HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Brexit Guide for Stakeholders
Organisations Responsible for Human Application of Tissues and Cells - Hospitals

1 BACKGROUND

The UK left the European Union on 31 January 2020 on the basis of the Withdrawal Agreement which was agreed by the European Council on 17 October 2019. The agreement includes a transition period until 31 December 2020. The period for the UK government to seek an extension to the transition period has now expired.

Negotiations are ongoing between the EU and the UK on a new future relationship agreement, which if agreed, is due to come into effect from 1 January 2021.

The Health Products Regulatory Authority's (HPRA) priority, working with all relevant stakeholders, is to ensure continuity in the supply of health products and continued access to products for patients. The guidance provided in this document on the key issues facing the HPRA and our stakeholders is based on the premise that as a result of future relationship negotiations the UK will become a third country at the end of the transition period.

2 IMPACT OF BREXIT ON THE TISSUES AND CELLS REGULATORY FRAMEWORK

As the UK will become a third country, following Brexit, we would like to draw your attention to the fact that import of tissues into Ireland from outside of the European Union (EU), i.e. a third country, must only take place under an authorisation by the HPRA. There is still uncertainty surrounding the content of the withdrawal agreement, but stakeholders should be prepared. It is important to consider the impact Brexit may have on your supply of tissues and cells.

The recently published Directive 2015/566 is an implementing Directive of 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells. It has been transposed into Irish legislation as S.I. No. 33 of 2019 European Communities (quality and safety of human tissues and cells) (amendment) Regulations 2019.

This legislation sets out the specific requirements in relation to an importing tissue establishment (ITE) authorisation, which is a requirement when importing tissues or cells from a supplier outside of the EU.

In respect of Northern Ireland, an ITE authorisation will not be required as the Ireland-Northern Ireland Protocol takes regard of health products (medicines and substances of human origin) and as such distribution of tissues and cells from Northern Ireland to the EU is not considered to be importation.

3 ACTIONS TO BE TAKEN

- When the UK becomes a third country, the requirements of S.I. No. 33 of 2019 will apply, and you will require an ITE authorisation if you intend to receive tissues and cells for human application directly from the UK. This places significant responsibility on your organisation. An example of the information required as part of the application for an importing tissue establishment can be found in Appendix 1 of this document. The process for authorisation involves at least one initial inspection prior to authorisation, an inspection a year after authorisation and an inspection every two years thereafter. The HPRA may conduct additional inspections of ITEs independent of the biennial frequency, as considered necessary.

  The application form 'application for a new or importing tissue establishment authorisation' is available on www.hpra.ie.

- Alternatively, you could engage with tissue establishments in Ireland, or elsewhere within the EU, who are already authorised for import to see if they already supply, or are willing to add your required product and supplier to their authorisation.

  A list of authorised tissue establishments can be found at the below link along with details of their authorised activities:

  https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml

  The sourcing of tissues and cells through an authorised tissue establishment will limit your responsibility to that of the responsibilities you already have as an organisation responsible for human application.

  Queries can be directed to compliance@hpra.ie.

APPENDIX 1 EXAMPLE OF INFORMATION REQUIRED AS PART OF ITE APPLICATION

A. Details of tissues and cells to be imported

- A list of the types of tissues and cells to be imported, including one-off imports of specific types of tissues or cells.
- The product name (where applicable, in accordance with the EU generic list) of all types of tissues and cells to be imported.
- The trade name (if different from the product name) of all types of tissues and cells to be imported.
- The name of the third country supplier for each type of tissue and cell to be imported.

B. Details of third country suppliers

- Name of third country supplier(s) (company name).
- Name of contact person.
- Visiting address.
- Postal address (if different).
- Telephone number including international dialling code.
- Emergency contact number (if different).
- Email address.

C. Location of activities

- A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by the third country supplier per type of tissue or cell.
- A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by sub-contractors of the third country supplier per type of tissue or cell.
- A list of all activities carried out by the ITE subsequent to import per type of tissue or cell.
- The names of the third countries in which the activities prior to import take place per type of tissue or cell.

D. Documentation relating to the importing tissue establishment

- A job description of the RP and details of their relevant qualifications as laid down in Directive 2004/23/EC.
- A copy of the primary label, repackage label, external package and transport container.
- A list of relevant and up to date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code (SEC), reception and storage of imported tissues and cells at the ITE, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

E. Documentation relating to the third country supplier or suppliers

- A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor family and whether the donation was voluntary and unpaid or not.
- Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres.
- Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical procedure.
- A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier.
- Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers.
- Details of any sub-contractors used by the third country suppliers, including the name, location and activity.
- A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the dates of the inspection, type of inspection and main conclusions.
- A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the ITE.
- Any relevant national or international accreditation.

HPRA
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