EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) (EU EXIT) REGULATIONS 2020

[2020] No. [XXXX]

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2020

[2020] No. [XXXX]

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2020

[2020] No. [XXXX]

AND

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) (EU EXIT) REGULATIONS 2020

[2020] No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instruments

2.1 On 31 January 2020, the United Kingdom (UK) left the European Union (EU). The Withdrawal Agreement agreed with the EU entered into force. These four instruments give effect to the Ireland/Northern Ireland Protocol ('the Protocol') in the Withdrawal Agreement, for the safety and quality of blood and blood components, organs, tissues and cells, and reproductive cells (gametes and embryos) for treating patients.

2.2 The Protocol sets out the EU law that will continue to apply to and in Northern Ireland (NI) after the end of the Implementation Period. This includes the EU Blood Directive (2002/98/EC), EU Tissues and Cells Directive (2004/23/EC), and EU Organs Directive (2010/53/EU) (including the Commission implementing directives), collectively referred to as 'the Directives' in this memorandum. This means that NI must continue to meet the requirements of the Directives for as long as the Protocol is in force. These four instruments make the changes needed to allow NI to meet these requirements.

2.3 There are four separate instruments, collectively referred to in this memorandum as 'the 2020 SIs':

- The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 - referred to here as the 'Blood SI';

- The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 - referred to here as the 'Organs SI';
- The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 - referred to here as the 'Tissues and Cells SI'; and
- The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 - referred to here as the 'HFE SI'.

2.4 The 2020 SIs have been drafted separately as each amends different underlying legislation but each one brings forward very similar provisions. It is proposed that these instruments are grouped and debated together.

Explanations

What did any relevant EU law do before exit day?

2.5 The UK law in this area transposes the EU Directives for the safety and quality of blood, organs, tissues and cells (including reproductive cells). They set a range of safety and quality standards, including:

- standards for all steps in the transfusion process for human blood and blood components, including collection, testing, processing and distribution;
- the procurement, testing, processing, and storage of tissues and cells;
- organ and donor characterisation, which sets out the information that must be collected so an organ is matched with a suitable recipient;
- traceability requirements for blood, organs, 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, organs, tissue and cells.

2.6 Four instruments were made in 2019[1] (collectively referred to in this memorandum as 'the 2019 SIs') to ensure that, upon leaving the EU, the UK would maintain the current safety and quality standards for blood, organs, tissues and cells. The 2019 SIs also made amendments to reflect EU Member States becoming third countries to the UK.

Why is it being changed?

2.7 The 2019 SIs amended retained EU law across the UK as a whole and they are due to come into force at the end of the Implementation Period (11pm on 31 December 2020). Following the conclusion of the Withdrawal Agreement, NI must continue to meet the requirements of the Directives, for as long as the Protocol is in force. The 2020 SIs restrict the changes made by the 2019 SIs to Great Britain (GB) only, therefore the current law will remain in place for NI. The fact that NI will remain subject to EU law in this area, whereas GB will not, also requires some additional changes. The 2020 SIs will retain a single set of UK rules, but within them, a small number of provisions will apply to NI or GB only.

[1] The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019/4;
The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019/483;
The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019/481;
The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019/482

What will it now do?

2.8 The 2020 SIs will ensure that NI continues to meet the provisions of the Directives after the end of the Implementation Period. A detailed breakdown of the changes these instruments make is included in section 7. The key changes in the 2020 SIs are to:

- allow the current regulators to continue to act as the competent authorities in relation to the EU for NI;
- make amendments to the import/export provisions;
- for tissues and cells (including reproductive cells), the Tissues and Cells SI and the HFE SI retain the requirement for NI tissue establishments to use the Single European Code for tissues and cells; and
- limit the regulation making powers introduced by the 2019 SIs to GB.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of these instruments is the UK.

3.3 Legislative competence for the donation, processing and use in treatment of human reproductive cells is reserved to Westminster (i.e. legislation is dealt with by the UK Parliament). Competence in respect of all other human tissues and cells, blood and organs is devolved.

