EU exit: HFEA preparations for the end of the transition period

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Authority
Agenda item:	9
Meeting date:	11 November 2020
Author:	Emily Tiemann, Regulatory Policy Manager Andrew Leonard, Senior Inspector Catherine Drennan, Head of Legal
Annexes	Annex 1: Imports and Exports to or from clinics in Northern Ireland Annex 2: Background information on General Directions, Licence conditions

Output from this paper

For information or decision?	For decision
Recommendation:	Approve arrangements relating to the Authority's preparedness for the end of the Transition Period including delegating authority to the Chair to make decisions in relation to practical implications of EU Exit.
Resource implications:	Allocated budget to allow for expenditure relating to the end of the transition period and external legal advice when required.
Implementation date:	31 December 2020
Communication(s):	As set out in the paper primarily to licensed treatment and storage centres.
Organisational risk:	Medium

Background

1.1. The United Kingdom (UK) officially left the European Union (EU) on 31 January 2020. The Withdrawal Agreement with the EU came into force and the UK entered a transition period (TP) which will end on 31 December 2020. Arrangements at the end of the TP will either be based on the Withdrawal Agreement only, or also on a Free Trade Agreement concluded with the EU, negotiations for which are ongoing at the time of writing.

1.2. The Withdrawal Agreement contains the Northern Ireland Protocol (NIP) which will respect the fact that Northern Ireland (NI) is an integral part of the customs territory of the UK and respect the need to bear as lightly as possible on the everyday life of NI. Although there will be some new administrative requirements, the government's aim is for these to be streamlined and simplified to the maximum extent. Under the NIP, NI will continue to enforce EU customs rules and follow its rules on product standards. Under the Withdrawal Agreement the rest of the UK will stop following those rules, meaning some new processes on movements between Great Britain (GB, i.e. England, Scotland and Wales) and NI. The government aims to reduce them to the absolute minimum so that the integrity and smooth functioning of the UK internal market is protected.

1.3. This paper sets out the preparations the HFEA is making for the end of the TP, particularly for the implementation of the NIP and The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020. These preparations will ensure that at the end of the TP, the regulatory framework reflects the legal and practical reality of the country having left the EU, and ensure that clinics understand the regulatory framework. These changes are required regardless of whether a Free Trade Agreement between the UK and the EU is concluded.

1.4. Section 2 below on the legal impact outlines specific changes to our regulatory framework as a result of new regulations and their impact on existing General Directions, Licence Conditions and other matters. Given the focus of the NIP, the changes will primarily affect movement of gametes and embryos, traceability and reporting. Section 3 outlines the impact on regulation, and looks at how the HFEA will continue to regulate clinics in Northern Ireland after the end of the TP. Though this will require changes to the way that the HFEA carries out elements of its work, it is important to note that most of our regulatory framework will remain the same. Finally, section 4 outlines how we will communicate these developments.

1.5. There are currently four HFEA licensed clinics in NI providing approximately 2,300 cycles per year.

2. Legal impact

2.1. The **EU Tissues and Cells Directives** (EUTCDs) have been transposed into domestic UK law, meaning licensed fertility clinics in the UK will continue to meet the EU standards of quality and safety after the end of the TP.

2.2. The **Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020**: The 2020 Statutory Instrument (SI) is the means by which the NIP is implemented in so far as it relates to reproductive tissues and cells (gametes and embryos).

2.3. The **Human Fertilisation and Embryology Act 1990** will continue to apply UK wide, with certain provisions applying in relation to NI only and, in some instances, to GB only. To reflect this, certain changes have been made to General Directions, Licence Conditions, and to the Special Direction decision tree, as well as to relevant application forms and templates. These can be found in the Annexes to this paper. Any necessary changes will also be made to the Code of Practice at the time of the next update (October 2021), including a new dedicated 'Guidance Note' specific to regulation in Northern Ireland (NI).

2.4. **Movement of gametes and embryos into and from NI and GB:** After the end of the transition period] countries within the EEA will become 'third countries' to the UK but will not be treated as 'third countries' to NI due the provisions of the NIP. The EEA includes the EU Member States, Iceland, Liechtenstein and Norway.

Previously, an Importing Tissue Establishment (ITE) import certificate was needed if a clinic in the UK wished to import gametes or embryos from outside the EEA or Gibraltar (i.e. from a third country). After the end of the TP, the definition of what a third country is will change depending on whether a clinic is in GB or NI, and therefore the need for an import certificate will also change.

We have amended the ITE import certificate application form which clinics will find in the clinic portal and have produced a flow chart that clinics can use to identify whether an ITE import certificate application is required. These will be provided to clinics in advance of the end of the TP so they can start to plan. After the end of the TP the need for an import certificate will be as follows:

- For clinics in Great Britain: Imports of gametes and embryos from all countries outside the UK (GB and NI) will be third country imports and will need an ITE import certificate from the HFEA.
- For clinics in Northern Ireland: Imports from all countries outside the EEA will be third country imports and will need an ITE import certificate from the HFEA. This will include movements from GB into NI.
- The NIP ensures unfettered access for Northern Ireland to the UK market.

See annex 1 for more detailed information about imports and exports to and from NI, and movements to and from GB.

To account for the different arrangements, we have produced two versions of General Direction 0006 on Import and Export of Gametes and Embryos, one for clinics in NI and one for clinics in GB. Where clinics seeking to import or export cannot satisfy the requirements of the relevant schedule under GD0006, as has always been the case, application can be made to the Authority for a Special Direction (SD) authorising the import or export. The SD application form and associated 'Further Information Sheet', as well as the decision tree for SD applications for import/export used by the Statutory Approvals Committee, have been/will be revised to account for changes to General Direction 0006. For more information on changes to other General Directions and changes to Licence Conditions, see annex 2.

2.5. **Reporting functions:** The requirements for the HFEA to report to the EU as the Competent Authority in NI (CA-NI) will remain for the activities of centres in NI. The UK and EU have agreed that for the purposes of the NIP, we will continue to have access to relevant EU databases. The HFEA will have no responsibility to report data to the EU concerning the activities of centres in GB after the TP.

3. HFEA regulation in Northern Ireland

3.1. After the TP the HFEA will remain the CA-NI and will continue to regulate licensed clinics and embryo research in NI in line with the requirements of the HFE Act 1990 (as amended) to reflect the provisions of the NIP. Some HFEA staff will have roles specific to the CA-NI function of the HFEA, in addition to their roles for the HFEA in GB.

3.2. The regulatory scheme that we currently follow will be applied across GB and NI equally, apart from the differences discussed in this paper specific to The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020.

3.3. After the TP there will be some changes to this legislation which mean that provisions which apply in NI will not apply in GB and vice versa. Other than to the extent dictated by these changes, the same regulatory scheme will be applied consistently across all clinics regardless of

location. Regulatory changes in GB and the EU will be reviewed on an ongoing basis so that the regulatory scheme applied in NI remains compliant with the terms of the NIP. Over time, there may be more significant differences should EU and GB rules diverge.

3.4. The HFEA will be the CA for Northern Ireland and use common staff and committees to inspect and licence clinics in both Great Britain and Northern Ireland.

4. Communication

4.1. We have periodically updated licensed clinics with information relating to EU exit as well as passing on information we have received from the Department of Health and Social Care and had a dedicated area on the Clinic Portal with relevant information. The changes outlined in the revised General Directions and licence conditions will be communicated to centres via a Chair's Letter and we will also issue a 'special edition' Clinic Focus on the changes resulting from the end of the TP.

4.2. To understand changes to guidance brought about by EU Exit, clinics will need to read and adhere to the guidance and information set out in the Chair's letter and the requirements in the revised versions of General Directions and Licence Conditions specific to their jurisdictions, notably concerning movement of materials and traceability. The flowchart will help clinics navigate the changes in relation to import and export, and movements from GB to NI.

4.3. At the end of the TP, the UK is leaving the Single Market and Customs Union, meaning that there will be significant changes at the GB-EU border. The HFEA wrote recently to ask all treatment and/or storage centres to undertake an 'End of the Transition Period risk assessment' in preparation for the end of the transition period. We asked that control measures are in place to mitigate, as much as is feasible, all the risks identified in these risk assessments. The HFEA will be seeking confirmation from clinics that the 'End of the Transition Period risk assessment' has been undertaken, and all risks identified have been controlled.

