for transfusion.
    - the HTA as the NI competent authority (and UK-wide regulator) for non-reproductive tissues and cells.
    - the HFEA as the NI competent authority (and UK-wide regulator) for reproductive tissues and cells; and
    - the FSA as the NI Competent Authority for HBM.

95. Further work is ongoing with the regulators and the Department of Health Northern Ireland to better understand these financial implications.

Andrew Gwynne MP
Parliamentary Under-Secretary of State for Public Health and Prevention

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