4. Extent and Territorial Application

4.1 The territorial extent of these instruments is the UK.

4.2 The territorial application of these instruments is the UK.

5. European Convention on Human Rights

5.1 The Minister of State for Health, Edward Argar, has made the following statement regarding Human Rights:

"In my view the provisions of The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020; The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020; The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 and The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The amendments made by these instruments are needed to give effect to the Protocol for the safety and quality of blood, organs, tissues and cells, for treating patients.

6.2 The relevant UK legislation is:

- The Blood Safety and Quality Regulations 2005;

- The Quality and Safety of Organs Intended for Transplantation Regulations 2012;
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007; and
- relevant amendments to the Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 1990.

6.3 This legislation was made under powers conferred by section 2(2) of the European Communities Act 1972 in order to implement the Directives (see paragraph 2.2).

6.4 Section 2 of European Union (Withdrawal) Act 2018 (EUWA) saves EU-derived domestic legislation so that it continues to have effect in domestic law, on and after exit day. The legislation in paragraph 6.2 is retained EU law and the 2019 SIs will amend it from 1 January 2021 to ensure it functions effectively once the UK is no longer subject to EU law, in reliance on section 8 of EUWA (power to remedy deficiencies in retained EU law arising from EU exit). As NI will need to remain subject to the Directives after the end of the Implementation Period, the 2020 SIs re-exercise the power in section 8 of EUWA to restrict the changes being made by the 2019 SIs to GB. The SIs also rely on the power in section 8C of EUWA (power to implement the Protocol), for example by ensuring that movements of blood, organs, tissue and cells into NI from GB are treated the same as movements of blood, organs, tissues and cells into NI from non-EU Member States.

7. Policy background

What is being done and why?

7.1 The donation of blood and blood components (red cells, platelets, and plasma) facilitate a wide range of essential, and often life-saving treatments, including blood transfusions used to deal with major surgery or trauma, and the manufacture of medicinal products such as clotting factors and immunoglobulins.

7.2 An organ transplant can be life-saving or life-transforming and is often the only treatment option available for the patient concerned.

7.3 Human tissues and cells are used in what can be life-changing therapies, such as: stem cells to treat blood cancers; corneas to restore sight; heart valves to treat heart conditions; and eggs and sperm to treat infertility. Other forms of tissue are more generic in use, for example bone products used in operations and in dental fillings.

7.4 The retained EU law (as set out in paragraph 6.2) sets the policy and legal framework in relation to all steps in the transfusion process for human blood and blood components and the donation, retrieval, processing, storage, transport, import and export of organs, tissues and cells used for transplantation.

7.5 The 2019 SIs (see paragraph 2.6) were made to amend the retained EU law so that it continues to function after leaving the EU and will be in force from 1 January 2021.

7.6 The 2020 SIs are needed to give effect to the Protocol. They restrict the changes being made by the 2019 SIs to GB only and therefore the current law will remain in place for NI. The fact that NI will remain subject to EU law in this area, whereas GB does not, also requires some additional changes. The 2020 SIs will retain a single set of UK

rules, but within them, a small number of provisions will apply to NI or GB only. Details of the main amendments made by these instruments are set out below.

Quality and safety standards

7.7 Neither the 2019 SIs, nor the 2020 SIs make changes to the safety and quality standards, which will remain the same across the UK from 1 January 2021. For NI these standards may be expressed by reference to EU legislation, whereas for GB they are not, however, the substance is the same in both cases. For example, to apply for a licence to make one-off imports of tissues and cells from a third country, the applicant must provide the regulator with certain information to demonstrate traceability and the one-off nature of the import. The current regulations refer to the information requirements as set out in the Tissues and Cells Directive. The 2019 SIs removed this cross-reference to the Tissues and Cells Directive for the UK; however, the 2020 SIs will now retain that cross-reference for NI. The substance of the information to be provided remains the same across the UK.

Regulators as competent authorities in Northern Ireland

7.8 The following UK regulators for blood, organs, tissues and cells will continue to act on a UK-wide basis after the end of the Implementation Period:

- the Medicines and Healthcare products Regulatory Authority (MHRA) for blood and blood components;
- the Human Tissue Authority (HTA) for organs, tissues and cells (excluding reproductive cells); and
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells.

7.9 The Directives require an authority to be designated as the 'competent authority' and the UK regulators will continue to act as the competent authorities for NI. The Blood Safety and Quality Regulations 2005 and the Blood SI refer to the Secretary of State as the relevant authority but the Secretary of State's regulatory and competent authority functions will continue to be carried out in practice by the MHRA, an executive agency of the Department of Health and Social Care.

7.10 The 2020 SIs make amendments to allow the competent authorities to continue to meet the same EU obligations they do now. For example, the Blood SI retains the requirement to notify the EU Commission, in respect of NI, of an epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations. As another example, in relation to NI, the Tissues and Cells and HFE SIs retain the requirement to notify the competent authorities in the European Economic Area (EEA) States of information relating to serious adverse events and reactions so that appropriate action can be taken. The competent authorities in relation to tissues and cells will also remain under an obligation to deal with requests from EEA States to carry out inspections of third country premises from which tissues and cells have been imported into NI and then moved into the EEA.

Movement of goods in and out of NI - GB establishments

7.11 The commitment to unfettered access means there should be no additional checks or processes imposed by GB when NI goods are placed on the market in GB. Therefore, there will be no change to the requirements for GB establishments to receive blood, organs, tissues and cells from establishments in NI. Similarly, GB establishments will

not treat blood, organs, tissues and cells sent to NI as exports. This is achieved as follows:

- in the Blood SI, for the purpose of the import and export of blood or blood components by a blood establishment in GB, a third county is defined as a country other than the UK – this means that for GB blood establishments the movement of blood or blood components between NI and GB has the same requirements as other intra-UK distribution;
- in the Organs SI, for GB there are no additional requirements when organs move from one part of the UK to another; and
- in the Tissues and Cells and HFE SIs, for the purpose of import and export of tissues and cells by GB establishments, a third country is defined as any country other than the UK – this means that for GB establishments the movement of tissues and cells between NI and GB has the same requirements as other intra-UK distribution.

Movement of goods in and out of NI - NI establishments

7.12 NI establishments will continue to send blood, organs, tissues and cells to GB as they do now. NI establishments will not treat movements to GB establishments any differently to movements within NI.

7.13 NI establishments will be able to continue receiving blood, organs, tissues and cells from GB establishments. However, NI establishments will now consider GB the same as a non-EU Member State for this purpose. NI establishments will be required to extend the existing non-EU import provisions to blood, organs, tissues and cells received from GB:

- for blood, blood establishments in NI must update their Blood Establishment Authorisation to include import, and ensure that the blood or blood components from GB have been prepared in accordance with equivalent standards;
- for organs, organs moving from GB to NI must be traceable from donor to recipient and meet equivalent safety and quality standards; and
- for tissues and cells, tissue establishments in NI must ensure they hold an import licence and import agreements to receive tissues and cells from GB.

Traceability

7.14 The current legislation, in relation to tissues and cells (including reproductive cells), requires tissue establishments to use the Single European Code to facilitate the traceability of tissues and cells within the EU.

7.15 From 1 January 2021, GB will be considered a third country under the Directives and will no longer be required to apply the Single European Code, instead using alternative existing traceability systems. However, the Tissues and Cells and HFE SIs retain this provision for NI, and NI establishments will be required to continue applying the Single European Code to tissues and cells.

7.16 The Blood and Organs SIs do not include such coding systems.

Transferred Commission tertiary powers

7.17 The 2019 SIs introduced some limited regulation-making powers into UK law, for each of the UK nations. These powers are similar to the EU Commission powers and ensure safety regulations can be updated in the future. The 2020 SIs limit the regulation-making powers in the 2019 SIs to GB, as EUWA now contains regulation making powers (section 8C and paragraph 11M of Schedule 2), enabling the Secretary of State and the devolved administrations to make regulations to implement the Protocol including in response to future changes in EU law.

Six-month transition period for tissues and cells

7.18 The 2019 SIs amended the retained EU law (paragraph 6.2) to account for the fact that the UK will consider EU Member States as third countries. This means that from 1 January 2021 establishments will be required to extend third country import and export provisions to EU Member States.

7.19 For tissues and cells, the 2019 SIs provide for a six-month transition period from exit day to allow tissue establishments time to put the necessary arrangements in place for importing and exporting tissues and cells with the EU. The 2020 SIs amend the start of this transition period so that it begins after the Implementation Period.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 These instruments are being made using the powers in section 8 and 8C of EUWA in order to give effect to the Protocol in the Withdrawal Agreement for the safety and quality of blood, organs, tissues and cells.

8.2 The Tissues and Cells and HFE SI also rely on the consequential power in section 41(1) of the European Union (Withdrawal Agreement) Act 2020 to revoke a spent provision in the legislation concerning the application of the Single European Code, and to limit the regulation-making powers introduced by the 2019 SIs to GB.

8.3 In accordance with the requirements of EUWA, the Minister has made the relevant statements, detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 These instruments do not involve consolidation and there are no plans to consolidate the legislation at this time.

10. Consultation outcome

10.1 The amendments introduced by these instruments are technical in nature and their purpose is to give effect to the Protocol by restricting the changes made by the 2019 SIs to GB. The current law will remain in place for NI. Therefore, there was no public consultation. The changes in these instruments were discussed with the UK regulators, along with issues of operational implementation.

10.2 The proposed amendments have been discussed with the Scottish, Welsh and Northern Ireland devolved administrations and their views have been considered in the drafting of these instruments. The Blood, Organs and Tissues and Cells SIs are being made on a UK-wide basis with the agreement of the devolved administrations.

11. Guidance

11.1 Guidance for establishments will be provided by the UK regulators. The regulators will work with licensed/authorised establishments in NI to support them as needed to prepare for 1 January 2021.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies.

12.2 There is no significant impact on the public sector.

12.3 An Impact Assessment has not been prepared for these instruments because the direct cost impact has been assessed as lower than the £5m threshold in any one year and the policy is not considered novel or contentious.

12.4 In practice there will be no significant changes in how blood and transplant establishments operate. There will be some minor costs for tissue establishments and fertility clinics in NI to meet the new import provisions.

Blood

12.5 There is one blood establishment in NI. It will be able to continue receiving blood and blood components from GB establishments; however, NI establishments will treat GB as a non-EU Member State for this purpose. The provisions for importing blood or blood components from a non-EU Member State are set out in 7.13. The NI blood establishment already has the required import authorisations in place and GB blood establishments currently prepare blood and blood components to meet the EU and UK standards, so the NI blood establishment can continue to receive blood or blood components from GB.

12.6 There are 10 hospital blood banks in NI. They will not need to take any action as a result of the Blood SI.

12.7 It is estimated that there will be no cost to businesses or to the NHS as a result of the changes in the Blood SI, therefore no Impact Assessment is required.

Organs for transplant

12.8 NHS Blood and Transplant (NHSBT) will continue to be responsible for organ donation and retrieval in the UK. Between April 2019 and March 2020, 32 organs from deceased donors moved from GB to NI, and 126 organs moved from NI to GB (data provided by NHSBT).

12.9 Organs will be able to continue moving from GB to NI, however NI based establishments will now treat GB as a non-EU Member State for this purpose. The provisions for importing organs from a non-EU Member State are set out in 7.13. These are the same provisions that currently apply to organs moving within the UK so the changes made by the 2020 SI will make no difference to how NHSBT operates in practice.

12.10 It is estimated that there will be no cost to businesses or to the NHS as a result of the changes introduced by the Organs SI, therefore no Impact Assessment is required.

