HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Routine Import/Export of Tissues and Cells for Human Application Involving Countries Outside the European Economic Area

1 SCOPE

This guide is issued by the Health Products Regulatory Authority (HPRA) to provide guidance on the routine import or export of tissues and cells for human application to or from countries outside the European Economic Area (EEA) by an authorised tissue establishment in Ireland. Non-routine import or export of tissues and cells is covered in a separate guideline, 'Guide to non-routine import/export of tissues and cells', available on the 'Publications and Forms' section of www.hpra.ie.

2 DEFINITIONS

Cells are individual human cells or a collection of human cells when not bound by any form of connective tissue.

Distribution means transportation and delivery of tissues and cells intended for human application.

Export of tissues/cells for human application is defined as sending tissues or cells to countries outside the EEA (i.e. third countries).

Human application is the use of tissues or cells intended for human applications.

Import of tissues/cells for human application is defined as receipt of tissues or cells from countries outside the EEA (i.e. third countries).

Storage means maintaining the product under appropriate controlled conditions until distribution.

Tissue is defined as all constituent parts of the human body formed by cells.

Tissue establishment is a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken.

3 GUIDANCE FOR IMPORTS

3.1 Legislative requirements for the import of tissues and cells for human application

Article 9 of Directive 2004/23/EC requires that the import of tissues and cells from third countries (i.e. outside the EEA) is undertaken **only** by tissue establishments that are authorised for the purpose of this activity.

The application form entitled 'Application for tissue establishment authorisation' can be found on the 'Publications and Forms' section of www.hpra.ie.

Tissue establishments must ensure that imported tissues and cells can be traced from donor to recipient and that such imports meet the standards of quality and safety equivalent to those laid down in Directive 2004/23/EC.

Imports of tissues and cells from third counties may only be undertaken by tissue establishments authorised by the HPRA for this purpose. Clinicians, dentists or individuals may import tissues or cells for human application only in association with a tissue establishment in Ireland which has been authorised for this activity by the HPRA.

3.2 Import of tissues or cells for human application 'on a routine basis'

Tissue establishments engaged in the import of tissues or cells on a routine basis from a specific organisation outside the EEA should have the names of such organisations listed on their tissue establishment authorisation.

The 'Notification of non-routine import/export of tissues or cells for human application' form does **not** need to be completed prior to such imports, as the HPRA has assessed on inspection the arrangements in place at tissue establishments for these routine imports.

4 GUIDANCE FOR EXPORTS

4.1 Legislative requirements for the export of tissues or cells for human application

Article 9 of Directive 2004/23/EC requires that all exports of tissues and cells to third countries (i.e. outside the EEA) are undertaken by tissue establishments authorised for the purpose of this activity.

Such exports to third countries must comply with the requirements of Directive 2004/23/EC.

4.2 Export of tissues or cells for human application 'on a routine basis'

Tissue establishments engaged in the export of tissues or cells on a routine basis to a specific organisation outside the EEA should have the names of such organisations listed on their tissue establishment authorisation.

The 'Notification of non-routine import/export of tissues or cells for human application' form does **not** need to be completed prior to such exports, as the HPRA has assessed on inspection the arrangements in place at tissue establishments for these routine exports.

5 TISSUE ESTABLISHMENTS NOT CURRENTLY AUTHORISED FOR THE IMPORT OR EXPORT OF TISSUES OR CELLS ON A NON-ROUTINE BASIS

Please note that any tissue establishment that is not currently authorised for the import or export of tissues or cells on a routine basis, but wishes to perform this activity, must first submit a variation application to vary the current tissue establishment authorisation to include this activity. The application form entitled 'Application to make a variation to a tissue establishment authorisation' and an associated guidance document on completing the form, can be found on the 'Publications and Forms' section of www.hpra.ie.

6 FURTHER INFORMATION

Please e-mail any queries to compliance@hpra.ie.

HPRA
18 April 2013