

New Zealand Pharmaceutical Schedule

Section A General Rules

Section A contains the restrictions and other general rules that apply to Subsidies for Community Pharmaceuticals and the Giving of Hospital Pharmaceuticals. In order to receive a Subsidy for a Community Pharmaceutical, all relevant requirements of these rules must be observed in each case. Similarly, all relevant requirements must be met if a Hospital Pharmaceutical is to be Given.

These rules only relate to eligibility for Subsidy for Community Pharmaceuticals and the circumstances in which a Hospital Pharmaceutical may be Given. Users of these rules should be aware that there are other requirements relating to the prescribing, dispensing, and Giving, of Pharmaceuticals including legislative and regulatory requirements, as well as contractual obligations.

As required by section 23(7) of the Act, in performing any of its functions in relation to the supply of Pharmaceuticals, a DHB must not act inconsistently with the Pharmaceutical Schedule.

Community Pharmaceuticals that are not Prescription Medicines, will only be Subsidised on a Prescription if the requirements relating to the prescribing and dispensing of Pharmaceuticals including legislative and regulatory requirements, as well as contractual obligations, are met, as they apply to Prescription Medicines,

Defined terms are capitalised. Part 10 of these rules contains a list of definitions.

Part 1 – Prescribing and initiating Subsidies for Community Pharmaceuticals

1.1 **Initiating Subsidies:** Subsidies for Community Pharmaceuticals may be initiated by any of the following:

1.1.1 **Authorised Prescribers** for Prescriptions and Practitioner's Supply Orders (PSO). Specific limitations may apply and these are in addition to any regulatory or scope of practice limitations.

- a Prescriptions written by a Pharmacist Prescriber or a Registered Nurse Prescriber for a Community Pharmaceutical will only be Subsidised where they are for:
 - i a Community Pharmaceutical classified as a Prescription Medicine and which a Pharmacist Prescriber or a Registered Nurse Prescriber is permitted under regulations to prescribe, or
 - ii a Community Pharmaceutical that is a Restricted Medicine (also referred to as a Pharmacist Only Medicine), a Pharmacy Only Medicine or a General Sales Medicine, or
 - iii a Community Pharmaceutical that is a therapeutic medical device or is a related product or related thing to a medicine or therapeutic medical device.

1.1.2 **Hospital Care Operators** only for Bulk Supply Orders (BSO).

1.1.3 **Quitcard Providers** only for nicotine patches, nicotine lozenges or nicotine gum, and when written on a Quitcard.

1.1.4 **Vaccinators** for vaccines, only in accordance with an agreement between the relevant Contractor and the DHB, and only for direct administration of a vaccine to a patient.

1.1.5 **Pharmacists**, by Direct Provision, only where specifically indicated in Section B of the Schedule, unless dispensing on Prescription, Quitcard or Supply Order.

- 1.2 **Periods of supply for Subsidy:** For Community Pharmaceuticals, periods of supply are as follows (note that legislative and regulatory requirements regarding periods of supply must also be met):
- 1.2.1 Only a quantity sufficient to provide treatment for a period of up to 3 Months will be Subsidised, and only if the Prescription under which the Community Pharmaceutical has been dispensed was presented to the Contractor within 3 Months of the date on which the Prescription was written, subject to the following exceptions:
- a **Class B Controlled Drugs:** Only a quantity sufficient to provide treatment for a period of up to 1 Month in total (or up to 5 days when prescribed by a Dentist) will be Subsidised.
 - b **Oral Contraceptives:** The Prescriber must specify on the Prescription the period of treatment for which the oral contraceptive is to be supplied. To be eligible for Subsidy, this period must not exceed 6 Months. Where the Oral Contraceptive is prescribed for non-contraceptive indications, then the Subsidised period of supply is up to 3 Months per Prescription.
 - c **Nicotine Replacement Therapy on Quitcard:** Only a quantity sufficient to provide treatment for a period of up to 3 Months with nicotine patches, lozenges or gum will be eligible for Subsidy.
- 1.3 **Mechanisms for claiming Community Pharmaceutical Subsidies:** Subsidies for Community Pharmaceuticals may be paid against a Prescription (including DHB Hospital chart), PSO, BSO, Quitcard and Direct Provision. Requirements to be eligible for Subsidy are set out below:
- 1.3.1 **Prescriptions** must meet all legislative and regulatory requirements and:
- a must not be used for Pharmaceuticals identified as “Only on a PSO”, and
 - b must meet all the requirements of the Schedule applicable to that Pharmaceutical.
- 1.3.2 **Practitioners Supply Orders (PSO):** For Pharmaceuticals to be Subsidised on a PSO:
- a the PSO must:
 - i be on a form supplied or approved by the Ministry of Health
 - ii be personally signed and dated by the Prescriber
 - iii include the Prescriber’s address, and
 - iv specify the Community Pharmaceuticals and quantities
 - b for a Class B Controlled Drug or for buprenorphine hydrochloride must be written on a triplicate PSO Controlled Drug Form supplied by the Ministry of Health
 - c all the requirements of Section B of the Schedule applicable to the Community Pharmaceutical must be met
 - d the Pharmaceutical must be identified in the Schedule as being Subsidised on a PSO and only be supplied in such quantities as set out in the Schedule (subject to the PSO for Rural Areas and Rheumatic Fever Prevention Programme rules in 1.3.3 and 1.3.4)
 - e Pharmaceuticals will only be Subsidised to ensure they are available for emergency use, teaching and demonstration purposes, and for provision to certain patient groups where an individual Prescription is not practicable, and
 - f Pharmaceuticals will not be Subsidised when supplied on a PSO to:
 - i Armed Forces or Prisons unless specified in Section B of the Schedule, or
 - ii DHB Hospitals or clinics, with the exception of antipsychotic injections for DHB mental health day clinics.

- 1.3.3 **Practitioners Supply Orders for Rural Areas:** Any Community Pharmaceutical may be supplied on a PSO provided rule 1.3.2 and all other applicable requirements are met, and:
- a the Prescriber's normal practice is in a Rural Area, or if the Prescriber is a locum for another Prescriber, then that other Prescriber's normal practice is in such an area, and
 - b the quantities ordered are reasonable for up to 1 Month's supply under the conditions normally existing in the practice. (The Prescriber may be called on to justify the amounts of Community Pharmaceuticals ordered.)
- 1.3.4 **Practitioners Supply Orders for the Rheumatic Fever Prevention Programme (RFPP):** RFPP exceptions to PSO quantity limits are identified in Section B of the Schedule under the specific Community Pharmaceutical. The following additional requirements must be met:
- a the RFPP provider name must be written on the PSO, and
 - b the total quantity ordered must not exceed the RFPP limit specified in Section B of the Schedule.
- 1.3.5 **Bulk Supply Orders (BSO):** For Pharmaceuticals to be Subsidised on a BSO, the BSO must:
- a be for supply of Community Pharmaceuticals to Private Hospitals that employ a Registered Nurse, for the treatment of people under the care of that facility
 - b be on a form supplied or approved by the Ministry of Health and signed by a Hospital Care Operator
 - c for a Class B Controlled Drug or for buprenorphine hydrochloride, be written on a triplicate BSO Controlled Drug Form supplied by the Ministry of Health
 - d not exceed what is a reasonable Monthly allocation for the particular institution
 - e meet all the Subsidy requirements of Section B of the Schedule applicable to that Community Pharmaceutical, and
 - f not be supplied to Armed Forces or Prisons unless specified in Section B of the Schedule.
- 1.3.6 **Quitcards:** Quitcards supplied by the Ministry of Health provide for a Subsidy on nicotine patches, nicotine lozenges or nicotine gum.
- 1.3.7 **Direct Provision:** Subsidies for pharmaceuticals denoted as being eligible for Direct Provision may be generated without a PSO, Prescription or Quitcard.
- 1.4 **Alternative mechanisms:** A DHB may fund a Community Pharmaceutical outside of the mechanisms established in the Schedule, provided that:
- 1.4.1 specific prior agreement is obtained from PHARMAC for such funding
 - 1.4.2 any funding restrictions set out in the Schedule for those Community Pharmaceuticals are applied, and
 - 1.4.3 no Contractor or DHB may claim a Subsidy for a Community Pharmaceutical dispensed and funded by the DHB via such an alternative mechanism.