4.4. We take part in periodic meetings with other ALBs and the relevant minister to update on the situation as the end of the TP nears. We are also in regular communication with DHSC officials and other health ALBs regarding overriding risks relating to the end of the transition period, the Covid-19 pandemic and the winter season. We have been asked for reassurances relating to the readiness of the organisation and those we regulate for the end of the TP.

5. Recommendation

5.1. The Authority is asked to:

- Note the arrangements relating to the Authority's preparedness for the end of the transition period.
- Delegate to the Chair the power to make any decisions in relation to the end of the transition period and practical implications of this including General Directions, Licence Conditions and any other matters.

Annex 1

Table 1, Imports 2018-19: Total number of imports of sperm, eggs and embryos into all centres in NI from third country providers inside and outside the EU (each import may comprise several straws or vials of a provider's gametes). Approximate numbers.

EU/Non-EU	Sperm 2018	Sperm 2019	Eggs 2018	Eggs 2019	Embryos 2018	Embryos 2019	Total 2018	Total 2019
NI total (EU)	58	69	0	0	0	0	**58**	**69**
NI total (non-EU)	8	1	3	0	0	0	**11**	**1**

Table 2, Exports 2018-19: Total number of exports of sperm, eggs and embryos from all centres in NI, to tissue establishments inside and outside the EU (each export may comprise several straws or vials of a provider's gametes). Approximate numbers.

EU/non-EU	Sperm 2018	Sperm 2019	Eggs 2018	Eggs 2019	Embryos 2018	Embryos 2019	Total 2018	Total 2019
NI total to EU	1	1	0	0	0	1	**1**	**2**
NI total to non-EU	0	0	0	1	1	0	**1**	**1**

Annex 2

Background information on GD 0013 and GD 0009

In 2018 we implemented the Single European Code (SEC) based on requirements set out in EU Directive 2015/565 (the Coding Directive) which amended the Second Technical Directive (2006/86/EC) in 2015. After the TP, to ensure compliance with section 24(12) of the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020, clinics in Great Britain (GB) will no longer need to apply a SEC while clinics in NI will still need to do so. In GB, Directive 2006/86/EC will be applied as it was before it was amended by Directive 2015/565, while in NI, the 2015 amended version of Directive 2006/86/EC will be applied. We have therefore produced two versions of General Direction 0013 on Traceability of Gametes and Embryos, one with reference to the SEC, which will apply to clinics in NI, and one without reference to the SEC which will apply in GB. Clinics in GB will need to implement procedures to ensure that all gametes and embryos, and all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa. The information needed is listed in the new GB version of GD0013. Centres in GB must also ensure that all containers (dishes, vials, ampoules, tubes etc.) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier.

We have also produced new versions of General Direction 0009 on Keeping Gametes and Embryos in the Course of Carriage Between Premises, to reflect the changes brought about to Sections 24 of the HFE Act in relation to GB.

Revised Licence Conditions

Clinics in GB will be required to comply with revised versions of Licence Conditions T100 and T101 which exclude reference to the SEC but include the need for a unique and accurate identification of each

patient/donor, date and place of procurement, type of treatment, and a description of any products associated with and all processing steps applied to the procurement, use and storage of any gametes and embryos.

For clinics in GB we have also revised Licence Conditions T20 and R49 to remove reference to Directive 2003/94/EC, as well as License Conditions T31 and R60 to remove reference to Council Directive 93/42/EEC and Directive 98/79/EC of the European Parliament, and replace these with Medical Devices Regulation 2002 (UK MDR 2002), which were amended by the 2019 EU Exit Regulations and further by the 2020 EU Exit Regulations.

Another change for clinics in GB is the introduction of the UKCA (UK Conformity Assessed) marking, which is a new UK product marking that will be used for goods being placed on the market in GB. This covers most goods which previously required the CE marking, meaning that T30, T51, T53, R59 and R67 will be amended for clinics in GB.

Background note:

Under the Human Fertilisation and Embryology Act 1990, we have the power to issue Directions – or rules. Directions can be 'general' which apply to all clinics and centres, or 'special' which apply to individual licensed clinics/centres. These can be found on our website here.

We also grant licences to fertility clinics and human embryo research centres and provide a list of Licence Conditions which must be followed to allow continuation of a clinic's licence. These can be found on our website here.

We are in the final process of reviewing the General Directions and Licence Conditions that will be amended for fertility clinics and they are currently undergoing a legal check.