EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

AND

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instruments

2.1 The three Statutory Instruments (SIs) on the safety of organs, tissues and cells, and reproductive cells (gametes and embryos) for treating patients are 'no deal' SIs. They have been developed as part of contingency planning and will be needed in the event that the United Kingdom (UK) leaves the European Union (EU) in March 2019 with no agreement in place; i.e. a 'no deal' scenario.

2.2 Withdrawal from the EU without a deal would mean that the law in this area will no longer work as it is intended to. This is because it contains a number of references that will no longer be appropriate, such as references to obligations that the UK is required to comply with as an EU Member State. Additionally, as the UK and EU Member States will consider each other to be third countries, amendments have been made to reflect this.

2.3 The SIs are being made under powers in the European Union (Withdrawal) Act 2018 (referred to here as the EU (Withdrawal) Act). There are three separate SIs:

- the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Tissues and Cells SI';
- Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'HFE SI'; and
- the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Organs SI'.

2.4 The SIs are being made on a UK-wide basis. The Tissues and Cells and Organs SIs are being made with the agreement of each of the Devolved Administrations (DAs) and the HFE SI is reserved to Westminster.

2.5 The SIs have been drafted separately as each amends different underlying legislation. The purpose of the SIs is to ensure that, in the unlikely scenario that the UK leaves the EU with no deal, the law in this area will still function properly and the UK regulatory framework for the safety and quality of organs and tissues and cells (including reproductive cells) is maintained.

2.6 It is proposed that these SIs should be grouped and debated together.

Explanations

What did any relevant EU law do before exit day?

2.7 Donated human organs, tissues and cells are used in potentially life-saving or life changing treatments for patients. The UK regulatory frameworks set high standards of patient safety.

2.8 UK law in this area transposes the EU Tissue and Cells Directives1 for tissues and cells (including reproductive cells) and the EU Organ Donation Directives2 for organs.

2.9 These directives are collectively referred to in this memorandum as 'the Directives'.

2.10 The Directives introduced a range of quality and safety standards, aiming to safeguard patient safety. These include the following: -

- The procurement, testing, processing, and storage of tissues and cells (including reproductive cells);
- Organ and donor characterisation, which means information, including tissue typing tests, which must be collected so an organ can be matched with a suitable recipient;
- Traceability requirements in respect of organs for transplantation, tissues such as corneas or bone, stem cells and sperm, eggs and embryos (reproductive cells) for assisted reproduction; and
- Notification requirements in the event of serious adverse events or reactions which may impact the quality and safety of organs, tissue and cells (including reproductive cells).

Why is it being changed?

2.11 The amendments in these instruments are to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function as intended after exit day. The UK and the EU will consider each other to be third countries if there is no deal on exit and the SIs redefine the term 'third country' to include EU countries and Gibraltar. As a result, licensed establishments will need

[1] The requirements in the EU Tissue and Cells Directives have been implemented in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Fertilisation and Embryology Act 1990. The EU Tissue and Cells Directives are Directive 2004/23/EC and the Implementing Directives 2006/17/EC, 2006/86/EC, 2012/39/EU, (EU) 2015/565, (EU) 2015/566.

[2] The requirements in the EU Organ Donation Directives have been implemented in the Quality and Safety of Organs Intended for Transplantation Regulations 2012. The EU Organ Donation Directives are Directive 2010/53/EU and the Implementing Directive 2012/25/EU.

to make administrative changes to continue to import organs, tissues and cells from EU countries and Gibraltar.

2.12 The legislation being amended also contains a number of references that will no longer be appropriate once the UK withdraws from the EU, such as references to obligations which the UK must comply with as an EU Member State, and some references to the EU, the European Economic Area (EEA), the European Commission (the Commission) and EU law.

2.13 The Commission also has a number of powers under the Directives, to update technical requirements in line with scientific developments or if there is a health threat from a new disease. The Commission will no longer exercise these powers on the UK's behalf so the regulation making powers are being conferred on the Secretary of State (and where within devolved competence, the DAs) so the quality and safety standards can be updated following EU exit if they need to be.

What will it now do?

2.14 The amendments made by these instruments will ensure that the UK maintains the current quality and safety standards for organs, tissues and cells (including reproductive cells) after exit. Some organs, tissues and cells move between the UK and EU countries but numbers are relatively small, the amendments will allow this to continue after exit with minimal additional administration.

2.15 The detailed breakdown of the various types of changes which these instruments will bring about is included in section 7. They will make the following changes:

- Amend or omit references to EU/EEA/Member State.
- Revoke obligations on UK organisations and reciprocal arrangements between UK and EU organisations (referred to as competent authorities in the Directives) that will no longer be relevant to the UK.
- Confer relevant Commission powers to make regulations under the Tissue and Cells Directives and the Organ Donation Directives to the Secretary of State and, in relation to the Organs and Tissues and Cells SIs, the Devolved Administrations (all of which are detailed in paragraph 7.23).
- Set out updated requirements for licensing and written agreements to import tissues and cells from EEA states and Gibraltar to align these with existing requirements for countries outside the EEA and Gibraltar.
- In relation to the HFE and Tissues and Cells SIs, make transitional provisions so that imports of tissue and cells (including reproductive cells) from EEA states and Gibraltar may continue for a six-month period after exit day whilst licences and written agreements are put in place.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The HFE SI contains, at regulation 2(14), a new regulation making power for the Secretary of State to make regulations in relation to standards of quality and safety for reproductive cells. This power may be used to make amendments to the Human Fertilisation and Embryology Act 1990 within the scope of the regulation making power in the new section 42A of the Human Fertilisation and Embryology Act 1990, as inserted by regulation 2(14) of the HFE SI. The current standards of quality and

safety are set out in the Human Fertilisation and Embryology Act 1990. The new regulation making power may be used to amend this Act to ensure that the current standards of quality and safety can be amended. The power is affirmative and any Regulations proposing changes to existing provisions would be affirmative and subject to consultation.

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 (sperm, egg and embryos) is reserved to Westminster (i.e. legislation is dealt with by the Westminster Parliament). Competence in respect of all other human tissues and cells 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 Regulations is set out in Section 3.2.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding Human Rights:

"In my view the provisions of The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The amendments in these instruments are needed to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function after exit if the UK leaves the EU without a deal in place.

6.2 The relevant UK legislation is:

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

This legislation was made under powers conferred by section 2(2) of the European Communities Act 1972 in order to implement the Tissue and Cells Directives and the Organ Donation Directives (see paragraph 2.2 above for a full description of relevant EU law).

6.3 Section 2 of the EU (Withdrawal) Act 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 will be preserved and is being amended pursuant to the power in Section 8 of the EU (Withdrawal) Act in order to function effectively after exit.

7. Policy background

7.1 An organ transplant can be life saving or life transforming and is often the only treatment option available for the patient concerned. Human tissues and cells are used in what can be life changing therapies, such as:

- stem cells used to treat blood cancers
- corneas to restore sight
- heart valves to treat heart conditions
- skin grafts to treat burns
- eggs and sperm to treat infertility

7.2 Other forms of tissue are much more generic in use, for example bone products used in operations and by dentists for fillings.

7.3 EU law sets the policy and legal framework in relation to the donation, retrieval, processing, storage, transport, import and export of organs, tissues and cells used for transplantation, as set out in paragraph 2.2.

7.4 These instruments are intended to ensure that UK law for the safety of organs, tissues and cells continues to apply effectively in the event of no deal. UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics that undertake licensable activities working in this area are regulated by:

- the Human Tissue Authority (HTA) for organs, tissues and cells other than reproductive tissues and cells; and
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells.

7.5 The HTA licenses UK establishments for activities such as procurement, testing, processing, storage, distribution, import and export of organs, tissues and cells. The HFEA licenses these activities for reproductive cells. Currently, any establishment that carries out imports or exports from / to third countries must have an import and / or export licence. The existing regulations make it a requirement that UK establishments that import tissues and cells from countries which are not EEA states or Gibraltar (third countries) must also have a written agreement with the third country supplier. The regulations set out the minimum requirements for these agreements.

