NOTIFICATION OF ADVERSE REACTIONS AND ADVERSE EVENTS ASSOCIATED WITH FRACTIONATED BLOOD PRODUCTS

REASON FOR ISSUE: Full review and update for K2.

1. PURPOSE

The NZBS Pharmacovigilance System collects data on adverse events and reactions to both monitor their frequency and nature and to provide an early warning system of adverse reactions to new or modified products. Manufacturers of medicines operate under regulatory systems that require them to have pharmacovigilance systems in place. One of the NZBS purposes for collecting the data is to provide a mechanism for reporting adverse reactions and events to manufacturers of product.

2. SCOPE

Clinicians in New Zealand are requested to notify all adverse reactions and events associated with the use of fractionated blood products and recombinant products.

The reporting and monitoring process applies to:

- Fractionated blood products manufactured from blood donations collected from New Zealand donors
- Imported fractionated blood products manufactured from human plasma
- Imported recombinant products
- Adverse reactions – as defined below
- Adverse events – as defined below
- Special situations – as defined below

Although most case reports will relate to product manufactured by CSL Behring, this process applies to product from all manufacturers.

3. DEFINITIONS

All definitions below are used in the Pharmacovigilance Agreement with CSL Behring. (Note that these definitions are slightly different from those used in the NZBS Haemovigilance system for blood components.)

Case report

A report:

- Coming from any source
- About one or several suspected adverse reactions/events/special situations
- Which might be associated with a medicinal product
- Occurring in a single patient
- At a specific point in time

Adverse event

Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product.

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Adverse reaction	A response to a medicinal product, which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure. Conditions of use outside the marketing authorization include off-label use, overdose, misuse, abuse, and medication errors.
Special situations	Special situation cases, regardless of being associated with an adverse reaction. Special situation cases include: • Exposure during pregnancy and breastfeeding, even if uneventful; embryo / foetal maternal or paternal exposure • Lack of efficacy, overdose, off-label use, occupational exposure, abuse or misuse / (symptomatic or not); drug-drug or drug-food interaction, falsified medicinal product • Medication errors, including intercepted medication errors • Suspected transmission of infectious agents via a medicinal product • Unexpected therapeutic or clinical benefit If in doubt about when to report, please contact the Pharmacovigilance Office.

4. KEY RESPONSIBILITIES

- Transfusion Nurse Specialists (TNS): Enter case reports from their region into the K2 Haemovigilance system. Obtain extra follow-up information for the manufacturer when requested.
- Transfusion Medicine Specialist (TMS): Review of case reports in regions, provision of clinical advice where appropriate, supply of relevant data to the Clinical Surveillance Manager (CSM).
- Blood Bank Staff: Notify TMS. Forward Notification Forms (111F003) to local TNS.
- Clinical Surveillance Manager (CSM): Management of case reports as per 111M018.

5. DOCUMENTS

5.1 Required Documents

- 111F003 Fractionated Blood Product – Adverse Event Notification *(case report form)*
- 111M021 Reporting Haemovigilance Adverse Events in K2

5.2 Related Documents

- 111M018 Management of Pharmacovigilance Notifications
- 160P002 Distribution and Supply of Plasma Derived Fractionated Blood Products and Recombinant Products in New Zealand
- 111F009 Form - Acute Transfusion Reaction (ATR) - Notification to Blood Bank

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6. PROCEDURE

6.1 Case Report Notification to Local Blood Bank

6.1.1 The clinical notification form for adverse reactions to blood components, 111F009 - *Acute Transfusion Reaction (ATR) – Notification to Blood Bank*, directs the clinical staff to use 111F003 *Fractionated Blood Product – Adverse Event Notification* for reporting adverse reactions and events to fractionated products. 111F003 may be obtained from the Blood Bank or the Blood Resource folder on the hospital intranet. Clinical staff complete this form, preferably electronically, and forward to the local Blood Bank, TNS or by email to adverse.reaction@nzblood.co.nz .

6.2 Local Blood Bank/TNS/TMS Actions

NOTE: *Deadlines in this procedure are required to enable NZBS to meet its contractual obligations to manufacturers.*

6.2.1 Blood Bank informs the TMS responsible for the Hospital/Region about the case.

6.2.2 The TNS, Blood Bank and the local TMS review the case report to ensure it is complete. Obtain additional information from clinical staff where necessary. As much of the required information as possible should be obtained for the initial report but if there are difficulties obtaining complete information, the minimum criteria for a valid initial case report for CSL Behring product are:

- At least one adverse reaction or event
- Name of suspected product
- An identifiable patient
- An identifiable reporter

6.2.3 NZBS TNSs: As soon as possible, enter the details of the case into K2 as per 111M021. This must occur within two working days of initial receipt of the report.

6.2.4 Non-NZBS Blood Banks/TNSs: After discussion with the local TMS, and within two working days of receipt of the report, forward it directly to the Pharmacovigilance Office on adverse.reaction@nzblood.co.nz. The Pharmacovigilance Office will acknowledge forms received from non-NZBS Blood Banks and enter them into K2.

6.2.5 The manufacturer may request the Pharmacovigilance Office to obtain further information from the reporter. Reporter will email all follow-up information to the Pharmacovigilance Office (or enter it into K2) within two working days of receipt of the information.

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7. MINIMUM TRAINING REQUIREMENTS *(FOR NZBS USE ONLY)*

☐	Complete Document Sign-Off Sheet (108F060). • Read specified sections: Sections:
☒	Complete Document Sign-Off Sheet (108F060). • Read and understand whole document
☐	Complete Document Sign-Off Sheet (108F060). • Formal training required. Specify: *(enter details of formal training)*
☐	Complete Training Module *(enter name of module)*
☐	No training required. Specify reason: