POLICY FOR ISSUING BLOOD COMPONENTS AND PRODUCTS AS STOCK TO NON-BLOOD BANK SITES

REASON FOR ISSUE: Added requirement to determine that the requester is legally entitled to possess medicines (4.3).

1. INTRODUCTION

NZBS has a responsibility to maintain an audit trail for all blood components and products issued within New Zealand. From time to time NZBS receives requests by hospital wards or independent healthcare practitioners for blood components or products to be held as stock by the requestor. This policy outlines the conditions under which such requests will be agreed to.

2. SCOPE

NZBS Blood Banks and Dispensing sites. This policy covers all requests to hold stock, whether from a DHB, private hospital or private health care practitioner. This policy covers all blood components and products issued by NZBS, with the exception of Section 29 products.

3. DEFINITIONS

For the purpose of this document,

- blood components are therapeutic components of blood that can be prepared by centrifugation, filtration or freezing. These are prepared from the blood of no more than five donors. Red cells, platelets, fresh frozen plasma are examples of blood components.
- Fractionated blood products are prepared from human blood by large scale pharmaceutical manufacturing preparations. Biostate and Rh(D) Immunoglobulin are examples of fractionated blood products.

4. REQUIREMENTS FOR HOLDING STOCK

4.1 Request

A request must be made in writing to the regional NZBS Transfusion Medicine Specialist.

4.2 Indication

The request must show that there is a good reason why the blood component or product cannot be issued directly to the patient on a regular basis. This must be approved by the Transfusion Medicine Specialist.

4.3 Legal entitlement to possess medicines

It must be determined that the requester is legally entitled to possess medicines as follows:

- Hospitals – all hospitals are legally entitled to possess medicines.
- Clinics and day stay facilities – must be under the supervision of a registered medical practitioner or registered nurse to be legally entitled to possess medicines.
- Individuals – must be registered medical practitioners or registered nurses to be legally entitled to possess medicines.

Medicines must not be supplied as stock to anybody outside the above categories.

4.4 Transportation of blood components and blood products

Transportation of blood components must meet NZBS requirements. See SOP 110M576, 110M535 and 110M571 for transportation of red cells, platelets and frozen components, and fractionated blood products..

4.5 Storage of blood components, including red cells for emergency use

The requestor must have a validated storage system that meets NZBS Refrigeration Guidelines (108I042). These will be provided on request by NZBS.

4.6 Storage of fractionated blood products, including immunoglobulins

The requestor must have a validated storage system that meets Ministry of Health requirements for vaccine storage, as laid out in the Immunisation Handbook. The relevant chapter will be provided on request by NZBS. No more than 6 weeks' stock should be held at any given time.

4.7 Dispensing of stock

The requestor must have staff and systems able to and competent to dispense stock in compliance with the Medicines Act of 1981.

4.8 Audit Trail

The requestor must have an audit trail of all stock issued. This must include:

4.8.1 Components

- the donation number
- component type
- expiry date
- patient's full name, address and date of birth
- patient's NHI number, where available, or other identifying record number (eg private hospital folder number)
- date of issue to patient
- requesting doctor's name
- name of person who issued the product

4.8.2 Products

- the batch number
- the dose, form, strength and product type
- expiry date
- patient's full name, address and date of birth
- patient's NHI number, where available, or other identifying record number (eg private hospital folder number)
- date of issue to patient
- requesting doctor's name
- name of person who issued the product

The audit trail must be able to identify the fate of all components/products, including those not transfused. The audit trail must be able to identify any/all patients to whom a given donation/batch number or of a component/product was issued. The information contained in the audit trail must be returned to NZBS on a regular basis not less often than every 3 months, for entry into eProgesa.

4.9 Audit

For all new requests, the system of transportation, storage and audit trail must pass an audit by an NZBS Quality Systems Associate before stock can be issued. For new requests to hold only fractionated blood products where the requestor holds Cold Chain Accreditation, this may be a minimal paper-based assessment. For sites that have already had stock issued, a timetable must be drawn up to have the system audited. Follow-up audits must be scheduled every two years. Failing to meet an audit's requirements requires correction by the requestor at the requestor's expense. If the corrections are not completed in a timely manner, then stock must be withdrawn from the requestor's site. Once approved, the requestor must be included on the distribution list of relevant NZBS documents (e.g. Refrigeration Guidelines). Once approved, any changes the requestor makes to the system must be approved of and audited by an NZBS Quality Systems Associate. Any significant costs incurred by the audit process shall be for the requestor's account.

5. NZBS RESPONSIBILITIES

NZBS shall be responsible for

5.1 Facilitating the request to hold stock by way of

- Providing the relevant NZBS guidelines (including this document)
- Providing access to equipment or details of suppliers thereof
- Providing examples of documents necessary to hold stock
- Ensuring the request is passed on to the relevant people within NZBS

5.2 Maintaining a list of approved holders of stock items

- It is the responsibility of the Area Manager Technical Services to maintain this list and ensure it is available for staff to check.
- It is the responsibility of the local Transfusion Medicine Specialist and Quality Systems Associate to authorise this list.

5.3 Entering product/component recipient details into eProgesa

5.4 Establishing that the site holds current Cold Chain Accreditation. If there are any doubts or concerns about storage facilities NZBS may elect to conduct an on-site audit.

5.5 NZBS shall not be directly responsible for sites to which non-NZBS Blood Banks issue directly. It shall be the responsibility of the non-NZBS Blood Bank to ensure transportation, storage, audit trail and dispensing requirements are met.

5.6 NZBS shall not be responsible for the purchase, maintenance, calibration, or disposal of any equipment related to the storage of blood components or products at sites outside any NZBS blood bank unless explicitly agreed to by NZBS.

6. DETAILED COLD CHAIN MANAGEMENT

6.1 Please Refer to Section 2.1 and Appendix 6 of the Immunisation Handbook, 2014 (Ministry of Health. *Immunisation Handbook 2014*. Wellington, New Zealand: Ministry of Health 2014. www.health.govt.nz/publication/immunisation-handbook-2014).