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

REASON FOR ISSUE: (DCR35023 applied to add email address/s as appropriate within section 5. Additional changes made for updating DHB to Te Whatu Ora; role designations updated to reflect current business and addition of monthly reporting to CSL Behring.

1. PURPOSE

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

2. SCOPE

NZBS supplies unapproved medicines to medical practitioners for the treatment of a named patient under their care. Section 29 of the Medicine Act (1981) 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

Staff who issue Section 29 medicines, including Te Whatu Ora Blood Banks, are responsible for ensuring that details of the issue are recorded in eTraceline.

Cellular Therapy staff that issue new section 29 cellular therapy components retrospectively into eTraceline will complete the unapproved medicine record 108F064 at the time of actual issue and send to the Regulatory Affairs (RA) team.

The RA team is responsible for reporting section 29 issues made in each reporting period (monthly) to the Medsafe Compliance Management Branch.

4. ITEMS REQUIRED

4.1 Required Documents

- 108F064 Unapproved Medicine Record
- 108F088 Medsafe Declaration/Notification Form for Medicines supplied Pursuant to Section 29 of the Medicines Act 1981
- 111D132 List of Fractionated Products and Recombinant Products Approved for Distribution
- 111D137 Blood and Cellular Therapy Components Issued Under Section 29 of the Medicines Act
- DWR9144 Section 29 Issues report for Medsafe
- DWR9162 CSL Section 29 Issues report for CSL Behring

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5. PROCEDURE

5.1 NZBS supplies a variety of unapproved medicines to medical practitioners including fractionated products and unapproved blood components. The following records are required to be kept:

- The name of the medical practitioner who requested 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 month and year the medicine was supplied
- The name of the place the medicine was supplied to

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 department completes all the details in eTraceline.

5.3 On rare occasions for new cellular therapy components that are unapproved medicines, issue through eTraceline will be carried out retrospectively. In these circumstances Cellular Therapy staff are required to complete the unapproved medicine record 108F064 and send to the RA team.

5.4 Each reporting period the RA team will run Data Warehouse Reports (DWR) which provides a summary of the Section 29 issues.
Access to the DWR is available via the NZBS intranet homepage, BI Portal application.

- **DWR9144** is the report to send to Medsafe of all Section 29 products issued. This is the hyperlink:
  http://aklvmsql12p/reports/report/Information%20Project%20Team/DWR9144%20-%20Section%2029%20Issues
- Input the specific month's start and end date then run the report. Export report data to Excel file and save under appropriate folder on the V drive:
  V:\Regulatory Affairs\Medsafe\Section 29\Section 29 reports\YYYY\Medsafe Notification \MM-YYYY folder
- Replace Header details in row 1 with NZBS logo and in row 2 with the following information:
  "Summary Report of Supply of Unapproved Medicines Under Section 29 of the Medicines Act **01 Month Year – End# Month Year"**.

- **DWR9162** is the report to send to CSL Australia consisting of CSL specific Section 29 products issued. This is the hyperlink:
  http://aklvmsql12p/reports/report/Information%20Project%20Team/DWR9162%20-%20Section%2029%20CSL%20Product%20Issues
- Input the specific month's start and end date then run the report. Export report data to Excel file and save under appropriate folder on the V drive:
  V:\Regulatory Affairs\Medsafe\Section 29\Section 29 reports\YYYY\CSL Notification
- Replace Header details in row 1 with NZBS logo and in row 2 with the following information:
  "Summary Report of Supply of CSL Unapproved Medicines Under Section 29 of the Medicines Act **01 Month Year – End# Month Year"**.

5.5 Any 108F064 forms received during the reporting period will be reconciled against the report and any missing issues will be added.

5.6 The RA team will complete Medsafe Declaration/Notification Form 108F088 with physical signature, scan and send together with report to the Medsafe Compliance Management Branch by email **section29@health.govt.nz**.

5.7 For the notification required to be sent to CSL, save a pdf copy of the signed Medsafe 108F088 page 1 and send with the CSL report produced in 5.4 to the generic email address grpapbmwsasorderenquiry@csl.com.au.

5.8 Updates to DWR9144 to ensure currency are managed via automatic Q-Pulse notification of new versions of data sheets 111D132 and 111D137 to the Business Analyst. Once update of the report is complete the Business Analyst will notify the RA Team.

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 Team
☐	Complete Document Sign-Off Sheet (108F060). • Formal training required
☐	Complete Training Module *(enter name of module)*
☐	No training required. Specify reason: