HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Completion of the Blood Establishment Annual Report

(Completion due 1 March annually)

1 SCOPE

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

2 INTRODUCTION

Article 9 paragraph 4 of S.I. 360 of 2005 states that all blood establishments must maintain records in relation to the prescribed activities for which they are responsible. Paragraph 4 of that article describes the information that must be retained. The HPRA requests that this information is submitted on an annual basis for the activities of the preceding year, in addition to activities undertaken by the blood establishment where it operates as a hospital blood bank.

What is the definition of a blood establishment?

A blood establishment is defined as any structure or body that is responsible for any aspect of the collection **and testing of human blood or blood components**, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks.

What is the definition of a hospital blood bank?

A hospital blood bank is defined as a unit within a hospital which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, and includes hospital-based transfusion services.

What is the definition of a facility?

A facility is defined as a hospital, clinic, manufacturer or biomedical research institution to which blood or blood components may be delivered. This includes hospital wards, hospices or care homes, etc., which receive blood components from a hospital blood bank for transfusion purposes (but do not perform compatibility tests on site).

Who needs to complete an annual report?

Blood establishments

- The Irish Blood Transfusion Service (IBTS) is required to complete all sections of the annual report (sections 1-5).
- All other blood establishments are required to complete sections 1, 3, 4 and 5.
- All relevant sections should be completed, typed or written in block capitals legibly using black ink.
- If particular sections ~~or /~~questions are not applicable, then enter 'Not applicable' in that section ~~or /~~question along with a brief explanation as to why that section ~~or /~~question is not applicable.

From where can annual report forms be obtained?

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

Submission of blood establishment annual reports

Completed and signed annual reports should be submitted to the HPRA ~~in hard copy or scanned document by e-mail~~via email to compliance@hpra.ie by 1 March annually. ~~Relevant~~

Reports can also be submitted in hard copy. The relevant addresses are included on the annual report forms.

Note: Each annual report submitted to the HPRA must contain appropriate signatures in ~~sections 5 and therefore unsigned~~section 5. Unsigned Word documents are not acceptable.

Any questions?

~~There are some~~See section 3 of this document for brief guidance notes on the completion of the annual report ~~below~~. If you have any other queries, please ~~e-mail~~email compliance@hpra.ie.

What does the HPRA do with the information provided in the annual report?

The HPRA will assess the level of compliance with the requirements of S.I. 360 of 2005. This will allow the HPRA to analyse this data in conjunction with the data received from all other hospital blood banks and provide relevant feedback where possible.

3 NOTES ON THE COMPLETION OF THE BLOOD ESTABLISHMENT ANNUAL REPORT

The following provides guidance notes on the details that are required for each section~~:~~.

Section 1 – Details

- Section 1.3
  Enter contact details for the blood establishment responsible person. These may be required during the investigation of serious adverse events or serious adverse reactions and in the event of a large scale recall.

- Section 1.4
  Enter the name and contact details of the Quality Manger or other relevant contact. This person should be familiar with the day-to-day running of the blood establishment.
  This person should complete the blood establishment annual report, sign the completion of annual report section (section 5) and be available to clarify information required by the HPRA in relation to the annual report.

- Section 1.5
  Enter the name and contact detail for the Haemovigilance Officer(s) or equivalent within the blood establishment. One or more names may be entered here.

Section 2 – Preceding year's activities

This information is required from the ~~IBTS~~Irish Blood Transfusion Service only and is consistent with information already provided on an annual basis.

Section 3 – Blood transfusion activity for the preceding year

This section relates to hospital blood bank activity carried out at the blood establishment on behalf of hospitals or facilities.

- Section 3.1
  Provide the number of 'group and save samples' processed, the number of 'crossmatch' samples processed and the number of 'antibody identifications' performed by the blood transfusion laboratory annually beginning 1 January and ending 31 December.

- Section 3.2
  Give details regarding blood usage annually beginning 1 January and ending 31 December.
  Please note the terms used in this section should be interpreted as follows:
  Received = number of units received from supplying blood establishment
  Issued = number of units issued for transfusion
  Transfused = number of units transfused and the number of recipients transfused
  Discarded = number of units to include both laboratory and clinical discards
  Expired = number of units which expired in the hospital blood bank without being transfused
  Returned = number of units returned to the supplying blood establishment (in date) for subsequent use~~.~~

- Section 3.3
  This section requests specific information relating to the traceability success rates and whether the ISBT labelling system is used.

- Section 3.4
  This section requests specific information relating to serious adverse events and reactions.

- Section 3.5
  This section requests specific information relating to the distribution of blood components to other hospital blood banks or facilities.

Section 4 – Comments/additional information

This allows for further information/comments to be provided from the blood establishment on data included in the annual report.

Section 5 – Completion of annual report

This section should be signed by the person who has completed the annual report.

HPRA
~~24 March 2017~~

16 November 2022