7.6 UK licensed establishments will continue to work to the same safety standards in place before exit and the changes contained within the instruments are designed to make the necessary changes to reflect the status of the UK outside the EU.

7.7 At present some organs, tissues and cells move between the UK and EU countries, but also between the UK and non-EU countries (third countries). A small number of organs are shared with EU and non-EU countries, with less than 30 organs on average being imported or exported each year. Tissues and cells are imported from and exported to EEA/EU countries less often than they are imported and exported from and to countries outside the EEA/EU. There are around 5,000 imports of tissues and

cells from the EU in a typical year. This includes around 600 imports of stem cells and 3,000 imports of bone products. The UK imports donated sperm, primarily from commercial sperm banks in the USA and Denmark.

What is being done and why?

7.8 As set out in Section 6, these instruments are being made so that the law in this area will continue to work as it is intended to after the UK leaves the EU.

Examples of the deficiencies addressed by these amendments are listed below.

EU obligations that will no longer be relevant or appropriate

7.9 In some cases, EU obligations are removed that will no longer be relevant or appropriate. For example, there are currently requirements on the HTA and the HFEA to report to the Commission and/or competent authorities of other Member States certain information submitted to them regarding serious adverse events and reactions that affect organs, tissues and cells used by UK establishments. The Tissues and Cells SI and the HFE SI remove this obligation as it is no longer appropriate.

7.10 Similarly, there is a requirement for the HTA to participate in a network of competent authorities established by the Commission and to co-ordinate UK input into the activities of that network. The Organs SI removes this requirement as it is no longer appropriate.

7.11 There is also an obligation under the EU Tissue and Cells Directives for EEA Member States to inspect third country premises at the request of another EEA Member State. As the UK will no longer be an EEA Member State after exit, there will no longer be an obligation on the HTA and the HFEA to inspect UK establishments on behalf of EEA Member States. These instruments therefore remove this obligation.

7.12 The current legislation, in relation to tissues and cells (including reproductive cells) requires tissue establishments to use the Single European Code (SEC) and the EU Coding Platform to facilitate the traceability of tissues and cells used to treat patients across the EU. The EU Coding Platform provides a list of all licensed establishments across the EU, the activities they are licensed for and the tissue and cells types they have been authorised by the competent authorities to work with. Competent authorities must ensure that entries for the establishments that they license are accurate and access to the platform is restricted to EEA countries. After exit day, the UK will be considered a third country under the Directives and UK tissue establishments will not use the SEC. The UK will not use the platform and there will be no need for the details for UK establishments to be added to the platform.

7.13 The obligation to use the SEC and associated obligations such as for the HTA and HFEA to update the details of UK licensed establishments on the platform has therefore been omitted in the Tissues and Cells SI and the HFE SI. UK licensed establishments were already using systems to ensure traceability from donor to recipient of tissues and cells before the introduction of the SEC, and in most cases the SEC was added to these existing systems. After exit, the UK licensed establishments will be able to use the traceability systems that were in place before the introduction of the SEC.

EU references which are redundant or inappropriate

7.14 There are a number of amendments being made by these instruments to take account of EU references which will be redundant or inaccurate. For example, the current law includes references to 'other Member States'. These references have been amended as they will not function correctly when the UK is no longer an EU Member State. Amendments have also been made to references to 'competent authority', to reflect that the Directives will not form part of domestic law after exit.

Exchange of organs, tissues and cells with EU countries as third countries

7.15 The Tissue and Cells Directives and the Organ Donation Directives allow for organ, tissue and cells exchange between EEA/EU Member States and third countries. In a no deal scenario, the UK and EEA/EU Member States will consider each other to be third countries and UK law has to be amended to reflect this change. In this case, a UK establishment would need an import / export licence to import / export tissues and cells from EEA countries.