Tissues and cells and reproductive cells

12.11 There are two tissue establishments and four fertility clinics in NI. They will continue to be able to receive tissues and cells from GB, however they will now treat GB as a

non-EU Member State for this purpose. The provisions for importing tissues and cells from a non-EU Member State are set out in 7.13. The regulators for the sector are working with these NI establishments to ensure the necessary actions are taken for 1 January 2021.

12.12 There will be some minor costs for these NI establishments to meet the new provisions. It is estimated that one tissue establishment in NI will need to put additional licensing arrangements in place to receive tissues and cells from GB, and that it will need to put in place two import agreements with GB establishments. It is estimated that three fertility clinics in NI will need to put additional licensing arrangements in place to receive tissues and cells from GB at no cost, and that they will need to put in place 10-15 import agreements with GB establishments between them. This represents a small administrative one-off cost in the first year of the Tissues and Cells and HFE SIs coming into force.

12.13 Information on HTA licensing fees is available at https://www.hta.gov.uk/policies/licence-fees-and-payments-202021

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small business. These instruments relate to safety, quality and traceability standards for patients and no exceptions would be applied to small businesses.

14. Monitoring & review

14.1 These instruments give effect to the Protocol for the safety and quality of blood, organs, tissues and cells. NI must continue to meet the requirements of the Directives for as long as the Protocol is in force. Changes to these instruments may be needed if there are changes to the Directives. It is for the elected institutions in NI to decide what happens to the Protocol alignment provisions in a consent vote that can take place every four years, with the first vote taking place in 2024.

14.2 As these instruments are made under the EUWA, no review clause is required.

15. Contact

15.1 Samantha Wheelhouse, Senior Policy Advisor at the Department of Health and Social Care, telephone: 0113 254 5200 or email samantha.wheelhouse@dhsc.gov.uk, can be contacted with any queries regarding these instruments.

15.2 Marina Pappa, Deputy Director for Health Ethics, at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Edward Argar, Minister of State for Health, at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) to make a Negative SI.	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC.
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain what, if any, amendment, repeals or revocations are being made to the Equality Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.

Explanations	Sub-paragraph (6) of paragraph 28, Schedule 77	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs.	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence.	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by SI.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Sch 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under s.2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA 1972	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny	Paragraph 16, Schedule	Anybody making an SI	Statement setting out:

statement where amending regulations under s.2(2) ECA 1972	8	after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA 1972	a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. **Appropriateness statement**

1.1 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020; The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020; The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 and The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 do no more than is appropriate".

1.2 This is the case because they do no more than amend legislation on blood, organs, tissues and cells and reproductive cells to give effect to the Ireland/Northern Ireland Protocol in the Withdrawal Agreement. They restrict the provisions in the 2019 SIs to GB only so the current law will remain in place for NI. The SIs will retain a single set of UK rules, but within them there are a small number of provisions which are stated as applying to NI or GB only. Further details, including examples of the changes included in the instruments, are detailed in section 7 of the main body of this Explanatory Memorandum.

2. **Good reasons**

2.1 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in these instruments, and I have concluded they are a reasonable course of action"

2.2 The Protocol sets out the EU law that will continue to apply to and in the UK in respect of NI, which includes the Blood, Tissues and Cells, and Organs Directives (including the Commission implementing directives). NI must continue to meet the requirements of the Directives for as long as the Protocol is in force. The instruments make the changes needed to allow NI to meet these requirements. Further details, including examples of the amendments made and reasons for making them, are set out in section 7 of the main body of this Explanatory Memorandum.

3. **Equalities**

3.1 The Minister of State for Health, Edward Argar, has made the following statement:

"The draft instruments do not amend, repeal or revoke a provision or provisions in the Equality Act 2006, or the Equality Act 2010 or subordinate legislation made under those Acts."

3.2 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instruments, I, Edward Argar, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.3 These instruments will have no impact on equalities.

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this Explanatory Memorandum.