STANDARD FORM OF EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION AND DOCUMENTS

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PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON STANDARDS OF QUALITY AND SAFETY FOR SUBSTANCES OF HUMAN ORIGIN INTENDED FOR HUMAN APPLICATION AND REPEALING DIRECTIVES 2002/98/EC AND 2004/23/EC

Submitted by the Department of Health and Social Care on 28 September 2022.

SUBJECT MATTER

1. The EU has proposed a new Regulation to address shortcomings identified in the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2004/23/EC (BTC Directives). These shortcomings are as a result of scientific, technical, and medical advances in the study of blood and tissues and cells since the publication of the BTC Directives. The BTC Directives set the safety and quality standards for blood, blood components, non-reproductive tissues and cells, and reproductive tissues and cells.

2. In the UK, blood and blood products are regulated by the Blood Safety and Quality Regulations 2005. Non-reproductive tissues and cells are regulated by the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Reproductive tissues and cells (i.e. eggs, sperm, embryos) are regulated by the Human Fertilisation and Embryology Act 1990.

3. The proposed Regulation on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application (SoHO Regulation) aims to ensure a high level of health protection and ensure access to safe and effective substances of human origin (SoHO) across EU Member States. The SoHO Regulation defines SoHO as any substance collected from the human body in whatever manner, excluding organs.

4. The previous BTC Directives were not broad enough to capture certain types of SoHO (e.g. human breast milk and intestinal microbiota). By repealing the BTC Directives, and introducing this SoHO Regulation, the EU aims to ensure that all SoHO that is intended to (or may in the future) be applied to humans falls within the scope of the legislation, and can be regulated throughout the Member States.

5. In 2019, the EU published an evaluation report which identified certain shortcomings with the current BTC legislation. These included out of date safety and quality requirements for blood, tissues and cells; divergent approaches across Member States causing barriers to cross-border exchange; exposure to avoidable risks for donors and offspring (i.e. children born from donated eggs, sperm or embryos); stifling innovation in the sector; and vulnerability to interruptions in supply.

6. The proposal provides measures to ensure safety and quality for patients treated with SoHO therapies and fully protect them from avoidable risks. The proposal also aims to facilitate the development of safe and effective, innovative SoHO therapies.

7. Under both the current BTC Directives and the proposed EU Regulation, SoHO need to be prepared and treated according to specific standards. To ensure these rules continually reflect scientific progress, the proposal moves for these rules to mostly be developed by scientific expert bodies active in the sector (a change from the current status quo). The proposal therefore either delegates, or allows for the delegation of, many of the technical standards for SoHO to the guidelines of the European Directorate for the Quality of Medicines (EDQM) and the European Centre for Disease Prevention and Control (ECDC). This means that new evidence can be included more rapidly than the previous EU legislation allowed, and safety requirements can be kept up to date (e.g. testing for infectious or non-infectious diseases).

8. The proposal provides measures to ensure that rigorous standards of safety and quality for SoHO are extended to SoHO donors; and children born from donated eggs, sperm or embryos.

9. The proposal provides measures to strengthen and allow for harmonisation of oversight practices amongst Member States, for example joint oversight activities, training, information and communications technology support tools and opportunities for exchanging best practices.

10. The proposal provides measures to improve the resilience of the sector, mitigating risk of shortage. This includes the requirement for SoHO entities to report their annual activity data and the establishment of an EU SoHO Platform to facilitate effective and efficient exchange of information, such as serious adverse occurrences related to SoHO and insufficiencies of supply.

11. The proposal also requires Member States, in collaboration with National SoHO Authorities, to draw up national SoHO emergency plans, in order to mitigate any vulnerability to interruptions in supply. In addition, the proposal stipulates that critical SoHO entities should launch a SoHO supply alert to

their Competent Authorities in case of a significant interruption, in order to reduce further impact.

