HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Completion of the Tissue Establishment Annual Report

Completion due by 31 March annually

1 SCOPE

This guide is issued by the Health Products Regulatory Authority (HPRA) to provide guidance on completion of the tissue establishment annual report.

2 INTRODUCTION

Regulation 10 of Statutory Instrument 158 of 2006, European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 requires that all tissue establishments submit to the HPRA an annual report on their activities.

What is the definition of a tissue establishment?

A tissue establishment means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues and cells for human application are undertaken.

Who needs to complete an annual report?

An annual report needs to be completed by all tissue establishments which are authorised by the HPRA and which performed prescribed activities during the year. Please note that the tissue establishment annual report applies to tissues and cells intended for human application only (and does not apply to tissues and cells which are only used for diagnostic or research purposes).

From where can annual report forms be obtained?

The 'Tissue Establishment Annual Report' form is available on the HPRA website. If you have any problems downloading this document you may request one via e-mail ~~to~~ from compliance@hpra.ie.

Submission of tissue establishment annual reports

Completed tissue establishment annual reports for the year ending 31 December should be submitted to the HPRA in hard copy, or scanned document by e-mail~~,~~ by 31 March, annually. Relevant addresses can be found on the annual report form.

Further guidance

The following are some brief guidance notes on the completion of the tissue establishment annual report form. If you have any other queries that are not addressed in this guidance note, please e-mail compliance@hpra.ie.

3 NOTES ON THE COMPLETION OF THE ANNUAL REPORT

Part A – Details of tissue establishment

Please enter the TE number which was assigned to the tissue establishment by the HPRA, e.g. TE 001.

Part B, section 1 – Activities undertaken

- Please tick activities undertaken by the tissue establishment, and activities undertaken by a third party on behalf of the tissue establishment (if activities are undertaken by both the TE and a third party, please tick both). If any activities are not applicable, please write 'Not Applicable'tick the relevant boxes.

- Note that the activity of donation includes autologous donations. However, tissues and cells used as an autologous graft (removed and transplanted back to the same individual) within the same surgical procedure and without being subjected to any banking process, are excluded from the tissues and cells legislation, and need not be included in the tissue establishment annual report.

- The activity of testing refers to the testing of blood samples to establish the serological status of the donor (including autologous donors).

- Distribution in this section means transportation and delivery of tissues and cells for human application (out of the TE but remaining within the European Economic Area).

- Import/export applies only to countries outside the European Economic Area.

- The European Economic Area consists of the 28 27 Member States of the European Union in addition to Iceland, Norway and Liechtenstein.

Part B, section 2 – Types of tissues and/or cells

Please tick **each** type of tissue and/or cell relevant to the tissue establishment authorisation.

Part B, section 3 – Quantities of tissues and/or cells

Then, Complete table 3.1 in section 3 is to be completed for each tissue/cell ticked on this the list in section 2.1. For example, if the types of tissue/cell relevant to a tissue establishment are peripheral blood stem cells and bone marrow, then a separate table 3.1 would need tomust be completed for both of those tissues/cells. Please cCopy and complete the table as required.

~~Part B, section 3 – Quantities of tissues and/or cells~~

A Common Approach document for the definition of reportable serious adverse events and reactions as laid down in the Tissues and Cells Directive 2004/23/EC and Commission Directive 2006/86/EC was issued by the European Commission in June 2015.

According to this document, the following approach to counting tissues and cells should be utilised when completing this annual report. This information will then be compiled and reported by the HPRA to the European Commission by the appropriate deadline.

The following are the proposed definitions of 'units' for counting tissues and cells (please specify in the 'additional information' section of the form if these units are not available and explain if different units are used for counting):

Haemopoietic stem cells:
A single donation will be considered to be one 'unit' for the purposes of this form. Where one donation procured is subsequently split during processing into several components, each of those components should also be considered to be one 'unit'.

Skeletal tissues:
One unit is one individually packaged graft (e.g. one femoral head, one unit of demineralised bone, one femoral strut, one osteochondral allograft, one individually packaged tendon or part of a tendon).

Skin:
One unit is one container of skin, regardless of the area of skin it contains.

Ocular:
One unit is one individually packaged or contained graft (e.g. one cornea, one piece of sclera~~.~~).

Cardiovascular tissues:
One unit is one individually packaged or contained graft (e.g. one valve, one package containing one or more lengths of vessel).

Amniotic membrane:
One unit is one container of tissue regardless of the area of tissue it contains.

Specific guidance on the Common Approach document relating to questions 3, 6 and 7 in table 3.1

Question 3: 'How many units processed?'
This should be understood as 'the total number of units of tissues and cells processed in the TE but not necessarily released for treatment'.

This figure will be used as a denominator by the European Commission for the calculation of the rates of Serious Adverse Events in relation to tissues and cells processed in the European Union.

Question 6: 'How many units released for treatment?'
This is to be understood as 'the number of units of tissues and cells of this type transported or delivered to a clinical unit, even if the clinical unit is in the same building or the same floor'.

- If units of tissues and cells are returned to the tissue establishment without use and for subsequent release, they should be counted only when subsequently released (i.e. they should only be counted once – when they are released and clinically applied/used).

- Where units of tissues and cells pass from one tissue establishment to another tissue establishment before release, they should not be included until finally released for clinical application.

Question 7: 'What is the total number of recipients for this type of tissue/cell?'
This is to be understood as 'the total number of patients who had at least one unit of tissues or cells applied during the year concerned'.

Both of these figures (from questions 6 and 7) shall be used as denominators by the European Commission to estimate the frequency of serious adverse reactions for each type of tissues or cells.

Any relevant additional information

Please use this section of the form as necessary to provide any additional information or clarification.

Part C – Declarations

Section 1 should only be completed by tissue establishments authorised by the HPRA for import of tissues/cells.

Section 2 must be completed by all tissue establishments.

HPRA
~~12 February 2016~~<>1 December 2021