Import from EEA/EU countries

7.16 UK establishments will be able to continue to import organs, tissues and cells from establishments in EEA/EU states. As noted above, EEA/EU states will be considered as third countries by the UK and the UK will therefore extend the existing third country provisions to EU countries. For example, regulation 3 in the Tissues and Cells SI removes specific provision in relation to imports from the EEA and Gibraltar. This has been omitted as post exit the same requirements for imports will apply to all third countries.

7.17 Regulation 4 of the Tissues and Cells and the HFE SIs sets out that UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states. This is to allow UK licensed establishments that import tissues and cells from EEA states to put in place new agreements or amend existing ones, to comply with the requirements in the legislation. This will also allow establishments sufficient time to apply for or amend existing import licences or authorisations.

7.18 The arrangements for accepting organs from third countries are less extensive for organs. NHS Blood and Transplant (NHSBT), the organisation responsible for organ donation and transplantation in the UK, and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI. There is therefore no need for a transitional period and NHSBT will be able to accept organs from EU countries from exit day provided that such organs can be traced from donor to recipient and meet quality and safety standards equivalent that required in UK law.

7.19 Information on export to EU countries is available in the technical notice published in August 2018: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal

References to EU Directives in UK law

7.20 UK law[3] implements EU Directives in part by cross-referring to the Directives. After exit, some of these references will be retained in UK law. These instruments amend UK law to clarify that where there is a reference to a requirement of a directive in UK law, the requirement will still apply after exit in the same way it did prior to exit.

7.21 To ensure that such references function correctly after exit, it is necessary to modify how some of the articles and annexes in the Directives are to be read. For example, where a reference is made to "the competent authority or authorities" this will be read as a reference to the HFEA or HTA. In addition, where specific provisions have been implemented in UK law, instead of referring to the relevant articles in the Directives, amendments have been made to refer to the specific requirements in the relevant UK law.

Transfer of Commission Powers

7.22 Prior to exit day, any amendments to legislation in the field of organs, tissues and cells (including reproductive cells), have been made under section 2(2) of the European Communities Act 1972. After exit, the European Communities Act 1972 will be repealed. Similarly, the European Commission will no longer have any functions in respect of the UK.

7.23 As noted in paragraph 2.2, there are a range of powers currently held by the European Commission under the Tissue and Cells Directives and the Organ Donation Directives. These instruments insert into UK law[4] similar powers for the Secretary of State and where the matters fall within devolved competence, the DAs, to update legislation on organs, tissues and cells in response to, for example, emerging threats, changing safety and quality standards, and technological advances.

7.24 These updating powers are likely to have minimal impact on industry. Their purpose is to make sure that the UK is still able to make changes after we leave the EU, where needed.

Powers in the HFE SI and the Tissues and Cells SI

7.25 The Commission currently holds powers in Articles 8, 9, 11 and 28 of Directive 2004/23/EC to update technical requirements relating to tissues and cells (including reproductive cells), to prescribe traceability requirements and notification requirements in relation to serious adverse events and serious adverse reactions and to verify equivalent standards of safety and quality where tissues and cells (including reproductive cells) are imported from third countries.

7.26 In relation to tissues and cells (excluding reproductive cells) these powers are being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

[3] The Human Fertilisation and Embryology Act 1990 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007

[4] The Human Fertilisation and Embryology Act 1990, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Quality and Safety of Organs Intended for Transplantation Regulations 2012

7.27 Policy on reproductive cells is reserved to Westminster and so these powers are only being conferred on the Secretary of State.

7.28 The powers which will be conferred are contained in the new section 42A of the Human Fertilisation and Embryology Act 1990 (power to make regulations in relation to standards of quality and safety) and the new regulation 34ZA (power to make regulations in relation to standards of quality and safety) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

7.29 These provisions contain powers akin to the current Commission powers contained in Directive 2004/23/EC. Details of the powers being conferred and examples as to how these powers could be used are as follows: -

- The power to prescribe requirements to ensure traceability of tissues and cells (including reproductive cells).

  This power could be used to introduce a UK national coding system for tissues and cells in the future, although there are no current plans to introduce such a system. The power could be used to make the use of the coding system a statutory obligation for tissue establishments and place duties on the two authorities in relation to the management of the coding system, and provide elements of it such as the product code, similar to the role the EU plays in the management of the Single European Code.