SCRUTINY HISTORY

12. This is the first time the Commission has published the Regulation, therefore there is no scrutiny history.

MINISTERIAL RESPONSIBILITY

13. The Minister of State for Health has, in regard to health, policy responsibility for the EU future relationship, Northern Ireland Protocol and international trade.

14. The Parliamentary Under Secretary of State (Minister for Primary Care and Patient Safety) has policy responsibility for blood, tissues and cells.

INTEREST OF THE DEVOLVED GOVERNMENTS

15. The existing BTC Directives are listed in Annex 2 to the Ireland/Northern Ireland Protocol ("the Protocol"), and therefore the SoHO Regulation would be caught by Article 13(3) of the Protocol when it replaces them in due course. This EU legislation will therefore apply in Northern Ireland (NI), and the Northern Ireland Executive has a particular interest in these proposals.

16. Reproductive tissues and cells policy is reserved, and blood and non-reproductive tissues and cells policy is devolved. The Scottish Parliament, Welsh Assembly and Northern Ireland Executive therefore have an interest. The devolved governments have been consulted in the preparation of this Explanatory Memorandum.

17. There will be close working between the UK Government and devolved governments on reserved and excepted matters that impact significantly on devolved responsibilities.

18. 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.

19. Both provisional frameworks have been jointly developed by the UK Government and devolved governments, and have been operational since March 2020. The Framework Agreements 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 governments

introduce 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. It also reflects the specific circumstances that arise as a result of the Protocol and reiterates the commitment to a UK-wide approach in terms of decision making, governance, and dispute resolution.

20. Following the processes set out in both Frameworks, policy decisions may be made in Great Britain (GB) to reflect changes to the BTC Directives.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

The proposed Regulation would be 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 of organs and substances of human origin, blood and blood derivatives).

ii. Voting Procedure

Qualified majority voting.

iii.. Timetable for adoption and implementation (or expected next steps for non-legislative documents)

The Regulation will enter into force on the twentieth day following its publication in the Official Journal and will become applicable in the EU and in Northern Ireland two years after that date. Transitional provisions are included in the proposed Regulation for establishments regulated, and material currently held, under the BTC Directives. Obligations in connection with those transitional provisions come into force three years after the Regulation's entry into force.

iv. Does the proposal affect the substance of EU law that will remain in effect under the Northern Ireland Protocol or is it likely to be the subject of a request by the EU to be added to the Protocol under Article 13(4) thereof?

The proposal repeals and replaces the BTC Directives which are included in Annex 2 to the Northern Ireland Protocol. This measure will therefore be treated as included in Annex 2 to the Protocol and will become applicable in Northern Ireland, in accordance with Article 13(3).

POLICY IMPLICATIONS

21. Under the Northern Ireland Protocol, the EU's proposals will become directly applicable in Northern Ireland. Secondary legislation will need to be made under the European Union (Withdrawal) Act 2018 to revoke the existing

legislation implementing the BTC Directives and to deal with enforcement of the new directly applicable Regulation.

22. Given the intention for the proposal to increase safety, quality, innovation and supply of SoHO within the EU, it is likely that the new Regulation will have an overall positive impact on the SoHO sector in NI.

23. The inclusion of updates to minimum safety and quality standards under the EU's proposals may introduce divergence between GB and NI; and GB and EU Member States. This divergence will only occur once the proposals are in force in NI and the EU, and if the UK, Scottish and Welsh Governments elect not to voluntarily align with these changes.

24. NI has a reliance on import of SoHO from GB (for example NI has a dependency on England for its import of blood, for use in patient transfusions). If there is significant divergence between GB and NI, this may cause disruption to supply and limit NI's ability to import much needed SoHO from GB. Unfettered Access currently preserves the movement of SoHO from NI to GB in any circumstances.

25. The Government is currently reviewing the EU's proposals, and a decision will be taken in due course as to whether to introduce similar changes in GB. This decision will take into account a number of factors that may be affected by the proposals, including: patient safety; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health inequalities.

