EXPLANATORY MEMORANDUM TO THE

THE HUMAN FERTILISATION AND EMBRYOLOGY (QUALITY AND SAFETY) REGULATIONS 2014

2014 No. 2884

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) REGULATIONS 2014

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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 two sets of Regulations transpose Commission Directive 2012/39/EU. This Directive (Amending Directive) amends Commission Directive 2006/17/EC as regards certain technical requirements for the testing of human reproductive and other tissue and cells

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 There are four Directives that set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells:

a) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 sets the overarching standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ("the first Directive")

b) Commission Directive 2006/17/EC, implementing Directive 2004/23/EC of the European Parliament and of the Council of 8 February 2006, provides certain technical requirements for the donation, procurement and testing of human tissues and cells ("the second Directive"),

c) Commission Directive 2006/86/EC, implementing Directive 2004/23/EC of the European Parliament and of the Council of 24 October 2006, as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, and storage and distribution of human tissues and cells ("the third Directive").

d) Commission Directive 2012/39/EU of 26 November 2012, amends Annexes 11 and 111 of Directive 2006/17/EC by providing certain technical requirements for the testing of human tissue and cells (the 'Amending Directive')

4.2 The first, second and third Directives were transposed by amendments to the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"), in relation to reproductive cells and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("2007 Regulations"), in relation to tissue and other cells. The Human Fertilisation and Embryology Authority in respect of human reproductive tissue and cells and the Human Tissue Authority in respect of all other human tissue and cells were designated as Competent Authorities and required to license establishments in line with the requirements of the three directives.

4.3 The 'Amending Directive' makes very minor amendments to the Annexes of the second Directive. The two sets of Regulations therefore **amend the definition of the second Directive**, in the 1990 Act and 2007 Regulations so it includes the changes made by the Amending Directive.

4.4 The date for the transposition of the Amending Directive was 17 June 2014.

4.5 Both of these Regulations are subject to the negative resolution procedure.

4.6 These Regulations have been made under section 2(2) of the European Communities Act 1972 (c.68).

5. Territorial Extent and Application

5.1 The '1990 Act', '2007 Regulations' and these instruments, apply to all of the United Kingdom.

5.2 The 'Second Directive' applies to Gibraltar therefore the Gibraltar Authorities are responsible for implementing the 'Amending Directive' in relation to Gibraltar and have done so.

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2014 and the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2014 are compatible with the Convention rights.

7. Policy background

Reproductive Tissue and Cells

7.1 In 2007, the Human Fertilisation and Embryology 1990 Act was amended, by means of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007[1] ("HFEA Regulations"), to bring into force, in respect of reproductive cells, the requirements of the following Directives:

a) 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 ("the first Directive").

b)Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells ("the second Directive"), and

c) Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 24 October 2006 as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, and storage and distribution of human tissues and cells ("the third Directive").

7.2 The Directives not only covered activities already regulated by the 1990 Act but also extended it, in line with the Directives, to cover gamete preparation processes that are used in fertility treatment and to services providing donated sperm for home insemination where no other treatment service was provided (referred to in the 1990 Act, as amended, as 'non-medical fertility services'). These gamete preparation processes were not previously subject to legislation, but did come within the remit of the Care Quality Commission (then known as the Healthcare Commission) as part of its role in ensuring high standards of healthcare provision in both the National Health Service and the independent healthcare sector.

7.3 Most of the requirements in the Directives were not new to fertility establishments already licensed under the 1990 Act. Although the Directives and the 2007 Regulations did address other areas not currently covered by the 1990 Act, in practice, many existing licensed establishments found that the standards represented what was already acknowledged as good practice.