Part 2 – Access criteria

- 2.1 **Specialist Restrictions:** Some Pharmaceuticals are restricted to use by, or on the recommendation of, certain Specialists for Subsidy. This is indicated for Community Pharmaceuticals by the designation “Retail Pharmacy-Specialist” and for Hospital Pharmaceuticals by Prescriber Restrictions and a list of relevant specialties. In such cases, the following requirements apply:
- 2.1.1 The Community Pharmaceutical is only eligible for Subsidy, or the Hospital Pharmaceutical may only be Given, if prescribed:
- by a Specialist specified in the restriction for that Pharmaceutical or on the recommendation of such a Specialist
 - in accordance with a protocol or guideline that has been approved by the relevant DHB Hospital, or
 - for Hospital Pharmaceuticals only, in an emergency situation, provided that the Prescriber has made reasonable attempts to comply with rule 2.1.1.a or 2.1.1.b above. If on-going treatment is required (that is, beyond 24 hours) subsequent prescribing must comply with rule 2.1.1.a or 2.1.1.b.
- 2.1.2 The Specialist recommendation requirements in rule 2.1.1 can be presumed to have been met, without specific Endorsement by the Prescriber:
- in the case of a Community Pharmaceutical, where a Medical Practitioner or Nurse Practitioner writes the Prescription on DHB stationery and is appropriately authorised by the relevant DHB to do so, and
 - in the case of a Hospital Pharmaceutical, where a Prescriber is working under supervision of a Specialist of a type specified in the restriction for that Hospital Pharmaceutical.
- 2.1.3 Where a Pharmaceutical is prescribed on the recommendation of a Specialist of the type specified for that Pharmaceutical and specific Endorsement is required by the Prescriber:
- the Prescriber must consult with a Specialist of the type specified in the restriction for that Pharmaceutical
 - the consultation must relate to the patient for whom the Prescription is written
 - the consultation may be in person, by telephone, letter, facsimile or email
 - appropriate records must be kept of the consultation, including recording the name of the advising Specialist on the Prescription/chart
 - the recommendation will expire at the end of 2 years and can be renewed by a further consultation, and
 - the Prescription or PSO must be:
 - Endorsed with the words “recommended by [name of Specialist and year of authorisation]” and signed by the Prescriber, or
 - Endorsed with the word “protocol” which means “initiated in accordance with DHB Hospital approved protocol”, or
 - Annotated by the dispensing Pharmacist, following verbal confirmation from the Prescriber or confirmation from an electronic record of the name of the Specialist and date of recommendation, with the words “recommended by [name of Specialist and year of authorisation], confirmed by [Prescriber]”.
- 2.1.4 A DHB Hospital may implement additional Specialist Restrictions (known as a “Local Restriction”), provided that:
- it ensures that the Local Restriction does not unreasonably limit funded access to the Hospital Pharmaceutical or undermine PHARMAC’s decision that the Hospital Pharmaceutical is to be funded, and
 - it provides PHARMAC with details of each Local Restriction that it implements
- 2.1.5 PHARMAC may, when it considers that a Local Restriction does not conform to rule 2.1.4, require a DHB to amend or remove that Local Restriction.

2.2 Hospital Indication Restrictions

- 2.2.1 A DHB Hospital may only Give a Hospital Pharmaceutical that has an Indication Restriction if it is prescribed for treatment of a patient with the particular clinical circumstances set out in the Indication Restriction in the Schedule.
- 2.2.2 If a patient has a current Special Authority Approval for the Hospital Pharmaceutical that the DHB Hospital wishes to Give, then the Indication Restriction is deemed to have been met.
- 2.2.3 If a Hospital Pharmaceutical has an Indication Restriction that is “for continuation only” then the DHB Hospital should only Give the Hospital Pharmaceutical where:
 - a the patient has been treated previously with the Pharmaceutical in the community, or
 - b the patient is unable to be treated with an alternative Hospital Pharmaceutical, and the Prescriber has explained to the patient that the Pharmaceutical is not fully Subsidised in the community.

2.3 Subsidy by Endorsement or Annotation: Prescriptions for some Community Pharmaceuticals require the addition of text by the Prescriber or Pharmacist for Subsidy.

- 2.3.1 Where Endorsement by a Prescriber is required for Subsidy:
 - a Endorsements must be either handwritten or computer generated by the Prescriber, and
 - b the Endorsement must be written as “Certified Condition”, or state the condition of the patient, where that condition is specified in the Schedule as one which is eligible for treatment using the Community Pharmaceutical. Where the Prescriber writes “Certified Condition” as the Endorsement, they are making a declaration that the patient meets the Subsidy criteria as set out in Section B of the Schedule.
- 2.3.2 Where Annotation by a Pharmacist is required for Subsidy:
 - a Annotation of a Prescription by a Pharmacist must be in the Pharmacist’s own handwriting
 - b the Annotation must include the details specified in the Schedule, including the date the Prescriber was contacted (if applicable) and be initialled by the dispensing Pharmacist, and
 - c the Annotation should clearly differentiate the information added by the Pharmacist from that written by the Prescriber

2.4 Special Authority: Special Authority applications are approved or declined via an application process in which a Prescriber requests a Subsidy on a Community Pharmaceutical for a named person.

- 2.4.1 Special Authority approvals may be valid for a defined period, or without further renewal unless notified of a change.
- 2.4.2 The valid Special Authority number must be present on the Prescription
- 2.4.3 Repeat dispensings will be eligible for Subsidy if a Prescription is first dispensed before the Special Authority expiry date, even if the repeats are collected after the Special Authority expiry date, unless the Pharmaceutical has been delisted from the Schedule.
- 2.4.4 Special Authority approvals are not retrospective. The Subsidy applies from the date the Ministry of Health receives a valid application form.
- 2.4.5 Only Medical Practitioners, Dietitians, Nurse Practitioners, Registered Nurse Prescribers, Pharmacist Prescribers and Optometrists are eligible to apply for Special Authority Approvals (initial or renewal).

Part 3 – Dispensing and Giving

- 3.1 **Subsidies and Contractors:** Subsidies are only payable for Community Pharmaceuticals where the Contractor has the appropriate agreement with the Funder.
- 3.1.1 **Community pharmacy Contractors:** Contractors with an agreement for provision of community pharmacy services can dispense and claim for Community Pharmaceuticals other than those specified as “HP3”, “HP4”, “PCT only” or “Xpharm”, unless they have a specific agreement that entitles them to reimbursement for those other specifications.
- 3.1.2 **DHB Hospital Contractors:** Contractors with an agreement to claim DHB Hospital Pharmaceutical can dispense and claim for Community Pharmaceuticals marked as “PCT” or “PCT only”.
- 3.1.3 **Other Contractors:** Other Contractors can claim as specified in their agreement with the Funder.
- 3.2 **Dispensing**
- 3.2.1 A Prescription, or part thereof, will be eligible for Subsidy if it is fulfilled within:
- in the case of a Prescription for the total supply of between 1 and 3 Months, 3 Months from the date the Community Pharmaceutical was first dispensed, or
 - in any other case, 1 Month from the date the Community Pharmaceutical was first dispensed.
- 3.2.2 Only that part of any Prescription that is dispensed within the time frames specified above in rule 3.2.1 is eligible for Subsidy.
- 3.3 **Oral contraceptives:** A Prescription for an oral contraceptive, or part thereof, will only be eligible for Subsidy if it is fulfilled within:
- 3 Months from the date the Prescription was written, or
 - 6 Months from the date the oral contraceptive was first dispensed if the quantity was dispensed in repeat dispensing.
- 3.4 **Dispensing variation:** There are certain circumstances where a Pharmacist may dispense at variance to what has been prescribed and receive a Subsidy. They are:
- 3.4.1 **Substitution:** Where a Prescriber has prescribed a brand of a Community Pharmaceutical that has no Subsidy or has a Manufacturer's Price that is greater than the Subsidy and there is an alternative fully Subsidised Community Pharmaceutical available, a Pharmacist may dispense and claim the fully Subsidised Community Pharmaceutical.
- 3.4.2 **Alteration to presentation of Pharmaceutical dispensed:** When it is not practicable to dispense the requested presentation, a Pharmacist may alter the presentation of a Subsidised Community Pharmaceutical to another Subsidised presentation but may not alter the dose, frequency and/or total daily dose dispensed.
- If the change will result in additional cost to the Funder, then the Pharmacist must Annotate the Prescription.
- 3.5 **Community supply of Hospital Pharmaceuticals from DHB Hospitals:** Except where otherwise specified in Section H of the Schedule, DHB Hospitals may Give any Hospital Pharmaceutical, including a Medical Device, to a patient for use in the community, provided that:
- 3.5.1 the quantity dispensed at any one time does not exceed the amount sufficient for up to 30 days' treatment, unless:
- it would be inappropriate to provide less than the amount in an original pack, or
 - the relevant DHB Hospital has a policy covering dispensing for discharge and the quantity dispensed is in accordance with that policy, and

3.5.2 the Hospital Pharmaceutical is supplied consistent with any applicable restrictions in Section H of the Schedule (includes Indication Restrictions, Local Restrictions and Prescriber Restrictions).

3.6 **Community supply of Medical Devices that are Community Pharmaceuticals from DHB Hospitals:** Medical Devices for use in DHB Hospitals are listed in the Addendum to Part III of Section H of the Schedule. However, there are also Medical Devices that are Community Pharmaceuticals listed in Section B of the Schedule for which the following rules apply:

3.6.1 If supplying for use in the community then the DHB Hospital must supply:

- a the brand of Medical Device that is listed in Section B of the Schedule, and
- b only supply that Medical Device to patients who meet the funding eligibility criteria set out in Section B of the Schedule.

3.6.2 Where a DHB Hospital has supplied a Medical Device and the patient requires a replacement the replacement Medical Device supplied must be consistent with the criteria in rule 3.6.1.

3.7 **Supply of Medical Device consumables from DHB Hospitals**

3.7.1 Where a DHB Hospital has supplied a Medical Device to a patient for use in the community, then the DHB Hospital may continue to fund the associated consumable products while that Medical Device is being used by that patient, provided that:

- a that Medical Device is, or is subsequently, listed in Section B of the Schedule
- b the patient would not meet any funding eligibility criteria for the Medical Device set out in the Section B of the Schedule, and
- c the Medical Device requires the use of associated consumable products to be effective.

3.7.2 DHB Hospitals may also continue to fund consumable products, in accordance with 3.5, in situations where the DHB has been funding consumable products but where the Medical Device was funded by the patient.

Part 4 – Community Pharmaceutical Dispensing Quantities for Subsidy

- 4.1 **Long Term Conditions (LTC) registered patients:** LTC patients can be dispensed to as often as the dispensing Pharmacist deems appropriate to meet that LTC patient's compliance and adherence needs.
- 4.2 **Community Pharmaceuticals identified in the Schedule with the * symbol**
- 4.2.1 Default dispensing is a single Lot, generally 90 days but 180 days for an oral contraceptive.
- 4.2.2 For a non-LTC patient:
- a Pharmacists may authorise dispensing in Monthly Lots without Prescriber authority, or
 - b with Prescriber approval Pharmacists may dispense more often than a Monthly Lot. Verbal approval from the Prescriber is acceptable if Annotated and dated by the Pharmacist on the Prescription.
- 4.3 **Community Pharmaceuticals identified in the Schedule with the ▲ symbol**
- 4.3.1 The Community Pharmaceutical may be dispensed in one Lot where the Prescriber Endorses or Pharmacist Annotates "Certified Exemption" on the Prescription and certifies that:
- a the patient wished to have the Pharmaceutical dispensed in a quantity greater than a Monthly Lot
 - b the patient has been stabilised on the same medicine for a reasonable period of time, and
 - c the Prescriber (or Pharmacist if applicable) has reason to believe the patient will continue to take the medicine as prescribed.
- 4.4 **Community Pharmaceuticals identified in the Schedule without the * or ▲ symbols**
- 4.4.1 Default dispensing is Monthly Lots, or 10 day Lots for Class B Controlled Drugs, other than methylphenidate hydrochloride and dexamfetamine sulfate, in which case default dispensing is Monthly Lots.
- 4.4.2 A Community Pharmaceutical may be dispensed in one Lot in the following circumstances:
- a a patient or their representative signs the Prescription to qualify for single Lot dispensing. In signing the Prescription, the patient or their nominated representative must certify which of the following criteria the patient meets:
 - i they have limited physical mobility
 - ii they live and work more than 30 minutes from the nearest pharmacy by their normal form of transport
 - iii they are relocating to another area, or
 - iv they are travelling and will be away when the repeat Prescriptions are due.
 - b A Class B Controlled Drug may be dispensed in Monthly Lots if the patient meets the requirements of the criteria in 4.4.2.a.
- 4.4.3 Community Pharmaceuticals identified in the Schedule without the * symbol (where default dispensing is Monthly Lots) and prescribed in a quantity sufficient to provide treatment for more than 1 Month may be dispensed in variable dispensing periods under the following conditions:
- a for stock management where the proprietary pack(s) result in dispensing greater than 30 days' supply
 - b to synchronise a patient's medication where multiple medicines result in uneven supply periods, or
 - c when the total quantity and dispensing period does not exceed the total quantity and period prescribed on the Prescription.

Part 5 – Community Pharmaceutical Modified Dispensing Quantities

For the purposes of Part 5, modified dispensing means: less than a single (90 or 180 day) Lot for Pharmaceuticals identified with *, and less than Monthly Lots for any other Pharmaceuticals.

- 5.1 **Unstable medicines:** Where a Community Pharmaceutical is stable for only a limited period, the quantity dispensed at a time may be modified and will remain eligible for Subsidy if the Prescriber has Endorsed or Pharmacist has Annotated the Prescription with:
- 5.1.1 the words “unstable medicine”, and
 - 5.1.2 the maximum quantity that may be dispensed at any one time.
- 5.2 **Residential care:** Community Pharmaceuticals may be dispensed in modified dispensing quantities to a person whose placement in a Residential Disability Care Institution is funded by the Ministry of Health or a DHB, or to a person residing in an Age Related Residential Care Facility, on the request of the person, their agent or caregiver provided that the following conditions are met:
- 5.2.1 The quantity or period of supply to be dispensed at any one time must not be less than:
 - a 7 days' supply for a Class B Controlled Drug, or
 - b 7 days' supply for clozapine in accordance with a Clozapine Dispensing Protocol, or
 - c 28 days' supply for any other Community Pharmaceutical (except under conditions outlined in rule 5.3), and
 - 5.2.2 The Prescriber or dispensing Pharmacist must:
 - a include the name of the patient's residential placement or facility on the Prescription, and
 - b include the patient's National Health Index (NHI) number on the Prescription, and
 - c specify the maximum quantity or period of supply to be dispensed at any one time.
 - 5.2.3 Any person satisfying the requirements of rule 5.2 who is being initiated onto a new medicine or having their dose changed may have their medicine dispensed in accordance with rule 5.3.
- 5.3 **Trial Periods:** Community Pharmaceuticals may be dispensed in modified dispensing quantities to a patient who requires close monitoring due to recent initiation onto a Community Pharmaceutical, or dose change (applicable to the patient's first changed Prescription only) provided that the following conditions are met:
- 5.3.1 The prescriber must:
 - a Endorse each Community Pharmaceutical on the Prescription clearly with the words “Trial Period” or “Trial”, and
 - b specify the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.
 - 5.3.2 Patients who reside in Prisons are not eligible for Trial Periods.
- 5.4 **Safety and co-prescribed medicines**
- 5.4.1 A Community Pharmaceutical identified in the Schedule as a Safety Medicine may be dispensed more frequently than the default frequency specified under rule 4, provided both of the following conditions are met:
 - a the patient is not a resident in a Prison, or one of the residential placements or facilities referenced under rule 5.2, and
 - b the Prescriber has determined the patient requires increased frequency of dispensing, and specified the maximum quantity or period of supply to be dispensed for each Safety Medicine at each dispensing.

5.4.2 A Community Pharmaceutical that is co-prescribed with a Safety Medicine may be dispensed at the same frequency as the Safety Medicine if deemed appropriate by the Pharmacist, in the following circumstances:

- a the criteria in 5.4.1 are met, and
- b the Pharmacist Annotates the Prescription with the amended dispensing quantity and frequency.

5.5 **Pharmaceutical Supply Management:** PHARMAC may activate this rule allowing more frequent dispensing to manage stock supply issues or emergency situations.

5.5.1 Rule 5.5 is activated when PHARMAC has approved and notified Pharmacists to Annotate Prescriptions for a specified Community Pharmaceutical(s) “out of stock” without Prescriber Endorsement for a specified time.

5.5.2 Pharmacists may dispense more frequently than the Schedule would otherwise allow provided that the following conditions are met. The Pharmacist must:

- a clearly Annotate each of the approved Community Pharmaceuticals that appear on the Prescription with the words “out of stock” or “OOS”, and
- b initial the Annotation in their own handwriting, and
- c comply with requirements as to the maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

5.5.3 No Subsidy will be payable for dispensing under this rule where dispensing occurs more frequently than specified by PHARMAC to manage the supply management issue.

Part 6 – Funding

6.1 Subsidies for Community Pharmaceuticals

- 6.1.1 The Subsidy amount that the Funder will pay Contractors for a Community Pharmaceutical dispensed to Eligible People is determined by:
- a the quantities, forms and strengths of Subsidised Community Pharmaceuticals dispensed under valid Prescription by each Contractor
 - b the amount of the Subsidy on the Manufacturer's Price payable for each unit of the Community Pharmaceuticals dispensed by each Contractor, and
 - c the contractual arrangements between the Contractor and the Funder for the payment of the Contractor's dispensing services.
- 6.1.2 A Community Pharmaceutical listed with the designation "Hospital Pharmacy" is eligible for Subsidy only if it is supplied by a hospital or pharmacy contracted by the Funder to dispense as a hospital pharmacy.

6.2 Cost, Brand, Source of Supply (CBS): Where the Subsidy for a Community Pharmaceutical is listed as "CBS" in the Price column in the Schedule, the Subsidy paid will be the purchase price (GST exclusive) of the Community Pharmaceutical, provided that the Contractor includes the following evidence with the Prescription when claiming the Subsidy:

- 6.2.1 the purchase price (GST exclusive), brand and source of supply of the Community Pharmaceutical Annotated on the Prescription, or
- 6.2.2 a copy of the invoice for the purchase of the Community Pharmaceutical attached to the Prescription.

6.3 Multiples: The Schedule includes a multiple field for each listing that may apply a sub-pack Subsidy. A Contractor will automatically be reimbursed on each dispensing to which the sub-pack Subsidy applies, at the time of claiming.

6.4 Wastage and Community Pharmaceuticals: Wastage may only be claimed where a Community Pharmaceutical is prescribed or ordered by a Prescriber in an amount that does not coincide with the amount contained in one or more standard packs from which that Community Pharmaceutical has been dispensed, provided that the following requirements are met:

- 6.4.1 The Pharmacist must minimise wastage by reducing the amount dispensed to make it equal to the quantity contained in a whole pack where:
- a the difference between the amount dispensed and the amount prescribed or ordered by the Prescriber is less than 10% (for example, if a Prescription is for 105 ml then a 100 ml pack would be dispensed), and
 - b in the reasonable opinion of the Pharmacist the difference would not affect the efficacy of the course of treatment prescribed or ordered by the Prescriber.
- 6.4.2 Wastage may only be claimed by the Pharmacist at the time of dispensing for a Community Pharmaceutical that is one of the following:
- a an oral liquid antibiotic that requires a diluent at the time of dispensing (unless the brand is specifically excluded), or
 - b an Unapproved Pharmaceutical supplied under section 29 of the Medicines Act 1981, but excluding any medicine listed as "Cost, Brand, Source of Supply", or
 - c any other Pharmaceutical that PHARMAC determines and identifies as wastage claimable in the Schedule.
- 6.4.3 Any residual product which is subject to a wastage claim must be discarded and must not be used for subsequent dispensing. Intentionally reusing product for which wastage has been claimed is likely to be an act of fraud.
- 6.4.4 At the time of dispensing, the Pharmacist must keep a record of the quantity discarded if wastage is claimed.

- 6.5 **Wastage and DHB Hospital Contractors:** Wastage may be claimed by DHB Hospital Contractors as it applies to Pharmaceuticals as marked as “PCT” or “PCT only”.
- 6.6 **Original Packs (OP):** The Subsidised quantity of a Community Pharmaceutical will be rounded up to the smallest number of containers of the Pharmaceutical sufficient to provide the amount prescribed or ordered when it is:
- 6.6.1 designated as OP in the Schedule, and
 - 6.6.2 packed in a container from which it is not practicable to dispense lesser amounts.

Part 7 – Compounds and Mixtures

- 7.1 **Combinations:** In relation to Community Pharmaceuticals with Subsidy restrictions conditional on whether they are prescribed or combined with or without another Subsidised Pharmaceutical:
- 7.1.1 A Community Pharmaceutical identified as “In Combination” is Subsidised only when prescribed in combination with another Subsidised Pharmaceutical, as specified in Section B or C of the Schedule.
 - 7.1.2 A Community Pharmaceutical identified as “Not In Combination” is Subsidised only when it is not combined with other Community Pharmaceutical ingredients, unless the particular combination of ingredients is separately specified in Section B of the Schedule, and then only to the extent specified.
- 7.2 **Extemporaneously Compounded Preparations (ECP):** For an ECP to be Subsidised, it must contain 2 or more Subsidised component Pharmaceuticals listed in the Schedule. The following ECPs are eligible for Subsidy:
- 7.2.1 the Standard Formulae
 - 7.2.2 oral liquid mixtures for patients unable to swallow Subsidised solid dose oral formulations
 - 7.2.3 the preparation of syringe drivers, and
 - 7.2.4 dermatological preparations when one or more Subsidised Dermatological Galenical(s) is combined in a Subsidised Dermatological Base. Dilution of proprietary topical corticosteroid-plain preparations listed in the Schedule with a Dermatological Base is Subsidised.
- 7.3 **Oral liquid mixtures:** An oral liquid mixture will be eligible for Subsidy if all the requirements of the Schedule applicable to the Pharmaceutical(s) are met.
- However, the following will not be Subsidised:
- 7.3.1 where a Standard Formula exists in the Schedule for a solid dose form, compounding the solid dose form in Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and/or Ora-Sweet SF
 - 7.3.2 mixing 1 or more proprietary oral liquids (for example an antihistamine with pholcodine linctus)
 - 7.3.3 extemporaneously compounding an oral liquid with more than 1 solid dose form
 - 7.3.4 mixing more than 1 extemporaneously compounded oral liquid mixture
 - 7.3.5 mixing 1 or more extemporaneously compounded oral liquid mixtures with 1 or more proprietary oral liquids, or
 - 7.3.6 the addition of a chemical, powder, agent, or solution to a proprietary oral liquid or extemporaneously compounded oral mixture.
- 7.4 **Standard Formulae:** In relation to the list of Standard Formulae in Section C of the Schedule:
- 7.4.1 All ingredients associated with Standard Formulae preparations will be eligible for Subsidy if all relevant requirements are met.
 - 7.4.2 Prescribers may prescribe, or Pharmacists may add, extra non-Subsidised ingredients to the Standard Formulae preparations, but these extra ingredients will not be eligible for Subsidy. The Subsidised ingredients in the formulae will be eligible for Subsidy if all relevant requirements are met.
- 7.5 **Dermatological Preparations:** In relation to dermatological preparations:
- 7.5.1 proprietary topical corticosteroid preparations may be diluted with a Dermatological Base listed under “barrier creams and emollients” in the Schedule and will be eligible for Subsidy
 - 7.5.2 one or more Dermatological Galenicals may be added to a Dermatological Base (including proprietary topical corticosteroid preparations) and will be eligible for Subsidy

- 7.5.3 Prescribers may prescribe or Pharmacists may add extra non-Subsidised ingredients, but these extra ingredients will not be eligible for Subsidy. The Subsidised ingredients in the formula will be eligible for Subsidy if all relevant requirements are met, and
- 7.5.4 the addition of Dermatological Galenicals to diluted proprietary topical corticosteroids-plain will not be Subsidised.
- 7.6 **Hospital use of ECPs:** A DHB Hospital may Give any ECP (whether it is manufactured by the DHB Hospital or by a Contract Manufacturer) to a patient in its care, provided that:
 - 7.6.1 all of the component Pharmaceuticals of the ECP are Hospital Pharmaceuticals, and
 - 7.6.2 the ECP is supplied consistent with any applicable rules or restrictions for its component Hospital Pharmaceuticals.

Part 8 – Funding Exceptions

The Schedule describes the situations under which a Subsidy is payable and/or a product can be used in a DHB Hospital. In general, a DHB Hospital may not Give an Unlisted pharmaceutical, or a Hospital Pharmaceutical outside of any relevant DHB Restrictions. However, there are exceptions and the following describes circumstances under which pharmaceuticals may be Subsidised or Given.

8.1 General Exceptions

- a **Named Patient Pharmaceutical Assessment (NPPA):** An Unlisted pharmaceutical or a Hospital Pharmaceutical outside of any relevant DHB Restrictions may be Given in accordance with the NPPA Policy, or
- b **Paediatric Oncology:** DHB Hospitals may Give (and will be eligible to receive a Subsidy for) any pharmaceutical for use within a paediatric oncology/haematology service for the treatment of cancer.

8.2 Hospital-specific exceptions: In the case of Giving in a DHB Hospital, additional exceptions also apply:

- 8.2.1 **Continuation:** Where a patient's clinical condition has been stabilised by treatment in the community with a pharmaceutical that has not been funded by the Funder, and that patient is admitted to hospital as an inpatient, a DHB Hospital may fund that pharmaceutical for the duration of the patient's stay, where:
 - a the patient has not brought (or cannot arrange to bring) the pharmaceuticals to the DHB Hospital, or the pharmaceuticals brought to the DHB Hospital by the patient cannot be used
 - b interrupted or delayed treatment would have significant adverse clinical consequences, and
 - c it is not considered appropriate to switch treatment to a Hospital Pharmaceutical.
- 8.2.2 **Clinical Trials:** DHB Hospitals may Give any pharmaceutical that is funded by an entity other than a DHB and is being used:
 - a as part of a clinical trial that has Ethics Committee approval, or
 - b for on-going treatment of patients following the end of such a clinical trial.
- 8.2.3 **Pre-Existing Use:** Where a DHB Hospital has Given a pharmaceutical to a patient prior to 1 July 2013, the DHB Hospital may continue to Give that pharmaceutical if it is considered that there would be significant adverse clinical consequences from ceasing or switching treatment, in the following circumstances:
 - a the pharmaceutical is an Unlisted pharmaceutical, or
 - b treatment of the patient would not comply with any relevant DHB Restrictions.
- 8.2.4 **Free stock:** DHB Hospitals may Give any pharmaceutical that is provided free of charge by a supplier, provided that the pharmaceutical is provided as part of a programme of which the DHB or supplier has notified PHARMAC.
- 8.2.5 **Other Government Funding:** DHB Hospitals may Give any pharmaceutical where funding for that pharmaceutical has been specifically provided by a Government entity other than PHARMAC or a DHB, provided the DHB complies with its Crown Funding Agreement.
- 8.2.6 **Out of Scope**
 - a DHB Hospitals have discretion over the use of items that are not currently managed by PHARMAC (except for any pharmaceuticals specifically listed in Section H Part II of the Schedule) including:
 - i Medical Devices
 - ii dialysis fluids
 - iii whole or fractionated blood products
 - iv diagnostic products which have an ex vivo use, such as pregnancy tests and reagents
 - v disinfectants and sterilising products, except those that are to be used in or on a patient

- vi foods and probiotics
 - vii radioactive materials
 - viii medical gases
 - ix parenteral nutrition
 - x pharmaceutical products for in vivo investigation of allergy, and
 - xi pharmaceutical treatments for DHB Hospital staff as part of an occupational health and safety programme.
- b DHB Hospitals may choose whether or not to fund pharmaceutical treatments in these categories, but if they do, they must comply with any National Contract requirements.

Part 9 – National Contracting for Hospital Pharmaceuticals

9.1 Hospital Pharmaceutical Contracts

- 9.1.1 A DHB Hospital may enter into a contract for the purchase of any Hospital Pharmaceutical, including any Medical Device, that it is entitled to fund in accordance with this Schedule and that is not a National Contract Pharmaceutical, provided that such a contract:
- a does not oblige the relevant DHB Hospital to purchase a volume of that Pharmaceutical, if that Pharmaceutical is a DV Pharmaceutical, that is greater than the relevant DV Limit
 - b enables PHARMAC to access and use future Price and volume data in respect of that Pharmaceutical, and
 - c enables the relevant DHB Hospital to terminate the contract or relevant parts of the contract in order to give full effect to any National Contract on no more than 3 Months' written notice to the Pharmaceutical supplier.
- 9.1.2 Following written notification from PHARMAC that a Pharmaceutical is a National Contract Pharmaceutical, either through Section H updates or otherwise, DHB Hospitals must, unless PHARMAC expressly notifies otherwise:
- a take any steps available to them to terminate pre-existing contracts or relevant parts of such a contract, and
 - b not enter any new contracts or extend the period of any current contracts, for the supply of that National Contract Pharmaceutical or the relevant chemical entity or Medical Device.

9.2 National Contract Pharmaceuticals

- 9.2.1 DHB Hospitals must take all necessary steps to enable any contracts between PHARMAC and a Pharmaceutical supplier in relation to National Contract Pharmaceuticals to be given full effect.
- 9.2.2 The contractual arrangement between PHARMAC and the relevant supplier of a National Contract Pharmaceutical requires it to be made available for purchase at the relevant Price by any or all of the following:
- a DHB Hospitals at Designated Delivery Points, and/or
 - b Contract Manufacturers (expressly for the purpose of compounding).
- 9.2.3 In the case of Medical Devices, a National Contract may require the Medical Device to be purchased by, and/or supplied to, a third-party logistics provider.
- 9.2.4 DHB Hospitals may choose whether or not to fund the National Contract Pharmaceuticals that are listed as Optional Pharmaceuticals in Section H Part III of the Schedule, but if they do, they must comply with any National Contract requirements.

9.3 Hospital Supply Status (HSS)

- 9.3.1 If a National Contract Pharmaceutical is listed in Section H of the Schedule as having HSS, DHB Hospitals:
- a are expected to use up any existing stocks of DV Pharmaceuticals during the First Transition Period
 - b must not purchase DV Pharmaceuticals in volumes exceeding their usual requirements, or in volumes exceeding those which they reasonably expect to use, within the First Transition Period
 - c must ensure that Contract Manufacturers, when manufacturing an extemporaneously compounded product on their behalf, use the National Contract Pharmaceutical with HSS, and
 - d must purchase the National Contract Pharmaceutical with HSS except:
 - i to the extent that the DHB Hospital may use its discretion to purchase a DV Pharmaceutical within the DV Limit, provided that the DV Limit has not been exceeded nationally

- ii if the Pharmaceutical supplier fails to supply that National Contract Pharmaceutical, in which case the relevant DHB Hospital does not have to comply with the DV Limit for that National Contract Pharmaceutical during that period of non-supply (and any such Month(s) included in a period of non-supply will be excluded in any review of the DV Limit in accordance with rule 9.3.3)
 - iii that where the DV Limit has been exceeded nationally, the DHB Hospital may negotiate with the Pharmaceutical supplier that supplies the National Contract Pharmaceutical with HSS for written permission to vary the application of that DHB Hospital's individual DV Limit for any patient whose exceptional needs require a DV Pharmaceutical.
- 9.3.2 The DV Limit for any National Contract Pharmaceutical which has HSS is set out in the listing of the relevant National Contract Pharmaceutical in Section H of the Schedule, and may be amended from time to time.
- 9.3.3 PHARMAC may, at its discretion, for any period or part period:
 - a review usage by DHB Hospitals of the National Contract Pharmaceutical and DV Pharmaceuticals to determine whether the DV Limit has been exceeded, and
 - b audit compliance by DHB Hospitals with the DV Limits and related requirements.
- 9.3.4 PHARMAC will address any issues of non-compliance by any individual DHB or DHB Hospital with a DV Limit by:
 - a obtaining the relevant DHB or DHB Hospital's assurance that it will comply with the DV Limit for that National Contract Pharmaceutical with HSS in the remainder of the applicable period and any subsequent periods, and/or
 - b informing the relevant supplier of the HSS Pharmaceutical of any individual DHB or DHB Hospital's non-compliance with the DV Limit for that HSS Pharmaceutical.
- 9.3.5 In addition to the steps taken by PHARMAC in accordance with rule 9.3.4 to address any issues of non-compliance by any individual DHB or DHB Hospital with a DV Limit, the relevant Pharmaceutical supplier may require, at its discretion, as financial compensation from the relevant DHB or DHB Hospital:
 - a an amount representing that DHB or DHB Hospital's contribution towards exceeding the DV Limit (where PHARMAC is able to quantify this based on the information available to it), or
 - b the sum of \$1,000 or \$5,000 (depending on the terms of the applicable National Contract applying to the HSS Pharmaceutical),
 whichever is the greater as between sub-paragraphs a and b within the number of business days specified in the notice from the Pharmaceutical supplier requiring such payment to be made.
- 9.3.6 The terms and conditions of a National Contract shall apply for a National Contract Pharmaceutical which has HSS for a Medical Device. If there is any inconsistency between such a National Contract and these General Rules, for example but not limited to a DV Pharmaceutical or DV Limit, the National Contract shall prevail.

9.4 **Principal Supply Status (PSS)**

- 9.4.1 If a National Contract Pharmaceutical is listed in Section H of the Schedule as having PSS, DHB Hospitals:
- a are expected to use up any existing stocks of DV Pharmaceuticals during the First Transition Period
 - b must not purchase DV Pharmaceuticals in volumes exceeding their usual requirements, or in volumes exceeding those which they reasonably expect to use, within the First Transition Period
 - c must ensure that Contract Manufacturers, when manufacturing an extemporaneously compounded product on their behalf, use the National Contract Pharmaceutical with PSS, and
 - d must purchase the National Contract Pharmaceutical with PSS except:
 - i to the extent that the DHB Hospital may use its discretion to purchase a DV Pharmaceutical within the DV Limit
 - ii to the extent that the DHB Hospital may purchase and Give a DV Pharmaceutical in line with any specific restrictions for use of DV Pharmaceuticals specified in the listing of the relevant National Contract Pharmaceutical
 - iii if the Pharmaceutical supplier fails to supply that National Contract Pharmaceutical, in which case the relevant DHB Hospital does not have to comply with the DV Limit for that National Contract Pharmaceutical during that period of non-supply (and any such Month(s) included in a period of non-supply will be excluded in any review of the use of DV Pharmaceuticals)
 - iv if the DHB Hospital has received approval from Pharmac to purchase and Give a DV Pharmaceutical in circumstances not otherwise provided for in rule 9.4.1.d.
- 9.4.2 The DV Limit for any National Contract Pharmaceutical which has PSS is set out in the listing of the relevant National Contract Pharmaceutical in Section H of the Schedule, and may be amended from time to time.
- 9.4.3 If national use of DV Pharmaceuticals exceeds the Alternative Brand Allowance specified in the applicable National Contract, DHB Hospitals may be required to contribute towards financially compensating the relevant Pharmaceutical supplier, under the terms of the National Contract, based on each DHB Hospital's contribution towards exceeding that Alternative Brand Allowance.
- 9.4.4 The terms and conditions of a National Contract shall apply for a National Contract Pharmaceutical which has PSS for a Medical Device. If there is any inconsistency between such a National Contract and these General Rules, for example but not limited to a DV Pharmaceutical or DV Limit, the National Contract shall prevail.

9.5 **Price and Volume Data**

- 9.5.1 DHB Hospitals must provide to PHARMAC, on a Monthly basis in accordance with PHARMAC's requirements, any volume data and, unless it would result in a breach of a pre-existing contract, Price data held by those DHB Hospitals in respect of any Pharmaceutical (including any Medical Device) listed in Section H of the Schedule.
- 9.5.2 All Price and volume data provided to PHARMAC under rule 9.4.1 will comply with any format and content requirements as reasonably notified by PHARMAC.

- 9.6 **Hospital Pharmaceuticals without contracts:** The Price of a Hospital Pharmaceutical is determined via contractual arrangements between PHARMAC and the relevant Pharmaceutical supplier. Where a Pharmaceutical is listed in Part II of Section H of the Schedule, but no Price and/or brand of Pharmaceutical is indicated, each DHB may purchase any brand and/or pay the Price that the DHB negotiates with the relevant Pharmaceutical supplier.

Part 10 – Definitions

- ▲ 3 Months' supply may be dispensed at one time if the exempted medicine is endorsed 'Certified Exemption' by the Practitioner or Pharmacist.
- * 3 Months' supply dispensed all-at-once or, in the case of oral contraceptives, 6 months' supply dispensed all-at-once, unless modified dispensing quantities apply.
- ✓ fully Subsidised brand of a given medicine. Brands without the tick are not fully Subsidised and may cost the patient a manufacturer's surcharge.
- S29 this medicine is an Unapproved Pharmaceutical supplied under section 29 of the Medicines Act 1981.
- HP3 Subsidised when dispensed from a pharmacy that has a contract to dispense special foods.
- HP4 Subsidised when dispensed from a pharmacy that has a contract to dispense in relation to clozapine services.

Act means the New Zealand Public Health and Disability Act 2000.

Age Related Residential Care Facility means a rest home or hospital that has a contract with a DHB for age related residential care.

Alternative Brand Allowance means, for a particular National Contract Pharmaceutical with PSS, the maximum amount of DV Pharmaceuticals that can be purchased by DHB Hospitals without financial compensation being required to the relevant Pharmaceutical supplier.

Annotation means text written by a Pharmacist on a Prescription, and **Annotate** and **Annotated** have corresponding meanings.

Armed Forces has the meaning given in the Defence Act 1990.

Authorised Prescriber has the meaning given in the Medicines Act 1981 and includes:

- a Practitioner (Medical Practitioner or a Dentist), Nurse Practitioner, Optometrist and Registered Midwife, or
- a Designated Prescriber (which includes a Dietitian, Pharmacist Prescriber and Registered Nurse Prescriber).

Bulk Supply Order (BSO) means a written order for the supply of Community Pharmaceuticals, on a form supplied by the Ministry of Health, or approved by the Ministry of Health.

Clozapine Dispensing Protocol has the meaning given in the current agreement for provision of community pharmacy services.

Community Pharmaceutical means a Pharmaceutical listed in Sections B to D or I of the Schedule that is Subsidised by the Funder from the Combined Pharmaceutical Budget.

Contractor means a person who is entitled to receive a payment from the Crown or a DHB under a notice issued by the Crown or a DHB under section 88 of the Act or under a contract with the Ministry of Health or a DHB for the supply of Community Pharmaceuticals.

Contract Manufacturer means a manufacturer or a supplier that is a party to a contract with the relevant DHB Hospital to compound Pharmaceuticals, on request from that DHB Hospital.

Controlled Drug means a controlled drug within the meaning of the Misuse of Drugs Act 1975 (other than a controlled drug specified in Part 6 of the Third Schedule to that Act).

Controlled Drug Form means a form approved by the Director-General or a form that is electronically generated from an approved system.

Cost, Brand, Source of Supply is a designation which, when applied to a specific Pharmaceutical, means that the Community Pharmaceutical is eligible for Subsidy on the basis of the Contractor's Annotated purchase price, brand, and source of supply.

Crown Funding Agreement means the agreement of that name between the Minister of Health and DHBs. Through the CFA the Crown agrees to provide funding in return for service provision as specified in the CFA.

Dentist means a health practitioner who is, or is deemed to be, registered with the Dental Council of New Zealand established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of dentistry.

Dermatological Base means a standard medicinal preparation used topically that may have a Dermatological Galenical added. For the purposes of the Schedule, Dermatological Bases are barrier creams and emollients, collodion flexible and proprietary topical corticosteroid-plain preparations in Section B of the Schedule.

Dermatological Galenical means an ingredient subsidised for use in a topical extemporaneously compounded product and listed in the Dermatologicals therapeutic group in Section B of the Schedule with the restriction - "Only in combination".

Designated Delivery Point means at a DHB Hospital's discretion:

- a. a delivery point agreed between a Pharmaceutical supplier and the relevant DHB Hospital, to which delivery point that Pharmaceutical supplier must supply a National Contract Pharmaceutical directly at the Price, and/or
- b. any delivery point designated by the relevant DHB Hospital or PHARMAC, such delivery point being within 30 km of the relevant Pharmaceutical supplier's national distribution centre.

Designated Prescriber has the meaning given in the Medicines Act 1981.

DHB means an organisation established as a District Health Board by or under section 19 of the Act.

DHB Hospital means a hospital and/or an associated health service that is provided by a DHB.

DHB Hospital Contractors means Contractors with an agreement to dispense and claim for Community Pharmaceuticals marked as "PCT" or "PCT only".

DHB Restriction means a limitation, put in place by PHARMAC or a DHB, restricting the funding of a Hospital Pharmaceutical and includes an Indication Restriction, a Local Restriction and a Prescriber Restriction.

Dietitian means a health practitioner registered with the Dietitians Board of New Zealand established by the Health Practitioners Competence Assurance Act 2003.

Direct Provision means supply of a Pharmaceutical for Subsidy not dispensed on Prescription, Quitcard or Supply Order.

DV Limit means:

1. for a particular National Contract Pharmaceutical with HSS, the national DV Limit or the individual DV Limit.
2. for a particular National Contract Pharmaceutical with PSS, the individual DV Limit.

DV Pharmaceutical means a "discretionary variance" Pharmaceutical that does not have HSS or PSS but is used in place of one that does. Usually this means it is the same chemical entity, at the same strength, and in the same or a similar presentation or form, as the relevant National Contract Pharmaceutical with HSS or PSS. Where this is not the case, a note will be included with the listing of the relevant Pharmaceutical.

Eligible People means people who are eligible to receive services funded under the Act, and **Eligible Person** has a corresponding meaning.

Endorsement means text written by the Prescriber on a Prescription to either gain a Subsidy, or gain a higher Subsidy, for a patient, where Subsidy criteria apply to the Community Pharmaceutical, and **Endorsed** has a corresponding meaning.

Ethics Committee means a Health and Disability Ethics Committee (HDEC) which is a Ministerial committee established under section 11 of the Act.

Extemporaneously Compounded Preparation means a preparation prepared for an individual patient in response to an identified need.

First Transition Period means the period of time after notification that a Hospital Pharmaceutical has been awarded HSS or PSS and before HSS or PSS is implemented.

Funder means the body or bodies responsible for the funding of Pharmaceuticals listed on the Schedule (which may be one or more DHBs and/or the Ministry of Health) and their successors, as set out in the Act.

Give means to administer, provide or dispense (or, in the case of a Medical Device, use) a Hospital Pharmaceutical, or to arrange for the administration, provision or dispensing (or, in the case of a Medical Device, use) of a Hospital Pharmaceutical, and **Given** and **Giving** have corresponding meanings.

General Sales Medicines has the meaning given in section 99 of the Medicines Act 1981.

Government means the Government of New Zealand.

GST means goods and services tax under the Goods and Services Tax Act 1985.

Hospital Care Operator means a person in charge of providing hospital care, in accordance with the Health and Disability Services (Safety) Act 2001.

Hospital Pharmaceuticals means the list of Pharmaceuticals set out in Section H Part II of the Schedule which includes some National Contract Pharmaceuticals.

Hospital Supply Status (HSS) means the status of being the brand of the relevant National Contract Pharmaceutical that DHBs are obliged to purchase, subject to any DV Limit, for the period of hospital supply, as awarded under an agreement between PHARMAC and the relevant Pharmaceutical supplier.

In Combination is a designation which, when applied to a specific Community Pharmaceutical, means that the Community Pharmaceutical is only Subsidised when prescribed in combination with another Subsidised Pharmaceutical as specified in Section B or C of the Schedule.

Indication Restriction means a limitation placed by PHARMAC on the funding of a Hospital Pharmaceutical which restricts funding to treatment of particular clinical circumstances.

Local Restriction means a restriction on the use of a Hospital Pharmaceutical in specific DHB Hospital(s) on the basis of Prescriber type.

Long Term Conditions has the meaning given in the current agreement for the provision of community pharmacy services.

Lot means a quantity of a Community Pharmaceutical supplied in one dispensing.

Manufacturer's Price means the standard Price at which a Community Pharmaceutical is supplied to wholesalers (excluding GST), as notified to PHARMAC by the supplier.

Medical Device has the meaning set out in section 3A of the Medicines Act 1981.

Medical Practitioner means a health practitioner who is, or is deemed to be, registered with the Medical Council of New Zealand continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of medicine.

Ministry of Health means the department of the Public Service referred to by that name.

Month means a period of 30 consecutive days, and **Monthly** has a corresponding meaning.

Monthly Lot means the quantity of a Community Pharmaceutical required for the number of days of treatment covered by the Prescription, being up to 30 consecutive days' treatment.

Named Patient Pharmaceutical Assessment means a mechanism to consider funding for pharmaceutical treatments in exceptional circumstances where pharmaceutical treatments are not listed or not listed for the same indication on the Schedule.

National Contract means a contractual agreement between PHARMAC and a Pharmaceutical supplier which sets out the basis on which any Pharmaceutical may be purchased for use in a DHB Hospital, including an agreement as to a national Price.

National Contract Pharmaceutical means a brand of Pharmaceutical listed in Section H of the Schedule, in respect of which PHARMAC has entered into a National Contract. Such Pharmaceuticals are identifiable in Section H of the Schedule because the relevant listing identifies the brand and Price.

National Health Index (NHI) Number means the unique identifier that is assigned to every person who uses health and disability support services in New Zealand.

Not In Combination is a designation which, when applied to a specific Pharmaceutical, means that Subsidy is only available when it is not combined with other Community Pharmaceutical ingredients unless the particular combination of ingredients is separately specified in Section B of the Schedule, and then only to the extent specified.

NPPA Policy means the policy which must be met for a Named Patient Pharmaceutical Assessment application to be considered for funding.

Nicotine Replacement Therapy means treatment with any of the nicotine products listed in Section B of the Schedule, namely nicotine patches, gum and lozenges.

Nurse Practitioner means a health practitioner who is, or is deemed to be, registered with the Nursing Council of New Zealand continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of nursing and whose scope of practice permits the performance of nurse practitioner functions.

Optional Pharmaceuticals means the list of National Contract Pharmaceuticals set out in Section H Part III of the Schedule.

Optometrist means a person who is, or is deemed to be, registered with the Optometrists and Dispensing Opticians Board as a practitioner of optometry, and for whom the Optometrists and Dispensing Opticians Board has authorised a scope of practice that includes prescribing medicines.

Original Pack (OP) is a designation applied to some Pharmaceuticals.

Outpatient in relation to a Community Pharmaceutical, means a person who, as part of treatment at a hospital or other institution funded by a DHB, is prescribed the Community Pharmaceutical for consumption or use outside the hospital or other institution.

PCT means a Pharmaceutical listed in Section B of the Schedule that a DHB Hospital Contractor may claim a subsidy payment for, and identified therein as a "PCT" or "PCT only" Pharmaceutical.

PCT only is a designation which, when applied to a specific Community Pharmaceutical, means a Pharmaceutical of which only a DHB Hospital Pharmacy can claim a subsidy.

PHARMAC means the Pharmaceutical Management Agency established by section 46 of the Act (PHARMAC).

Pharmaceutical means a medicine, therapeutic medical device, or related product or related thing listed in Sections B to I of the Schedule.

Pharmacist Only Medicine has the same meaning as Restricted Medicine, given in the Medicines Act 1981.

Pharmacist means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy.

Pharmacist Prescriber means a Pharmacist for whom the Pharmacy Council has authorised a scope of practice that includes prescribing medicines.

Pharmacy Only Medicine has the meaning given in section 3 of the Medicines Act 1981.

Practitioner means a Prescriber or any of the following: a Quitcard Provider, a Pharmacist, or a Vaccinator as those terms are defined in the Schedule.

Practitioner's Supply Order (PSO) means a written order made by a Prescriber on a form supplied by the Ministry of Health, or approved by the Ministry of Health, for the supply of Community Pharmaceuticals to the Prescriber.

Prescriber means a Medical Practitioner, a Dentist, a Dietitian, a Registered Midwife, a Nurse Practitioner, a Registered Nurse Prescriber, an Optometrist, or a Pharmacist Prescriber.

Prescriber Restriction means a restriction placed by PHARMAC on the funding of a Hospital Pharmaceutical on the basis of Prescriber type (and where relevant in these rules, includes a Local Restriction).

Prescription means an order, in a form complying with Part 7 of the Medicines Regulations 1984, for a quantity of a Community Pharmaceutical prescribed for a named person by a Prescriber.

Prescription Medicine has the meaning given in clause 3 of the Medicines Act 1981.

Price means the standard national price for a National Contract Pharmaceutical in Section H of the Schedule, and, unless agreed otherwise between PHARMAC and the Pharmaceutical supplier, includes any costs associated with the supply of the National Contract Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Point, or to a Contract Manufacturer (expressly for the purpose of compounding), but does not include the effect of any rebates which may have been negotiated between PHARMAC and the Pharmaceutical supplier. Price has a different meaning to Manufacturer's Price.

Principal Supply Status (PSS) means, in relation to a Hospital Pharmaceutical, the status of being the principal brand of the relevant National Contract Pharmaceutical that DHBs are obliged to purchase, subject to any DV Limit or any other provisions outlined in these Rules, for the period of hospital supply, as awarded under an agreement between Pharmac and the relevant Pharmaceutical supplier.

Prison means a prison, as that term is defined in the Corrections Act 2004.

Private Hospital means a hospital certified to provide hospital care under the Health and Disability Services (Safety) Act 2001 that is not owned or operated by a DHB.

Quitcard means an individually numbered exchange card issued by an authorised Quitcard Provider to an Eligible Person for the purposes of that Eligible Person accessing Subsidised Nicotine Replacement Therapy.

Quitcard Provider means a person registered with the Ministry of Health as a Quitcard Provider.

Registered Midwife means a health practitioner who is, or is deemed to be, registered with the Midwifery Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of midwifery.

Registered Nurse means a health practitioner who is, or is deemed to be, registered with the Nursing Council of New Zealand continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of nursing.

Registered Nurse Prescriber means a Registered Nurse for whom the Nursing Council has authorised a scope of practice that includes prescribing medicines as a Designated Prescriber.

Residential Disability Care Institution means premises used to provide residential disability care in accordance with the Health and Disability Services (Safety) Act 2001.

Restricted Medicine has the meaning given in section 3 of the Medicines Act 1981.

Rheumatic Fever Prevention Programme (RFFP) means a programme so designated by the Ministry of Health.

Rural Area means an area locally determined as rural by the appropriate DHB.

Safety Medicine means a Community Pharmaceutical identified in the Schedule as a Safety Medicine.

Schedule means this Pharmaceutical Schedule and all its sections and appendices.

Section 29 is a designation which, when applied to a specific Pharmaceutical, means this medicine is an Unapproved Pharmaceutical supplied under section 29 of the Medicines Act 1981.

Specialist, in relation to a Prescription, means a Medical Practitioner or Nurse Practitioner who satisfies any of the criteria set out in the paragraphs below:

- a. the Medical Practitioner is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the Health Practitioners Competence Assurance Act 2003 and has written the Prescription in the course of practising in that area of medicine, or
- b. the Medical Practitioner is recognised by the Ministry of Health as a Specialist for the purposes of this Schedule and who has written that Prescription in the course of practising in that area of competency, or
- c. the Medical Practitioner is recognised by the Ministry of Health as a Specialist in relation to a particular area of medicine for the purpose of writing Prescriptions and has written the Prescription in the course of practising in that area of competency, or
- d. the Medical Practitioner or Nurse Practitioner writes the Prescription on DHB stationery and is appropriately authorised by the relevant DHB to do so.

Specialist, in relation to a Specialist recommendation requirement, means a Medical Practitioner who satisfies any of the criteria set out in the paragraphs below:

- a. the Medical Practitioner is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the Health Practitioners Competence Assurance Act 2003 and has written the Prescription in the course of practising in that area of medicine, or
- b. the Medical Practitioner is recognised by the Ministry of Health as a Specialist for the purposes of this Schedule and has written that Prescription in the course of practising in that area of competency, or
- c. the Medical Practitioner is recognised by the Ministry of Health as a Specialist in relation to a particular area of medicine for the purpose of writing Prescriptions and has written the Prescription in the course of their employment by a DHB and while practising in that area of competency.

Specialist Restriction means a restriction on use for Subsidy indicated on Community Pharmaceuticals by the designation "Retail Pharmacy-Specialist" and, on Hospital Pharmaceuticals, Prescriber restrictions and a list of relevant specialties.

Special Authority is a designation in relation to a Pharmaceutical which means that the Pharmaceutical is only eligible for Subsidy or additional Subsidy on approval of an application for a named person which meets the criteria specified in the Schedule.

Special Authority Approval means an approval relating to an application for Special Authority.

Standard Formulae means a list of formulae for Extemporaneously Compounded Preparations that are Subsidised.

Subsidy means the amount the Funder will pay Contractors for a Community Pharmaceutical dispensed to an Eligible Person (excluding GST). Subsidy does not include mark-ups and service fees. **Subsidised** has a corresponding meaning.

Supply Order means a Bulk Supply Order or a Practitioner's Supply Order.

Trial Period means a modified dispensing quantity of a Community Pharmaceutical to a patient in circumstances specified in rule 5.3.

Unapproved Pharmaceutical means a Pharmaceutical that is an unapproved medication supplied under section 25 or section 29 of the Medicines Act 1981.

Unlisted Pharmaceutical means a Pharmaceutical that is within the scope of a Hospital Pharmaceutical that is not specifically listed in Section H Part II of the Schedule.

Vaccinator means either:

- a. a Pharmacist who has successfully completed a Vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, or
- b. any other person who is authorised by the Director-General of Health or a Medical Officer of Health to administer vaccines in accordance with regulation 44A of the Medicines Regulations 1984.