# NZBS DISPENSING POLICY

**REASON FOR ISSUE: Added new definition for Biosimilars and corrected a typo on p.9 under 42 (4) (a). Updated section 4.3 prescription requirements; Updated section 4.4 for packaging and the change to eTraceline; Updated section 4.5 for hand over details; Clarified the use of eTraceline as the NZBS dispensing register.**

## 1. INTRODUCTION

This document aims to outline the policy for Dispensing of Medicines within NZBS. It is important that systems for dispensing are clearly documented to ensure that the process is undertaken in a manner that is compliant with the requirements of both the Medicines Act 1981 and also the Medicines Amendment Regulations 2011. The policy should be read in conjunction with the relevant regulations of the Medicines Regulations 1984 and the Amendments. These are clearly identified in the text and attached as appendices to the document.

## 2. SCOPE

All Blood Centres and Blood Banks directly managed by NZBS, and Registered Medical Laboratory Scientists working in District Hospital Blood Banks working under a contractual relationship with NZBS (the NZBS supply agreement).

## 3. DEFINITIONS

- **Prescription:**

A request by a Registered Medical Practitioner or Midwife for a Registered, or Section 29, Medicine to be provided for administration by the patient or by a family member or other lay individual. In the context of NZBS this will relate exclusively to prescriptions for fractionated blood products and recombinant coagulation factor products. Such prescriptions shall always be in writing. Prescriptions are valid only if they comply with the requirements of Regulations 39-41 of the Medicines Regulation 1984 and the Medicines Amendment Regulations 2011. Prescriptions that do not meet these requirements shall be returned to the prescriber.

- **Dispensing:**

This involves the process whereby a prescription for a registered medicine is received at an NZBS site and this results in the medicine being provided directly to the patient or his representative for administration by the patient, relative or lay treater. This must be clearly distinguished from issuing of blood products to hospitals or wards for administration by a registered health professional. The policy also applies to Section 29 medicines.

For the purposes of this policy the issuing of a specific immunoglobulin product to a patient or the patient's representative for subsequent administration by a General Practitioner, Midwife or Registered Nurse shall be considered as dispensing.

The rules for dispensing of registered medicines are contained within Regulation 42 of the Medicines Regulations 1984 and the Medicines Amendment Regulations 2011.

At NZBS sites dispensing must be carried out only by Registered Medical Laboratory Scientists or Registered Medical Practitioners.

- **Interchangeable medicines:**

Every medicine will have a *pharmacopeal title* and a *trade name.* The pharmacopeal title describes the product and the trade name defines the product from a single manufacturer.

For example: Pharmacopeal title: Intravenous immunoglobulin
Trade name: Intragam P

Medsafe's website page 'How Medicines are Regulated' defines 'Multi-Source (generic) Medicines' and outlines the rules whereby medicines with a common pharmacopeal title might be interchangeable. Aqueous injectable solutions are considered interchangeable where they are labelled for the same route of administration, and have the same concentration, and are considered therapeutically equivalent to the brand originator. Hence CSL Hepatitis B immunoglobulin and the equivalent product HyperHEP B provided by Talecris can be considered interchangeable.

- **Biosimilars:**

A biosimilar medicine is a new biological product that is similar to another biological medicine that has been granted consent to be marketed in New Zealand (the biological reference). The active substance of a biosimilar is similar, but not identical, to that of the biological reference. Approval is based on pharmacokinetic and pharmacodynamics studies as well as comparative clinical studies.

Data provided to support the application should show no important difference between biosimilar medicines and the biological reference in terms of efficacy and safety. However, consensus regarding the interchangeability of a biosimilar medicine and its reference product has yet to be reached. The prescribing physician should therefore take this into account when considering interchanging the medicines.

- **Substitution:**

It is permissible to substitute one interchangeable medicine for another to fulfil a prescription provided that the authorised prescriber has not marked the prescription 'No brand substitution permitted' or with words of similar meaning; the medicine contains the same active ingredient(s) and is in the same dose form and strength; and there is no clinical reason why the substituted brand should not be supplied (Refer Regulation 42(4) Medicines Amendment Regulations 2011 and Multi-Source (generic) Medicines (Medsafe website). Allowable substitutions for blood products are identified on the NZBS 'approved substitution list' (see 111D003).

- **Informed Consent:**

The requirements for Informed Consent are clearly identified within the NZ Code of Health and Disability Services Consumers' Rights. Specific responsibilities can be identified in the context of dispensing of Medicines. Where a substitution is undertaken then the patient must be informed that this has taken place. This provides an opportunity for the patient to discuss the implications of the substitution with the prescriber prior to self-administration.

Where a substitution is undertaken in a patient who is on regular treatment with a product then the requirement for informed consent is particularly important.

## 4. OUTLINE PROCEDURE FOR DISPENSING WITHIN NZBS

**4.1** Dispensing will be performed only by a Registered Medical Practitioner or a Registered Medical Laboratory Scientist. The person dispensing the medicine must initial the prescription.

**4.2** Blood products will normally be dispensed only when a valid written prescription is provided. However, urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing as defined in Regulations 40A and 42(3)(a). In exceptional circumstances blood products can be dispensed without a prescription as defined in Regulation 44 of the Medicines Regulations 1984 with 2011 amendments. In addition, the Director-General of Health will have the ability to waive the limit on the period of supply in certain circumstances as defined in Regulation 39A(2).

**4.3** On receipt of the prescription the dispenser will:

- Confirm that the prescription is valid as defined in Regulation 41 including-
  - the prescribers' name, signature, street address of their place of work (or postal address if the prescriber does not have a fixed place of work) and telephone number
  - the surname, given name(s) and address of the person for whose use the prescription is written. A date of birth is required if the person is under 13 years old.
  - the specified total amount of medicine or total period of supply.

- Check whether the prescription is for a pharmacopeal title medicine or a trade medicine.
- If a pharmacopeal title medicine then the standard available product will automatically be dispensed.
- If a trade name is used then this product should be dispensed if available.
- Where the specific medicine is not available the following approach must be adopted.
  - Where a valid notification of routine substitution to an individual prescriber is in place then the notified alternative can be routinely substituted. The substitution must be clearly documented on the prescription form.
  - Where a valid notification of routine substitution is not available the prescriber must be informed of the intention to substitute an alternative product before the medicine is dispensed. Where the prescription states 'No brand substitution permitted' or with words of similar meaning then this instruction must be followed.

**4.4** When dispensing the medicine the dispenser will:

- Identify the amount of medicine indicated on the prescription i.e. does not exceed 3 months' supply as defined in Regulation 39A. The prescription shall normally be dispensed in full and must not be dispensed on any occasion after 6 months have elapsed from the date on which the prescription was printed or communicated orally (under 40A). All dispensing details must be recorded each time a prescription is dispensed.
- Select the product. Record the site at which the prescription is dispensed, date dispensed, quantity of medicine dispensed and prescription number as defined in Regulation 42 (3) of the Medicines Amendment Regulations 2011.
- Attach a label to each outer package of the medicine. There is no requirement for individual bottles to be labelled if an outer wrapping covering several bottles is attached by the manufacturer or NZBS. NZBS will provide standard packaging and labels for this purpose.
- The label must comply with Regulation 23 of the Medicines Regulations 1984 as amended in 2011. This requires the label to indicate
  - The surname and given name(s) of the patient
  - The name and address of the facility dispensing the medicine (i.e. NZBS site)
  - The name of the product
  - Instructions for use (in most cases of home treatment this need only state 'use as instructed by your doctor')
  - The date on which the medicines was packed, sold or supplied
  - A unique identifying number or code for the prescription or record of supply. This will be site specific. Where the eTraceline system is installed then the number shall be the 'Issue number' automatically generated by the system.

**4.5** When the medicine is being handed to the patient or patient's representative the dispenser must:

- Confirm that the individual receiving the prescription has authority to do so by asking for a copy of the patient's prescription or asking for the patient's family name, first name, and address.
- Inform the receiver of the storage requirements (e.g. protection from light, refrigeration) and any other specific advice (e.g. Transport time for temperature sensitive products, 'Do not use if seal is broken'). These requirements will normally be clearly identified within the package insert provided by the manufacturer.
- Inform the individual receiving the product if a substitution has been made. In such circumstances the person receiving the prescribed products must be informed that:
  - The product that is being dispensed is different to the product on the prescription
  - That the prescriber is aware that an alternative product is being dispensed.
  - The patient should be advised to contact the doctor who provided the prescription if further advice is requested.

**4.6** When the medicine is sent to the patient by courier or forwarded to another blood bank for issue then the following approach will be adopted:

- The person dispensing the prescription must contact the patient by telephone and provide all relevant information (see point 4.5 above). The patient must be informed if a substitution is being undertaken.
- Where external transport is utilised the person dispensing the prescription must ensure that the medicine is transported in appropriate conditions (e.g. temperature of storage). The patient should also be informed when the product is to be dispatched and the anticipated time of arrival.

**4.7** NZBS must retain the original prescription for record purposes. Where a substitution has been undertaken then this should be clearly documented. Similarly where a patient has been advised of the substitution this should be clearly documented.

**4.8** A record of the dispensing of the product must be entered into a 'Prescription Register' on the day of issue. The Prescription Register shall conform to the requirements of Regulations 55 & 57-58 of the Medicines Amendment Regulations 2011. In addition the batch number of dispensed products will be clearly documented. NZBS will use the 'Dispensing Register' statistics report in eTraceline to demonstrate compliance with this.

## Appendix 1: Extracts from the Medicines Regulations 1984 and Medicines Amendment Regulation 2011

The following Regulations from the Medicines Regulations 1984 and Medicines Amendment Regulations 2011 are attached:

- Regulation 23
- Regulation 39 & 39A
- Regulation 40 & 40A
- Regulation 41
- Regulation 42
- Regulation 43
- Regulation 44
- Regulation 55
- Regulation 57
- Regulation 58

## Requirements for label to be attached to medicine at the point of dispensing

## 23. Labels on containers of medicines sold by authorised prescribers or pharmacists

It shall not be necessary to comply with the requirements of regulation 13 or regulation 16(1) or regulation 22 of these regulations in respect of any label on a container of a medicine that is packed, supplied, or sold by an authorised prescriber or a pharmacist with reference to the needs of a particular patient or (as the case may be) a particular customer, if the label contains the following:

(a) the name of, or a description of the nature of, the contents; and
(b) the name of the patient; and
(c) the name and address of the seller; and
(d) in the case of a medicine for internal use, the dose and frequency of dose; and
(e) in the case of a medicine for external use, a statement of the directions for use and frequency of use, and one or other of the following statements, or words of similar meaning: ``Caution: Not To Be Taken'', or ``For External Use Only''; and
(f) a unique identifying number or code for the prescription or record of supply; and
(g) the date on which the medicine was packed, sold or supplied.

## Requirements of a valid prescription

### 39. Conditions under which authorised prescribers and veterinarians may prescribe prescription medicines

(1) An authorised prescriber (including a designated prescriber) may only prescribe a prescription medicine if the authorised prescriber-
  (a) is prescribing the prescription medicine-
    (i) for the treatment of a patient under the authorised prescriber's care; and
    (ii) within, and in accordance with all conditions (if any) stated in, the authorised prescriber's scope of practice, as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003 by the authority responsible for the registration of the authorised prescriber; and
  (b) is not prohibited by a notice under Section 48 (1) of the Act from prescribing that prescription medicine or any prescription medicines of a class or description that includes that prescription medicine.

(2) An authorised prescriber who is a designated prescriber may only prescribe a prescription medicine if-
  (a) the prescription medicine is of a class or description that the designated prescriber is authorised to prescribe by regulations made under the Act; and
  (b) the requirements specified in or imposed under those regulations are satisfied.

(3) A veterinarian may only prescribe a prescription medicine that is for the treatment of an animal under the veterinarian's care.

(4) Subclause (1) does not apply to an authorised prescriber who is acting in the course of his or her employment by the Crown.

### 39A Limit on period of supply of prescription medicines

(1) An authorised prescriber may not on any occasion prescribe for any patient a quantity of any prescription medicine that exceeds-
  (a) 6 months' supply in the case of an oral contraceptive; or
  (b) 3 months' supply in any other case.

(2) However, the Director-General may, at his or her discretion, authorise-
  (a) an authorised prescriber to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b):
  (b) a class of authorised prescribers to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b).

### 40. Prescriptions to comply with regulations—

(1) Except as provided in regulation 40A, every authorised prescriber or veterinarian who issues a prescription to any person shall comply with regulation 41.

(2) Subclause (1) applies to a prescription for any medicine (whether a prescription medicine or not).

(3) Subclause (2) does not prevent the sale by retail, or the supply in circumstances corresponding to retail sale, or the dispensing, of a medicine (other than a prescription medicine) without a prescription.

## 40A. Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing

(1) Where an authorised prescriber or veterinarian finds it necessary to do so, he or she may communicate orally to a pharmacist to whom he or she is known personally (whether in the pharmacist's presence or by speaking to the pharmacist on the telephone) a prescription relating to a prescription medicine that the authorised prescriber or veterinarian requires urgently.

(2) Within 7 days after a communication made by an authorised prescriber or veterinarian to a pharmacist under subclause (1), the authorised prescriber or veterinarian must forward to the pharmacist a written prescription confirming the oral communication.

## 41. Form of prescription—

Every prescription given under these regulations shall—

(a) be legibly and indelibly printed; and

(b) be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp), and dated; and

(c) set out the following information in relation to the prescriber:

- (i) the prescriber's full name; and
- (ii) the full street address of the prescriber's place of work or, in the absence of the prescriber having a place of work, the postal address of the prescriber; and
- (iii) the prescriber's telephone number; and

(d) set out—

- (i) the surname, each given name, and address of the person for whose use the prescription is given; and
- (ii) in the case of a child under the age of 13 years, the date of birth of the child; and

(e) indicate by name the medicine and, where appropriate, the strength that is required to be dispensed; and

(f) indicate the total amount of medicine that may be sold or dispensed, or the total period of supply; and

(g) if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of dose; and(h) if the medicine is for application externally, indicate the method and frequency of use; and

(j) in the case of a prescription relating to the treatment of an animal,-

(i) set out the surname, each given name, and the address of the owner of the animal; and

(ii) contain the following statement, or words of similar meaning:
``Not for human use".

## Requirements for dispensing

## 42. Dispensing of prescription medicines

(1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinarian, pharmacist, pharmacy graduate, a pharmacy technician, a student or dispensary technician may dispense a prescription medicine.

(1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:
- (a) dispensary technicians:
- (b) pharmacy graduates:
- (c) pharmacy technicians;
- (d) students.

(2) An agent or employee of a veterinarian may, in any particular case, dispense any prescription medicine at the direction of the veterinarian for use in the treatment of any animal under the care of the veterinary surgeon.

(3) Every person dispensing a prescription relating to a prescription medicine must comply with the following requirements:
- (a) if the prescription has been communicated orally under regulation 40A(1), the prescription must not be dispensed more than 1 occasion before the pharmacist has received the written confirmation of the prescription, as required by regulation 40A (2):
- (b) the following information must be recorded on the prescription:
  - (i) the name and address of the proprietor of the business at which the prescription is dispensed; and
  - (ii) the date on which the prescription is dispensed; and
  - (iii) the quantity of medicine dispensed; and
  - (iv) a unique identifying number or code for the prescription:
- (c) a prescription for a medicine other than an oral contraceptive must not be dispensed on any occasion after 6 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:
- (d) a prescription for a medicine that is an oral contraceptive must not be dispensed on any occasion after 9 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:
- (e) every prescription must be retained for a period of 3 years by the pharmacist on the premises on which it was dispensed or at a place approved by the Medical Officer of Health and must be kept in an orderly and consecutive manner so as to be readily available for inspection.

(4) If an authorised prescriber or veterinarian refers in a prescription to a medicine by its trade mark or trade name, or by reference to the name of its manufacturer, a pharmacist may supply an alternative brand of medicine, provided that-
- (a) the authorized prescriber or veterinarian has not marked the prescription “No brand substitution permitted” or with words of similar meaning; and
- (b) the substituted brand contains the same active ingredients, and no other active ingredients; and
- (c) the substituted brand is in the same dose form and strength as the prescribed brand; and.
- d) there is no clinical reason why the substituted brand should not be supplied; and
- (e) the pharmacist records the brand substitution on the prescription; and
- (f) the pharmacist signs and dates the prescription; and
- (g) the pharmacist informs the patient of the brand substitution.

(5) This regulation is subject to regulation 43.

## Scenarios in which a prescription is not required

## 43. Director-General may waive certain requirements

(1) Despite the requirements in regulations 41 and 42, the Director General may, at his or her discretion,-

(a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and

(b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.

(2) A form of prescription that may be authorised under subclause (1)(a) includes, but is not limited to, an electronic form of prescription.