7.4 Establishments seeking a licence under the 1990 Act and 2007 Regulations are required to comply with a number of provisions derived from the Directives. This includes the requirement that donors, except, in the case of reproductive cells for couples being treated together using their own gametes, are subject to screening for infections including HIV 1 & 2, Hepatitis B & C, Syphilis and Chlamydia. Donors who, or whose sexual partners, come from high incidence areas must also be screened for human T-lymphotropic virus (HTLV) antibodies. The Amending Directive amends this requirement, so instead of requiring the screening of donors or their sexual partners from

[1] S.I. 2007/1522

areas of **high-incidence,** measures the rate of occurrence of new cases of infection, this is amended to the screening of donors from areas of **high-prevalence**, which is the proportion of the population of an area affected by a disease at a specific time. In addition, in the case of reproductive cells, the Amending Directive relaxes the requirements for blood samples to be taken at the time of donation by partners in order to determine biological markers.

Tissues and Cells

7.5 Likewise, in respect of all other tissue and cells, the 'first', 'second' and 'third' Directives were transposed by the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These Regulations were made under section 2(2) of the European Communities Act 1972 and, in respect of Part 6, section 46(1) of the 2004 Act. With the agreement of Scottish Ministers, and by virtue of the power of the Secretary of State under section 2(2) of the European Communities Act remaining exercisable in relation to Scotland by virtue of section 57(1) of the Scotland Act 1998, these Regulations (except part 6, which amends the 2004 Act) extended to Scotland. Their purpose was to make such provision as was necessary to ensure full implementation of Directive 2004/23/EC and Commission Directives 2006/17/EC and 2006/86/EC, which laid down standards of quality and safety for human tissues and cells intended for human application, otherwise than in relation to human gametes and embryos. The Regulations amended the Human Tissue 2004 Act, which established a licensing framework for the regulation of various activities involving human material, including research, public display, and storage for the purposes of transplantation. A United Kingdom regulatory body, the Human Tissue Authority ("the HTA"), was also created by the 2004 Act.

7.6 Currently, establishments seeking a licence under the '2007 Regulations' are required to comply with a number of provisions derived from the Directives. This includes the requirement that donors are subject to screening for infections including HIV 1 & 2, Hepatitis B & C, Syphilis and Chlamydia. Donors who come from high incidence areas must also be screened for HTLV antibodies. The Amending Directive amends this requirement, so instead of requiring the screening of donors from **high-incidence** areas, this now requires the screening of donors from **high-prevalence** areas

8. Consultation outcome

8.1 A consultation was held with licensed establishments through the Human Fertilisation and Embryology Authority and Human Tissue Authority. The changes were thought minimal and these Regulations are not expected to increase enforcement costs for the HFEA or the HTA.

9. Guidance

9.1 The HFEA and Human Tissue Authority will issue guidance or Directions on the revised biological testing requirements to its licensed establishments and amend their codes of practice.

10. Impact

10.1 An Impact Assessment is attached to this memorandum, in relation to the impact on private sector fertility establishments.

10.2 These Regulations will primarily impact on the public sector, particularly the National Health Service. However, the changes they make to exiting biological testing practices are minimal and, in fact, reflect existing practice in many establishments. The blood testing requirements for donors of reproductive cells also better reflect the potential health risk to recipients of these cells and should be less burdensome for clinic's to implement than existing requirements.

11. Regulating small businesses

11.1 The revised biological testing requirements could have a beneficial impact on HFEA licensed establishments that would be classified as small businesses. The Directive changes the requirement for blood screening tests from the point of each donation to within 3 months of the first donation. Further donations require another test within 24 months of the first test. This is a potential cost-saving to businesses. With a lower number of blood tests mandated, costs could fall. The potential for savings will be ongoing.

12. Monitoring and review

12.1 The Department will keep implementation of the revised biological testing requirements under review through accountability meetings with the HFEA and Human Tissue Authority.

13. Contact

Kim Hayes: (020) 7210 6339 or e-mail: kim.hayes@dh.gsi.gov.uk can answer any queries regarding the Human Fertilisation and Embryology (Quality and Safety) Regulations 2014

Triona Norman (020) 7210 5191 or email: triona.norman@dh.gsi.gov.uk can answer any queries regarding the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2014