26. UK Regulators made recommendations to the EU as part of the consultation on and evaluation of the BTC Directives, which directly fed into the development of the SoHO Regulation. Therefore it is likely that, for GB, external stakeholders will support voluntary alignment with the minimum safety and quality standards included in the EU's proposal.

27. Certain parts of the proposal, for example the harmonization of Member State legislation and regulation of SoHO, and the encouragement of Member State collaboration, will be unsuitable for GB to implement since the UK is no longer an EU Member State, and is unlikely to affect the maintenance of equivalent safety and quality standards with the EU and between GB and NI.

28. The proposal delegates certain standards and technical guidance to the updated guidelines of the EDQM and ECDC. It is unclear without further scoping whether the UK Government and devolved governments will choose to voluntarily align with such guidelines, and, if they did, a legislative mechanism to allow for future updates to the guidelines would need to be put in place. The proposal also mentions the introduction of Implementing Acts, where further detail on SoHO regulation is needed at EU legislative level. The content of any Implementing Acts is unknown, and so the UK Government's

policy direction will need to be assessed once there is further information on this.

29. One of the overarching purposes of the SoHO Regulation is to increase the scope of legislation and capture all forms of SoHO (beyond just blood, tissues and cells). It is unclear what the effect of such change could be in the UK. The expansion of regulation will automatically apply in NI; however, this expansion of regulation has not been considered by the UK Government and devolved governments previously. Further time and work will be required to assess whether there is any benefit to voluntarily implementing such a change at a UK-wide level.

30. GB SoHO establishments will continue to have a strategic supply dependency on some EU Member States for SoHO. Patients often require a match to be able to proceed with their treatment, where a match cannot be found in the UK, registers in the EU are also searched. It will be important to maintain minimum standards with the EU to allow the movement of NI and EU SoHO which is used in life-saving and life-changing treatments for patients across the UK.

31. It should be noted that the UK Government intends to address issues facing communities in Northern Ireland under the current operation of the Northern Ireland Protocol. While the Government's preference is to resolve these issues through talks with the EU, in the absence of a negotiated solution, the NI Protocol Bill, introduced on 13 June 2022, will restore the balance inherent in the objectives of the Northern Ireland Protocol: protecting the integrity of the UK, avoiding a hard border and safeguarding the EU Single Market. Government has been engaged in consultation over the summer with stakeholders on how the Bill will work in practice, including in the SoHO sector. This work will continue during the passage of the Bill and we will give plenty of notice to those who may be affected.

32. There have been no discussions between the UK Government and the EU about this proposal.

CONSULTATION

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

34. 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:

a. The Human Fertilisation and Embryology Authority (HFEA);
b. The Human Tissue Authority (HTA);
c. The Medicines and Healthcare products Regulatory Agency (MHRA);
d. NHS Blood and Transplant (NHSBT);
e. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO); and
f. Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).

FINANCIAL IMPLICATIONS

35. It is unclear what the precise financial implications will be as a result of the SoHO Regulation becoming applicable in NI. The EU intends to fund costs through the EU4Health programme, and to find synergies with other EU policies related to resilience building of national healthcare services (REFORM, Recovery and Resilience Facility, European Investment Bank/Fund) and research into personalised medicine (Horizon Europe). The financial implications are to be directly managed by the Commission and indirectly (entrusting budget implementation tasks) by international organisations and their agencies (to be specified) and bodies referred to in Articles 70 and 71 of the Financial Regulation. As such, projected implementation costs cannot be applied to NI (or to GB if the UK Government and devolved governments choose to adopt the EU proposals).

36. There will be financial implications for the MHRA as the NI Competent Authority (and UK-wide regulator) for blood and blood products, the HTA as the NI Competent Authority (and UK-wide regulator) for non-reproductive tissues and cells, and the HFEA as the NI Competent Authority (and UK-wide regulator) for reproductive tissues and cells.

MINISTERIAL NAME AND SIGNATURE

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