RECORDING AND REPORTING THE SUPPLY OF UNAPPROVED MEDICINES UNDER SECTION 29 OF THE MEDICINES ACT

REASON FOR ISSUE: include a section for managing issue of Section 29 medicines to ships for stock; change person responsible for review and signoff of Section 29 issues.

1. PURPOSE

To ensure that the details of all unapproved medicines supplied by NZBS are reported to the Director General of Health.

2. SCOPE

NZBS supplies some unapproved medicines to medical practitioners for the treatment of a named patient under their care. Section 29 of the Medicine Act covers this process and places an obligation on the supplier to report details of the supply to the Director General of Health.

3. KEY RESPONSIBILITIES

NZBS and DHB Blood Banks are to ensure that the form Unapproved Medicine Record 108F064 is made available, fully completed and sent to National Office.

The Transfusion Nurse Specialists will assist in the follow up of Section 29 forms if these have not been sent to NZBS when a Section 29 product has been issued.

The Executive Assistant to the National Medical Director is to maintain records, pass them to the Regulatory Affairs Associate for review and send completed Medsafe Declaration/Notification Forms 108E001 to the Compliance Management Branch at Medsafe.

The Regulatory Affairs Associate is to review the Section 29 records, complete the Medsafe Declaration/Notification Form 108E001 and return the records to the Executive Assistant to the National Medical Director.

4. ITEMS REQUIRED

4.1 Related Documents

- 108E001 - Medsafe Declaration Form for Medicines supplied Pursuant to Section 29 of the Medicines Act 1981
- 108F064 - Unapproved Medicine Record

5. PROCEDURE

5.1 NZBS supplies a variety of different products which are unapproved medicines from time to time to medical practitioners. The following records are required to be kept:

- The name of the Medical Practitioner who requested the supply of the medicine
- The name of the patient the medicine was required for
- The dose form, strength, pack size of the medicine and number of packs supplied
- The date the medicine was issued to the patient
- The name of the place the medicine was supplied to

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Note – occasionally Section 29 medicines are issued to ships for stock (e.g. Australian Tetanus Ig). In these situations there is no named patient, instead traceability is maintained by recording the ship identification number.

5.2 The issuing Blood Bank obtains the form 108F064, completes all the details and sends it to the Executive Assistant to National Medical Director, National Office, Private Bag 92071, Victoria Street West, Auckland 1142 within 24 hours of issuing the product to the patient.

5.3 Each month the Executive Assistant to the National Medical Director collates the forms and reconciles these against the Section 29 issues report received from the Business Analyst. The Executive Assistant sends the records to the Regulatory Affairs Associate for review.

5.4 The Regulatory Affairs Associate reviews the Section 29 forms against the issues in eProgesa, completes the Medsafe Declaration/Notification Form 108E001 and returns the records to the Executive Assistant to the National Medical Director.

5.5 The Executive Assistant to the National Medical Director then sends completed 108E001 forms to Medsafe.

5.6 The Executive Assistant to National Medical Director ensures that all records are retained so that they are available for auditing purposes.

6. MINIMUM TRAINING REQUIREMENTS

☐	Complete Document Sign-Off Sheet (108F060). • Read specified sections: Sections: *(enter section numbers)*
☒	Complete Document Sign-Off Sheet (108F060). • Read and understand whole document – Regulatory Affairs Associate, EA to NMD
☐	Complete Document Sign-Off Sheet (108F060). • Formal training required
☐	Complete Training Module *(enter name of module)*
☐	No training required. Specify reason: