EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) REGULATIONS 2024

2024 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 His Majesty.

2. Declaration

2.1 Maria Caulfield, the Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

2.2 Amanda Davies, Deputy Director for Health Ethics, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Steve Pugh at the Department of Health and Social Care. Telephone: 02027 210 4350 or email: steve.pugh@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"). Firstly, it allows people living with HIV with a sustained viral load of no more than 200 per millilitre ('undetectable viral load') to donate to friends, family or a person they have been introduced to by a third party for the purpose of conceiving ("known recipients") where the donor has been receiving antiretroviral treatment for at least 6 months prior to donation and the recipient is aware of the HIV diagnosis, understands the health risks involved with the donation and consents to be treated. Secondly, it creates a new definition of partner-donated eggs enabling female same sex couples wishing to donate eggs to each other to undergo the same testing requirements as heterosexual couples.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the United Kingdom.

5. Policy Context

What is being done and why?

5.1 The 1990 Act was amended by the Human Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522) ("the 2007 Regulations") and subsequently the Human Fertilisation and Embryology Act 2008. The amendments made by the 2007 Regulations included provisions that impose specific requirements about the quality and safety of reproductive cells to implement European Law namely Commission Directive 2004/23/EC of the European Parliament and of the Council Directive which sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and Commission Directive 2006/17/EC ("2006 Directive"). The 2006 Directive introduced the definition of "partner donation" and the requirement for donors who are donating outside of partner donation to be HIV negative.

5.2 The definition of partner-donated sperm in the 1990 Act and partner donation in the 2006 Directive limits the donation of reproductive cells between a man and a woman who are in an intimate physical relationship. This means that when accessing fertility services, female same-sex couples who are in an intimate physical relationship that wish to have IVF treatment where embryos are created using eggs from partner 1 and a donor sperm, for partner 2 to carry the pregnancy ("shared motherhood"), have to undergo different, more rigorous, screening and testing in relation to those eggs than heterosexual couples using partner-donated sperm.

5.3 The 1990 Act further requires conditions of licences issued under the Act to require donors to be HIV negative unless donation is taking place between a man and a woman who declare they have an intimate physical relationship.

5.4 In June 2023, the National Advisory committee for the safety of blood, tissues and organs (SaBTO) recommended that the additional screening and testing requirements for female same-sex couples in an intimate physical relationship should be removed as there is no microbiological reason for the requirements. This would also create parity with heterosexual couples.

5.5 The June 2023 SaBTO report further recommended that legislation should be amended to allow gamete and embryo donation to occur from individuals living with HIV to known recipients where the 'Undetectable = Untransmittable' criteria are met. This means that a person living with HIV must have an undetectable plasma HIV viral load and have been receiving antiretroviral therapy for at least 6 months. This recommendation was based on current scientific evidence that showed advances in the treatment of HIV, such as antiretroviral therapy (ART), which meant that the risk of transmission is now regarded as 'negligible' through unprotected sexual intercourse.

5.6 As the established scientific evidence has changed, this instrument seeks to make the following policy changes by way of amendment to the 1990 Act:

(a) enable shared motherhood donations to undergo the same testing requirements as heterosexual couples and

(b) enable people living with HIV to donate gametes and embryos where donation is to a known recipient where donors are able to demonstrate they have a sustained undetectable viral load and have been receiving antiretroviral therapy for at least six months. In these cases, recipients of the donation must be aware of the HIV diagnosis, the health risks of the donation and consent to the donation.

5.7 This instrument aims to amend legislation in respect of Great Britain, using powers under s.42A and 45(3A) of the 1990 Act. In respect of the amendment for Northern Ireland, this instrument uses powers under 8C(1) and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 ("the 2018 Act").

What was the previous policy, how is this different?

5.8 Under the 1990 Act, with the exception of gamete and embryo donation between heterosexual couples, a person who tested positive for HIV would not be able to donate their gametes.

5.9 The definition of "partner-donated sperm" in the 1990 Act and "partner donation" in the 2006 Directive limits the donation of reproductive cells between a man and a woman who are in an intimate physical relationship. As female same sex couples undergoing shared motherhood arrangements did not fall within this definition, it resulted in additional screening costs for infectious diseases under the 2006 Directive which created disparity with heterosexual couples.

