EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) REGULATIONS 2018

2018 No. [XXXX]

AND

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) REGULATIONS 2018

2018 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instruments

2.1 These Regulations transpose (i.e. incorporate into UK law) two European Union (EU) Commission Directives relating to human tissue and cells intended for use in a patient's treatment (e.g. stem cells, bone, corneas, gametes and embryos) into UK legislation:

- "the coding Directive" (2015/565[1]) creates a standard "Single European Code" that provides basic information so that the material can be traced from the person who donated it to the patient who receives it;
- "the import Directive" (2015/566[2]) introduces measures to ensure that tissue and cells imported from countries outside the EU or EEA meet the quality and safety standards that exist within the EU.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 These Instruments apply to the United Kingdom. Directives 2015/565 and 2015/566 also apply to Gibraltar and the Government of Gibraltar has confirmed that it has transposed the Directives.

3.3 The United Kingdom Government has an obligation to ensure that the Directives are transposed into legislation applicable in all parts of the UK. Legislative competence for the donation, processing and use in treatment of human reproductive cells (sperm,

[1] Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.

[2] Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

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 is devolved.

4. Legislative Context

4.1 In July 2007, the UK transposed three EU Directives: 2004/23/EC[3] (referred to here as the Mother Directive) plus two Commission Directives 2006/17/EC[4] and 2006/86/EC[5]. The Directives set quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human application as part of medical treatment. These Directives were transposed into UK law by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, which amended the Human Fertilisation and Embryology Act 1990, and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (referred to here as the 2007 Regulations).

4.2 The coding Directive (2015/565) amends Directive 2006/86/EC, to establish the format of the Single European Code that must be applied to all tissues and cells unless a specified exemption applies. The import Directive (2015/566) supplements provisions in the Mother Directive, setting out procedures that must be followed to ensure that tissues and cells imported into EU/EEA member states meet the quality and safety standards required of tissues and cells procured within the EU/EEA countries. The import Directive also sets requirements for national competent authorities with regard to the authorisation of importing establishments together with provisions for confirming the operational standards of third country suppliers. The coding and import Directives were adopted on 8 April 2015.

4.3 For reproductive cells, the coding and import Directives are transposed by The Human Fertilisation and Embryology (Amendment) Regulations 2018, which amend the Human Fertilisation and Embryology Act 1990. For all other human tissues and cells, with the exception of organs and blood that are subject to their own legislative frameworks, the coding and import Directives are transposed by The Human Tissue (Quality and Safety for Human Application (Amendment) Regulations 2018 (referred to here as the Human Tissue Regulations), which amend the 2007 Regulations.

Approach to transposition

4.4 A minimal approach to transposition has been taken. The Regulations apply all of the exemptions provided for in the Directives and a transposition note is attached at Annex A.

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[3] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[4] Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

[5] Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

5. Extent and Territorial Application

5.1 The territorial application of these Regulations is set out in Section 3 under "Other matters of interest to the House of Commons".

6. European Convention on Human Rights

6.1 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) Regulations 2018 and The Human Fertilisation and Embryology (Amendment) Regulations 2018 are compatible with the Convention rights.

7. Policy background

What is being done and why

7.1 The Mother Directive sets quality and safety standards for the procurement, handling and processing of human tissue and cells intended for use in the treatment of others. The aim is to ensure the same high standards for patients, wherever they are treated within the EU/EEA.

7.2 The Mother Directive included provision to make four Commission Directives to set out the detail of the procedures needed to meet the prescribed standards. The coding and import Directives are the final two Commission Directives specified by the Mother Directive. Being able to trace tissue and cells from the original donor to final use in a patient's treatment and back again is important for identification purposes and, if a patient suffers a serious adverse reaction, donors and other recipients can be traced quickly to minimise the risk of further harm. It is important for patient safety that tissue and cells imported from countries outside the EU or EEA meet the same quality and safety standards as within the EU.

7.3 Although the UK has not experienced any major incidents involving problems with identification or traceability in the past, tissue and cells now regularly move between licensed establishments and across international borders, making the need for an internationally recognisable identification code more important in order to mitigate future patient safety risks.

The UK already has legislation in place that achieves the aims of the coding and import Directives but needs to amend the existing legislation to fully transpose the provisions in the coding and import Directives and hence be consistent with the rest of the EU/EEA. The existing legislation has been amended as follows:

2015/565 – Coding Directive

- The addition of new definitions, for example "Single European Code" and "EU tissue establishment code".
- That the Single European Code, in the format specified, is applied in an eye readable form (as opposed to e.g. a barcode) to all tissues and cells intended for human application, unless one of the following exemptions apply:
    - the tissue is intended for immediate transplant or has been imported for emergency treatment,
    - the tissue is procured, processed and used for treatment within the same tissue establishment

- the tissue was already in storage on 29 October 2016 and is distributed within 5 years of that date,
- sperm used in a wife/partner's treatment (described as "Partner Donation").

- That tissue establishments retain data relating to the Single European Code for 30 years.
- Requirements for the UK competent authorities, the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA), to ensure that the code is correctly applied by tissue establishments and notify the European Commission of updates to the relevant databases: the EU Tissues and Cells Establishment Compendium and the EU Tissues and Cells Product Compendium.

2015/566 – Import Directive

- The addition of new definitions for example "Emergency" and "One-off imports".
- Tissue establishments wishing to import tissues or cells from suppliers outside the EU/EEA must:
  - first seek authorisation to do so from the HFEA or HTA, providing supporting evidence as specified in the Directive and confirming that the third country supplier operates to equivalent standards. There are some exemptions from the requirements for one-off imports.
  - notify the HFEA or HTA of any change of circumstance relating to a third country supplier (including any serious adverse event and reaction).
  - provide the HFEA or HTA with a copy of the written agreement with the third country supplier; this must document the quality and safety requirements to be met, including, as a minimum, the information listed in the Directive and the right of the UK competent authority to inspect the activities, including premises, of the third country supplier.
  - keep a record of all imports, including the type of tissues or cells imported, their origin and intended use, including for one-off imports.

7.4 The transposition tables for both Directives in Annex A set out how each Article will be transposed by both Regulations.

Consolidation

7.5 There are no plans, at this time, to consolidate the Human Fertilisation and Embryology Act 1990 or the Human Tissue Act 2004.

Further background

7.6 The coding and import Directives set a transposition date of 29 April 2017. However, the transposing Regulations have proved complex to draft, particularly in respect of non-reproductive tissue, in order to appropriately amend existing legislation to fully implement the provisions of the Directives. The drafting has required considerable input from the HFEA, HTA and stakeholders. Work on transposition had to be paused on a number of occasions, for example when the most recent General Election was called. The European Commission has been kept informed of the progress on

transposition and the reasons for the delays. The Regulations will come into force on 1 April 2018.

7.7 The Human Tissue Regulations include a transitional provision for any licence for third country imports in force immediately before 1 April 2018. If the HTA is satisfied that the tissue establishment has provided sufficient information and documentation to meet the requirements of the import Directive, then the licence will be treated as authorising import under the new Regulations from 1 April 2018. It is not practicable to apply the provisions of the import Directive to imports from 29 April 2017 (when the requirements in the Directives should have been transposed) given that the new rules require written agreements with third country suppliers which contain certain terms. It is proportionate to apply the new requirements from 1 April 2018 particularly given that the current licensing requirements for imports are sufficiently stringent to provide assurance of the quality and safety of material imported.

7.8 On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. The government respected the result and triggered Article 50 of the Treaty on European Union on 29th March 2017 to begin the process of exit. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation.

8. Consultation outcome

8.1 A range of consultation activities have taken place to assess the impact of the Directives and the transposing regulations on UK tissue establishments:

- The Department of Health set up a stakeholder advisory group which included representatives of professional bodies, tissue banks and service providers, to give guidance on transposition and the potential impact on tissue establishments.
- The HFEA and HTA also consulted their licensed establishments: HFEA has a standing licensed establishments advisory committee while the HTA held a workshop for its licensed establishments to assess the likely impact of the Instruments on their activities.

8.2 There was a public consultation exercise, which ran from 10 March to 7 April 2017. The consultation document was circulated to stakeholders, including all establishments licensed by the HFEA and HTA. The questions in the consultation document focused on the practicalities of implementing the Directives, e.g. whether new IT systems would be required for coding and what the potential costs of compliance would be. 15 responses were received, largely from the non-reproductive cell sector. The responses made some useful suggestions in relation to a number of operational issues, including the practical implementation of exemptions and provided useful additional information for the assessment of the impact of implementation of the requirements of the Directives. The operational information will help the competent authorities to provide guidance to stakeholders to provide further clarity on the requirements set out in the regulations. The Government response to the consultation is published at https://www.gov.uk/government/consultations/coding-and-import-regulations-for-human-tissues-and-cells

9. Guidance

9.1 Guidance for tissue establishments will be provided by the two UK competent authorities. For reproductive cells, guidance will be included in the Code of Practice published by the HFEA. In respect of all other human tissues and cells, guidance will be published by the HTA.

10. Impact

10.1 The Regulations apply equally to the public and private sectors. The main costs identified would be associated with the implementation of new labelling and IT systems, updating of standard operational procedures and other governance documents and training of staff on the new procedures. For some establishments, however, the cost will be negligible as they will introduce minor changes to existing systems and any training needs will be incorporated to routine training programmes. Following consultation, the impact assessments were updated to reflect more accurately the costs associated with the implementation of the new requirements and are submitted with this memorandum.

10.2 The equality impact assessment concluded that the Regulations would not lead to any unlawful discrimination, harassment or victimisation of any particular group.

11. Regulating small business

11.1 The Instruments apply to activities that are undertaken by small businesses. The Regulations relate to quality, safety and traceability standards for patients and no exceptions would be applied to small businesses. The competent authorities have discussed detailed operational aspects with the full range of tissue establishments, including small businesses, to make sure the accompanying guidance fully reflects the way their business operates.

12. Monitoring and review

12.1 The Regulations are intended to ensure that tissue can be traced from donor to patient and back again and that imported tissues meet the quality and safety standards required by the Mother Directive. The effectiveness of the Regulations in doing so will be regularly evaluated as part of a programme of accountability meetings between the Department of Health and the HFEA and HTA.

13. Contact

13.1 Emma Wilbraham: (020) 7972 3013 or email: emma.wilbraham@dh.gsi.gov.uk can answer any queries regarding The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018

Kim Hayes: (020) 7210 6339 or email: kim.hayes@dh.gsi.gov.uk can answer any queries regarding the Human Fertilisation and Embryology (Amendment) Regulations 2018