Blood Establishment Annual Activity Report

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| --- |
| 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. This will allow the HPRA to analyse this data in conjunction to the data received from all other hospital blood banks and to provide relevant feedback where possible. |

**Please complete all sections relevant to your establishment’s activities in this form, typed or in block capitals legibly using black ink.**

|  |  |
| --- | --- |
| Annual report year: |       |

Section 1: Details of blood establishment

|  |  |
| --- | --- |
| **1.1** Blood establishment name |       |
| **1.2** Full address |       |
| **1.3** Responsible Person (include job title) |       |
|  Telephone no. |       |
|  E-mail |       |
| **1.4** Quality Manager (or other relevant contact person) |       |
| Telephone no. |       |
|  E-mail |       |
| **1.5** Haemovigilance Officer (or equivalent) |       |
|  Telephone no. |       |
|  E-mail |       |

Section 2: Preceding Year’s Activities

2.1 Total number of donors who give blood and blood components

|  |  |
| --- | --- |
| Whole blood |       |
| Apheresis |       |

* 1. Total number of donations

|  |  |
| --- | --- |
| Whole blood |       |
| Apheresis |       |

* 1. Total number of donations not used

|  |  |
| --- | --- |
| Whole blood |       |
| Apheresis |       |

* 1. Number of each component produced and distributed

|  |  |  |
| --- | --- | --- |
|  | Produced  | Distributed |
| Whole blood |       |       |
| Red cells |       |       |
| Red cells in additive leucodepleted solution |       |       |
| Neonatal red cells |       |       |
| Plasma reduced red cells |       |       |
| Red cells re-suspended |       |       |
| Red cells for intra-uterine transfusion |       |       |
| Platelets (apheresis) |       |       |
| Platelets (apheresis) neonatal use |       |       |
| Platelets (pooled) |       |       |
| Cryoprecipitate (pooled) |       |       |
| Cryoprecipitate (single) neonate use |       |       |
| Fresh frozen plasma |       |       |
| Other (please specify and insert additional rows as required)       |       |       |

* 1. Number of product recalls:
	2. Number of serious adverse events and reactions investigated and reported:

|  |  |
| --- | --- |
| Serious adverse events investigated |       |
| Serious adverse events reported to NHO |       |
| Serious adverse reactions investigated |       |
| Serious adverse reactions reported to NHO |       |

2.6.1 Reported serious adverse event specification

|  |  |
| --- | --- |
|  | Specification |
| Serious adverse event | Total number | Product defect | Equipment failure | Human error | Other (specify) |
| Whole blood collection  |       |       |       |       |       |
| Apheresis collection |       |       |       |       |       |
| Testing of donations |       |       |       |       |       |
| Processing |       |       |       |       |       |
| Storage |       |       |       |       |       |
| Distribution |       |       |       |       |       |
| Materials |       |       |       |       |       |
| Other *(please specify)*       |       |       |       |       |       |

2.6.2 Reported serious adverse reaction classification

| Serious adverse reaction | Total | Deaths |
| --- | --- | --- |
| Anaphylaxis/hypersensitivity |       |       |
| Delayed serological transfusion reaction |       |       |
| Febrile non haemolytic transfusion reaction |       |       |
| Graft versus host disease |       |       |
| Hypotensive transfusion reaction |       |       |
| Immunological haemolysis due to ABO incompatibility |       |       |
| Immunological haemolysis due to other allo-antibody (Acute <24hrs) |       |       |
| Immunological haemolysis due to other allo-antibody (Delayed > 24hrs) |       |       |
| Non-immunological haemolysis |       |       |
| Other – unclassified suspected adverse reaction |       |       |
| Pre-deposit autologous donation |       |       |
| Previously un-reported complication of transfusion (PUCT) |       |       |
| Post transfusion purpura |       |       |
| Transfusion associated circulatory overload |       |       |
| Transfusion associated dyspnoea |       |       |
| Transfusion related acute lung injury (TRALI) |       |       |
| Transfusion transmitted bacterial infection |       |       |
| Transfusion transmitted parasitical - malarial |       |       |
| Transfusion transmitted parasitical – other *(please specify)*  |       |       |
| Transfusion transmitted viral infection (HBV) |       |       |
| Transfusion transmitted viral infection (HCV) |       |       |
| Transfusion transmitted viral infection (HIV-1/2) |       |       |
| Transfusion transmitted viral infection – other *(please specify)*  |       |       |

2.7 Incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components:

|  |  |  |  |
| --- | --- | --- | --- |
| Marker  | Initial reactive | Repeat reactive | Confirmed reactive |
| HIV |       |       |       |
| HBsAg |       |       |       |
| Anti HBc |       |       |       |
| HCV |       |       |       |
| HTLV |       |       |       |
| Syphillis |       |       |       |
| Other *(please specify)*            |       |       |       |

* 1. An updated list of the hospital blood banks which you supply

<insert list>

Section 3 Blood Transfusion Activity for Preceding Year

3.1 Blood transfusion laboratory activity in the year ending 31 December

|  |  |
| --- | --- |
| Please indicate the number of ‘group and save samples’ processed |       |
| Please indicate the number of ‘crossmatch’ samples processed |       |
| Please indicate the number of ‘antibody identifications’ performed |       |

3.2 Details of blood component usage in the year ending 31 December

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Component | Received | Issued | Transfused | Discarded | Expired | Returned |
| Units  | Recipients |
| Red cells (excluding paedipacks) |       |       |       |       |       |       |       |
| Paedipacks |       |       |       |       |       |       |       |
| Platelets |       |       |       |       |       |       |       |
| Plasma (fresh frozen plasma) |       |       |       |       |       |       |       |
| Plasma (solvent detergent plasma) |       |       |       |       |       |       |       |
| Other (e.g. cryoprecipitate, cryo-depleted plasma)*Please specify*       |       |       |       |       |       |       |       |

3.3 Please provide the traceability success rate for the year ending 31 December

Is the hospital blood bank currently using the ISBT labelling system for blood and blood components?

[ ]  Yes

[ ]  No

* 1. Number of serious adverse events and reactions investigated and reported:

|  |  |
| --- | --- |
| Serious adverse events investigated |       |
| Serious adverse events reported to NHO |       |
| Serious adverse reactions investigated |       |
| Serious adverse reactions reported to NHO |       |

3.5 Distribution of blood and blood components:

To whom does your hospital blood bank distribute blood and/or blood components? (Provide a list with the names and addresses of any other hospitals, hospices, community hospitals etc.)

3.5.1 Provide details on the services provided to these sites and the number and type of blood components distributed to other hospital bank(s) or facility(ies)

|  |
| --- |
| **Site name**       |
| Services | Number and type of blood components distributed: |
| [ ]  Patient ABO / Rh group / Antibody Screen / Antibody Identification  | Red cells (excluding paedipacks) |       |
| [ ]  Crossmatching  | Paedipacks |       |
| [ ]  Maintenance and calibration of storage units  | Platelets |       |
| [ ]  SAR/E reporting to the National Haemovigilance Office | Plasma (fresh frozen plasma) |       |
| [ ]  Traceability  | Plasma (solvent detergent plasma) |       |
| [ ]  Other (please specify)       | Other (please specify) |       |
| Are blood and blood components stored at this site? [ ]  Yes [ ]  No |
| Is there a service level agreement in place to describe the responsibility of these functions? [ ]  Yes [ ]  No |
| Serious adverse events investigated |       |
| Serious adverse events reported to NHO |       |
| Serious adverse reactions investigated |       |
| Serious adverse reactions reported to NHO |       |

(Please copy and insert this section for additional sites as required.)

Section 4: Comments/Additional information

Section 5: Completion of Blood Establishment Annual Activity Report

|  |
| --- |
| I hereby declare that, to the best of my knowledge and belief, the details provided in the information given above are correct and complete. Signature       Date      Name       Position      (To be signed by the person who has completed the annual activity report) |

Please complete and return annually by **1 March** to:

Blood Establishment Annual Activity Report,

Compliance Department,

Health Products Regulatory Authority,

Kevin O’Malley House,

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2

D02 XP77

Alternatively the completed form may be scanned and emailed to compliance@hpra.ie

Please use subject heading: ‘Blood Establishment Annual Activity Report – <Insert Blood Establishment Name>’