5.10 This instrument will allow people living with HIV to donate to known recipients who have a sustained undetectable viral load provided the requirements in s7A of the instrument can be met, that the donor (a) has a undetectable viral load providing two laboratory tests before donation (b) has been receiving antiretroviral treatment for at least 6 months prior to the date of donation and (c) that the recipient is aware of the donor's HIV diagnosis, is aware of the risks and provides consent to be treated with the donation.

5.11 It will also create the definition of "partner-donated eggs" in the 1990 Act and modify how the definition of "partner donation" in the 2006 Directive is applied in the UK to include the donation of reproductive cells between a woman and a woman who declare that they have an intimate physical relationship, ensuring that female same sex couples undertaking shared motherhood fertility treatment will undergo the more limited donor-related screening tests that are required in a partner donation.

6. Legislative and Legal Context

How has the law changed?

6.1 The 1990 Act (as amended), provides the legislative framework for the use and storage of sperm, eggs and embryos for human use. As explained in paragraph 5.1, the 2007 Regulations implemented the 2006 Directive. Schedule 3A to the 1990 Act was inserted by the 2007 Regulations and implemented the technical requirements for the donation, procurement and testing of human cells and tissues.

6.2 This instrument is made in exercise of powers conferred in sections 42A(4) and 45(3A) of the 1990 Act. The powers enable the Secretary of State to make regulations specifying technical requirements in relation to selection criteria for donors of gametes and embryos, laboratory tests required for donors and gamete and embryo processing, storage and distribution. The power can only make regulations in relation to Great Britain. The power for the Secretary of State to make regulations in respect of Northern Ireland is in the 2018 Act (as amended by the European Union (Withdrawal Agreement) Act 2020).

6.3 The amendments to Schedule 3A to the 1990 Act will:

(a) Enable female same sex couples donating eggs (which are not intended to be used without processing and storage) to one another to undergo less stringent selection and testing criteria. The amendments:

i. except such donations from the requirement to comply with the more stringent criteria in section 3 of the 2006 Directive and instead require conditions of licences issued under the 1990 Act to comply with the selection criteria set out in section 2 of the 2006 Directive;

ii. create a new definition of "partner-donated eggs" in the 1990 Act; and

iii. modify the application of the definition of "partner donation" in the 2006 Directive to include the donation of reproductive cells between a woman and a woman who declare that they have an intimate physical relationship.

(b) Enable people diagnosed with HIV with a sustained undetectable viral load to donate gametes and embryos to known recipients. The instrument prohibits licence conditions from including the requirement in section 3.2 of the 2006 Directive (that donors be HIV negative) if all four conditions in s7A are met. The first condition is the donor must demonstrate that they have a sustained undetectable viral load of no more than 200 copies per millilitre. The second condition is the donor must be receiving ART for at least 6 months prior to the donation. The third condition is the donation must be to family, friends or to a person the donor has been introduced to by a third party for the purpose of conceiving. The fourth condition is the recipient must be aware of the HIV diagnosis, the health risks of the treatment and consent to the treatment.

(c) Exempt partner-donated eggs from the requirements under the 2006 Directive in relation to donation and procurement procedure and reception of tissue and cells at the tissue establishment.

Why was this approach taken to change the law?

6.4 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 There is no statutory requirement to consult. However, the Department has worked closely with Devolved Administrations during policy development and have been sighted on the proposals.

8. Applicable Guidance

8.1 Fertility clinics will receive guidance from the Human Fertilisation and Embryology Authority (HFEA) following the instrument coming into force about the impact of these regulations and any immediate action that needs to be taken. The HFEA will also update its Code of Practice in 2024.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because as based on information provided by the HFEA, the estimated cost to the fertility sector of these changes falls within a potential cost range of £46,000 to £92,100 and would fall outside the scope of a full Impact Assessment. A De minimis assessment has been completed and will be published on Legislation.gov.uk.

Impact on businesses, charities and voluntary bodies

9.2 There is no significant impact on business, charities or voluntary bodies because it is expected that IVF clinics will recoup this additional cost through their client charges.

9.3 There is no, or no significant, impact on the public sector.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015. Maria Caulfield has made the following statement "As the impacts of the measures are expected to be under £10 million to the fertility sector, a statutory review clause would not be appropriate."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy, Maria Caulfield has made the following statement regarding Human Rights:

"In my view the provisions of the Human Fertilisation and Embryology (Amendment) Regulations 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made under 8C(1) and paragraph 21 of Schedule 7 to the 2018 Act and relates to the Windsor Framework in the Withdrawal Agreement. This instrument does not trigger the statement requirements under the 2018 Act.