## 44. Prescriptions for prescription medicines not required in certain cases—

A prescription medicine may be sold or dispensed otherwise than under prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber if it is sold to or dispensed for—

(a) a person licensed to sell the prescription medicine by wholesale; or
(b) a person obtaining the prescription medicine for use in any process of manufacture or trade not involving the resale of the medicine; or
(c) an analyst under the Act, or a person approved by the Director-General and in charge of a laboratory maintained for the purposes of research, study, or analysis; or
(d) a hospital care operator within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or
(e) a pharmacist in control of any pharmacy or any dispensary in a hospital care institution within the meaning of section 58(4) of the of the Health and Disability Services (Safety) Act 2001; or;
(f) an authorised prescriber or veterinarian; or
(g) a patient under his or her care by an authorised prescriber; or
(h) a patient under the care of an authorised prescriber, provided that-
    (i) the medicine is administered by a person who has been instructed by the authorised prescriber (either verbally or in writing) to do so, and
    (ii) the person administering the medicine records the administration in the patient's medical records; and
    (iii) the authorised prescriber records the instruction under subparagraph (i) in the patient's medical records; or
(i) the master of a New Zealand ship within the meaning of the Maritime Transport Act 1994.-
    (i) if the medicine is prescribed by rules under section 36(1)(e) of that Act; or
    (ii) at a time before the commencement of the first rules made under section 36(1)(e) of that Act, if the medicine is authorised or required by scales issued under section 138 or section 239 of the Shipping and Seamen Act 1952; or
(ia) the master of a foreign ship within the meaning of the Maritime Transport Act 1994, if the law of the State whose flag the ship is entitled to fly requires the master to carry the medicine; or
(j) a person for inclusion in an emergency medical kit kept or to be kept for use in any vessel to which paragraph (i) of this regulation does not apply, and is so sold or dispensed pursuant to an order signed by a Medical Officer of Health; or
(k) the person in charge of an aircraft if the medicine is required to be carried on the aircraft as a condition of the issue of a certificate of airworthiness; or
(l) a person for inclusion in an emergency medical kit pursuant to an order signed by a Medical Officer of Health for use in a place of a class approved by the Director-General; or

(m) a person who has previously been supplied with the medicine on the prescription of an authorised prescriber for a particular condition, and is so sold or dispensed—
  (i) by a pharmacist who is satisfied that the person requires an emergency supply of the medicine for that condition; and
  (ii) in an amount not exceeding the quantity reasonably required by that person for a period of 72 hours, or a minimum pack of a special container from which it is not practicable to dispense a lesser amount; or

(n) any person by a veterinarian for the treatment of an animal under the care of the veterinarian; or

(o) a person or body authorised to distribute, or a person authorised to administer, the prescription medicine in an approved immunisation programme.

## Record keeping requirements

## 55. Records of sales by retail or wholesale—

(1) Subject to subclause (3) of this regulation, every person who—

(a) Sells by retail any restricted medicine otherwise than pursuant to a prescription; or

(b) Sells by wholesale any prescription medicine, restricted medicine, or pharmacy-only medicine—

shall, before delivery of the medicine to the purchaser, record the sale in a ``Sale of Medicines'' register, or in such other form as the Director-General may from time to time approve.

(2) Subject to subclause (3) of this regulation, the Sale of Medicines register shall, on each page, be ruled in vertical columns so as to make provision for the following entries:

(a) The date of each transaction:

(b) The name of the purchaser:

(c) The address of the place of business or residence of the purchaser:

(d) The name of the medicine sold:

(e) The quantity of the medicine sold:

(f) The signature of the person making the sale.

(3) It shall not be necessary to comply with subclause (1) or subclause (2) of this regulation where, in the case of a sale by wholesale of any prescription medicine, restricted medicine, or pharmacy-only medicine, the matters required to be recorded by subclause (2) of this regulation appear in the books and documents kept by the seller for the purposes of his business.

## 57. Record of supplies pursuant to prescriptions—

(1) Every person who dispenses or supplies any prescription medicine or restricted medicine pursuant to a prescription shall, not later than the ordinary business day next following the day on which the medicine was dispensed or supplied, record that dispensing or supply of the medicine in a ``Prescriptions'' register, or in such other form, or within such other period of time, as the Director-General may from time to time approve.

(a) The date of each transaction:

(b) The name of the patient or (as the case may require) the owner of the animal:

(c) The address of the patient or (as the case may require) the owner of the animal:

(d) The name of the medicine supplied:

(e) The quantity of the medicine supplied:

(f) The name of the prescriber:

(g) In the case of a prescription medicine, the unique identifying number or code of the prescription.

## 58. Records to be kept—

(1) The person responsible for a record to which this Part applies must keep it for at least 3 years after it was made (or, if it is kept together with other records, for at least 3 years after the most recent of them was made).

(2) The person must keep the record-

(a) in a secure place at his or her place of business; or

(b) in some other place authorized by the licensing authority.