STATUTORY INSTRUMENTS

2006 No. 2013

The Blood Safety and Quality (Amendment) Regulations 2006

Insertion of regulations 12A and 12B

7. After regulation 12 (objections to suspensions, revocations atc.) insert the following regulations—

"**Requirement that facilities retain certain data**

12A.—(1) A person responsible for management of a facility shall ensure that the facility—

(a) retains the data set out in Section B of Part 6 of the Schedule, in an appropriate and readable storage medium, for a period of at least 30 years; and

(b) has in place a system in place to record each unit of blood or blood component received, whether or not locally used, and the final destination of that received unit whether transfused, used in the manufacture of medicinal products, discarded or returned to the blood establishment or hospital blood bank.

Requirement to report serious adverse reactions and events

12B.—(1) A person responsible for management of a reporting establishment shall ensure that the reporting establishment—

(a) has in place procedures to retain the record of transfusions for a period of at least 30 years**;**

(b) notifies blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood or blood components; and

(c) notifies the Secretary of State as soon as is known all relevant information about suspected serious adverse reactions using the notification formats set out in Section A and Section C of Part 7 of the Schedule.

(2) A person responsible for management of a reporting establishment shall ensure that the reporting establishment**—**

(a) notifies the Secretary of State of all relevant information about serious adverse reactions of imputability level 2 and 3 as referred to in Section B of Part 7 of the Schedule, which may be attributable to the quality and safety of blood or blood components;

(b) notifies the Secretary of State, as soon as is known, of any case of transmission of infectious agents by blood or blood components;

(c) as part of the notification referred to in paragraph (a), describes the actions taken with respect to other implicated blood or blood components that have been distributed for transfusion or for plasma fractionation;

(d) as soon as is reasonably practicable after each suspected serious adverse reaction, evaluates that reaction according to the imputability levels set out in Section B of Part 7 of the Schedule;

(e) completes the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Section C of Part 7 to the Schedule; and

(f) submits a complete report to the Secretary of State on serious adverse reactions in any calendar year by no later than 1st April in the following calendar year, using the format set out in Section D of Part 7 to the Schedule.

(3) A person responsible for management of a reporting establishment shall ensure that the reporting establishment notifies the Secretary of State as soon as is known, using the notification formats set out in Section A of Part 8 of the Schedule, of all relevant information about serious adverse events which may put in danger donors or recipients other than those directly involved in the event concerned.

(4) A person responsible for management of a reporting establishment shall ensure that the reporting establishment—

(a) as soon as is reasonably practicable after each serious adverse event, evaluates that serious adverse event to identify preventable causes within the process;

(b) upon completion of the investigation, completes the serious adverse event notification, using the format set out in Section B of Part 8 of the Schedule; and

(c) submits a complete report to the Secretary of State on serious adverse reactions in any calendar year by no later than 1st April in the following calendar year, using the format set out in Section D of Part 7 to the Schedule.

(5) Provided that either the condition set out in paragraph (6)(a), or the conditions set out in paragraph (6)(b) and (c) are satisfied, a facility may make arrangements with a hospital blood bank for the hospital blood bank to submit to the Secretary of State or the blood establishment the reports required by paragraphs (1)(b) and (c), (2)(a),(b),(e) and (f) and (3)(b) and(c) on the facility's behalf.

(6) The conditions referred to in paragraph (5) are that—

(a) the person responsible for management of the hospital blood bank is the same person as the person responsible for management of the facility with which the arrangement is made; or

(b) the arrangements referred to in paragraph (5) must be—

(i) evidenced by a written agreement, and

(ii) made with the person responsible for management of the hospital blood bank who supplied the blood or blood components to the facility for transfusion; and

(c) the facility must supply the information necessary to enable the hospital blood bank to make the reports within the timescale specified by this regulation in relation to that report .".