- The power to make provision in relation to the notification of serious adverse events and serious adverse reactions.

  This power could be used to specify that certain information that relates to a serious adverse incident is provided by tissue establishments or that information related to an incident is provided to another authority. For example, the HTA or HFEA may need to know if certain reagents were used in the preparation of tissue to which a patient suffered a severe adverse reaction, for the Medicines and Healthcare products Regulatory Agency (MHRA) to consider if the chemical should be prohibited from use with human material.

- The power to make provision specifying to requirements to be met for verifying equivalent standards of safety and quality in relation to imports of tissues and cells (including reproductive cells).

  This power could be used in the event of an outbreak of a serious infectious disease or a new infection that could be transmitted, through tissue transplantation, to the recipient, or adversely affect the development of a child conceived using gametes from an infected person. In such cases, the Secretary of State may wish to specify in regulations that tests specified by the UK Advisory Committee of the Safety of Blood, Tissues and Organs had been conducted by the third country exporting establishment and the tissues sent to the UK are certified as infection free.

- The power to prescribe technical requirements relating to tissue establishments.

  This power would be used to update the requirements related to the quality and safety of tissues and cells, in response to technical advances or the development of new therapies. For example, the power could be used to update the requirements that need to be met to demonstrate that a new

technique used to process tissues or cells is safe and does not adversely affect the quality of the tissues or cells.

Powers in the Organs SI

7.30 The Commission currently holds a power in Article 24 of Directive 2010/53/EU to adopt delegated acts in order to supplement or amend the Annex to Directive 2010/53/EU (the Annex). The Annex contains the information requirements for organ and donor characterisation. As the European Commission will no longer have any functions in respect of the UK, in the event of a serious adverse event which presents a serious risk to human health, any delegated acts made by the Commission will not apply to the UK.

7.31 A similar power is therefore being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

7.32 As noted above, this power would be used to update organ and donor characterisation requirements to mitigate risk to human health, usually in response to an emerging disease outbreak. In such cases, the Secretary of State may wish to add additional requirements to characterise donors, such as additional tests.

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

8.1 These instruments are being made using the power in section 8 of the EU (Withdrawal) Act in order to enable retained EU law to operate effectively following withdrawal of the United Kingdom from the European Union.

8.2 The Organs SI is also made under section 23(1) of the EU (Withdrawal) Act in order to make a consequential amendment to regulation 24 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012. This requires the Secretary of State to have regard to how the Organ Donation Directives have been implemented in EU member states when reviewing the regulations. This provision has no effect post exit in light of paragraph 9 of Schedule 8 of the EU (Withdrawal) Act.

8.3 As set out in paragraph 7.17, UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EU countries. This provision has been made under schedule 7, paragraph 21(b) of the EU (Withdrawal) Act.

8.4 In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 These Statutory Instruments do not involve consolidation and there are no plans to consolidate the Human Fertilisation and Embryology Act 1990 or the Human Tissue Act 2004 at this time.

10. Consultation outcome

10.1 The amendments introduced by these SIs are technical in nature and their purpose is to maintain the current UK regulatory framework for the safety and quality of organs and tissues and cells. There was therefore no public consultation. The changes in the SIs were discussed with the UK regulators, the HTA and HFEA, along with issues of operational implementation.

10.2 The proposed amendments have been discussed with the Scottish, Welsh and Northern Irish devolved administrations and their views have been taken into account in the drafting of these instruments. The 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 tissue establishments will be provided by the two UK competent authorities. For reproductive cells, guidance will be published by the HFEA. In respect of organs and all other human tissues and cells, guidance will be published by the HTA.

11.2 A technical notice was published in August 2018, setting out the actions organisations, businesses and members of the public should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive cells, in the unlikely event that the UK leaves the EU in March 2019 with no agreement in place: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal . The Department of Health and Social Care, in collaboration with the regulators, will provide further information for establishments. As advised in the technical notice, establishments are encouraged to contact the regulators if they have any questions.

11.3 NHSBT and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI.

11.4 UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states.

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 The instruments are intended to maintain the current regulatory framework so UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics will continue to work to the same standards that they did prior to exit. Some organs, tissues and cells move between the UK and EU countries. Numbers are relatively small and the amendments allow this to continue after exit.

12.5 The impact of these instruments on businesses will be low. The only key impacts are in relation to agreements that licensed establishments will need to put in place to be able to import tissues and cells from EU countries. Establishments that already hold

an import licence to import tissues and cells from third countries will be able to use their existing written agreements with third country organisations as a template. There is no impact for organ transplant centres.

12.6 For non-reproductive cells, it is estimated that 12 will need to put new agreements in place, mostly privately operated small businesses. And that each one will need between 1 and 5 new agreements. For reproductive cells, it is estimated that some establishments will need to put a number of agreements in place, with 60-120 new agreements potentially needed in total.

12.7 The cost of the required agreements is subject to the terms of individual agreements entered into by each establishment. Based on an earlier impact assessment (available at http://www.legislation.gov.uk/uksi/2018/335/impacts), it has been estimated that most if not all of the establishments will already have agreements and the costs will therefore be small.

12.8 Written agreements between establishments are renewed on a frequent basis, usually every year to every 5 years. Some of these costs would therefore be likely to be incurred regardless of the changes introduced by these SIs.

12.9 UK establishments that already hold import / export licences do not need to apply for a new one to import from / export to the EEA. It is estimated that none of the existing establishments will need to apply for an import or export licence.

12.10 A new establishment set up in the future would need to apply for a licence. Information on HTA licensing fees is available at https://www.hta.gov.uk/guidance-professionals/hta-fees and on HFEA licensing fees at https://portal.hfea.gov.uk/knowledge-base/other-guidance/fees/ .

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. The SIs relate to quality, safety and traceability standards for patients and no exceptions would be applied to small businesses.

14. Monitoring & review

14.1 The SIs are intended to ensure that appropriate arrangements are in place for organs, tissues and cells to continue to be exchanged with EU countries and that quality and safety standards are maintained post exit. The effectiveness of the SIs in doing so will be regularly evaluated as part of a programme of accountability meetings between the Department of Health and Social Care and the HFEA and HTA.

14.2 As these instruments are made under the EU (Withdrawal) Act, no review clause is required.

15. Contact

15.1 Emma Wilbraham: (020) 7972 3013 or email: emma.wilbraham@dhsc.gov.uk can answer any queries regarding The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019.

Kim Hayes: (020) 7210 6339 or email: kim.hayes@dhsc.gov.uk can answer any queries regarding the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019.

15.2 Jeremy Mean at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Jackie Doyle-Price 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 Equalities 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
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 Statutory Instrument.	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 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	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, 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	Statement setting out: 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 Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 do no more than is appropriate".

1.2 This is the case because they do no more than amend legislation on organs, tissues and cells to correct deficiencies arising from the withdrawal of the United Kingdom from the European Union or to correct legislation on organs, tissues and cells where it would otherwise fail to operate effectively after the UK leaves the EU. This includes removing redundant provisions, amending references to obligations or reciprocal agreements that will no longer exist, and transferring appropriate Commission functions to the Secretary of State and the DAs (where within devolved competence). Further details, including examples of all 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 Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP 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 Following exit day, without amendments to the relevant legislation, policy on organs, tissues and cells would cease to function effectively. These instruments seek to remove or amend provisions in UK legislation and EU legislation saved by the EU (Withdrawal) Act 2018, in order to ensure that policy on organs, tissues and cells will continue to function at the same level as prior to exit. The instruments make a number of technical amendments, and provide the Secretary of State and DAs (where within devolved competence) with powers previously held by the EU Commission which will allow the Secretary of State and DAs to update legislation on organs, tissues and cells in in response to emerging threats, changing safety and quality standards, and technological advances. 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 Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP 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 Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Jackie Doyle-Price 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 This instrument will have no impact on equalities.

4. Explanations

4.1 The explanations statement has been made in paragraph 2.2 of the main body of this explanatory memorandum.