Draft for consultation

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 under the Community Pharmacy Services Agreement or otherwise.

Defined terms are capitalised. A list of definitions is contained in Part 10 of these rules.

Part 1 – Prescribing and initiating Subsidies for Community Pharmaceuticals

1a. **Initiating Subsidies.** Subsidies for Community Pharmaceuticals may be initiated by any of the following:

i. **Authorised Prescribers** for Prescriptions, direct provision and Practitioner's Supply Orders. 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 either:
      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. any other Community Pharmaceutical that is a Restricted Medicine (also referred to as a Pharmacist Only Medicine), a Pharmacy Only Medicine or a General Sales Medicine.

ii. **Hospital Care Operators**, only in the case of Bulk Supply Orders.

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

iv. **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.

v. **Pharmacists** only where specifically indicated in Section B of the Pharmaceutical Schedule, unless dispensing on Prescription, Quitcard or Supply Order.

1b. **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):

i. Only a quantity sufficient to provide treatment for a period of up to three Months will be Subsidised, and only if the Prescription under which the Community Pharmaceutical has been dispensed was presented to the Contractor within three 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 one Month in total (or up to five days when prescribed by a Dentist) will be Subsidised and only if presented to the Contractor within eight days of the date on which the Prescription was written (or within four days for a Midwife Prescription).
b. **Oral Contraceptives**. The Prescriber must specify on the Prescription the period of treatment for which the Oral Contraceptive is to be supplied. In order to be eligible for Subsidy, this period must not exceed six Months. Where the Oral Contraceptive is prescribed for non-contraceptive indications, then the Subsidised period of supply is up to three Months per Prescription.
c. **Nicotine Replacement Therapy on Quitcard**. Only a quantity sufficient to provide treatment for a period of up to three Months with nicotine patches, lozenges or gum will be eligible for subsidy.

1c. Mechanisms for claiming Community Pharmaceutical Subsidies. Subsidies for Community Pharmaceuticals may be paid against Prescriptions (including DHB Hospital charts), Practitioners Supply Orders, Bulk Supply Orders, Quitcards and as a result of direct provision by a Prescriber. Requirements to be eligible for subsidy are set out below.

i. **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.

ii. **Practitioner's Supply Orders (PSO)**. For Subsidy on a PSO, pharmaceuticals:
   a. 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 Practitioner's Supply Order Controlled Drug Form supplied by the Ministry of Health;
   c. must meet all the requirements of Section B of the Schedule applicable to that Community Pharmaceutical;
   d. must be identified in the Schedule as being Subsidised on a PSO and only in such quantities as set out in the Schedule (subject to the PSO for rural areas and Rheumatic Fever Prevention Programme rules in 1(c)(iv);
   e. will only be Subsidised to ensure pharmaceuticals 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. will not be Subsidised when supplied 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.

iii. **Practitioner's Supply Orders (PSO) for rural areas.** Any Community Pharmaceutical may be supplied on a PSO provided:
   a. Rule 1 c (ii) and all other applicable requirements are met; and
      I. the Prescriber's normal practice is in a rural area, or if the Prescriber is a locum for another Prescriber, that other Prescriber's normal practice is in such an area; and
      II. the quantities ordered are reasonable for up to one 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).

iv. **Practitioner's Supply Orders (PSO) 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.

v. **Bulk Supply Orders (BSO).** For Subsidy on BSO, pharmaceuticals:
   a. must be for supply of Community Pharmaceuticals to Private Hospitals that who employ a Registered Nurse, for the treatment of people under the care of that facility;
   b. must 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, must be written on a triplicate Practitioner's Supply Order Controlled Drug Form supplied by the Ministry of Health;
   d. must not exceed what is a reasonable Monthly allocation for the particular institution;
   e. must meet all the Subsidy requirements of Section B of the Schedule applicable to that Community Pharmaceutical; and
   f. must not be supplied to Armed Forces or Prisons unless specified in Section B of the Schedule.

vi. **Quitcards.** Quitcards provide for a Subsidy for nicotine patches, nicotine lozenges or nicotine gum where these are written on a Quitcard supplied by the Ministry of Health.

1d. Alternative mechanisms. A DHB may fund a Community Pharmaceutical outside of the mechanisms established in the Pharmaceutical Schedule, provided that:

i. specific prior agreement is obtained from PHARMAC for such funding;
ii. any funding restrictions set out in the Pharmaceutical Schedule for those Community Pharmaceuticals are applied; and
iii. 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

2a. Specialist Restrictions. Some pharmaceuticals are restricted to use by, or on the recommendation of, certain Specialists, for Subsidy. This is indicated on Community Pharmaceuticals by "Retail Pharmacy-Specialist" and, on Hospital Pharmaceuticals, Prescriber restrictions and a list of relevant specialties. In such cases, the following requirements apply:

i. The Community Pharmaceutical is only eligible for Subsidy, or the Hospital Pharmaceutical may only be Given if prescribed:
   a. by a Specialist specified in the restriction for that Pharmaceutical or on the recommendation of such a Specialist;
   b. in accordance with a protocol or guideline that has been approved by the relevant DHB Hospital; or
   c. for Hospital Pharmaceuticals only, in an emergency situation, provided that the Prescriber has made reasonable attempts to comply with rule 2a(i)(a). above. If on-going treatment is required (i.e. beyond 24 hours) subsequent prescribing must comply with rule 2a(i)(a).

ii. The Specialist recommendation requirements can be presumed to have been met, without specific Endorsement by the Prescriber:

a. in the case of a Community Pharmaceutical, where a Doctor or Nurse Practitioner writes the Prescription on DHB stationery and is appropriately authorised by the relevant DHB to do so.

b. 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; and

iii. 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:
   a. the Prescriber must consult with a Specialist of the type specified in the restriction for that Pharmaceutical;
   b. the consultation must relate to the patient for whom the Prescription is written;
   c. the consultation may be in person, by telephone, letter, facsimile or email;
   d. appropriate records must be kept of the consultation including recording the name of the advising Specialist on the Prescription/chart; and
   e. the recommendation will expire at the end of two years and can be renewed by a further consultation.
   f. the Prescription or Practitioner's Supply Order must be:
      I. Endorsed with the words "recommended by [name of Specialist and year of authorisation]" and signed by the Prescriber;
      II. Endorsed with the word 'protocol' which means "initiated in accordance with DHB Hospital approved protocol"; or
      III. Annotated by the dispensing Pharmacist, following verbal confirmation from the Prescriber (or 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]".

iv. A DHB Hospital may implement additional Specialist Restrictions (known as a "Local Restriction"), provided that:
   a. 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;
   b. it provides PHARMAC with details of each Local Restriction that it implements; and
   c. PHARMAC may, when it considers that a Local Restriction does not conform to the rule 2(a)(iv), require a DHB to amend or remove that Local Restriction.

2b. Hospital Indication Restrictions

i. 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.

ii. 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.

iii. 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.

2c **Subsidy by Endorsement or Annotation**. Prescriptions for some Community Pharmaceuticals require the addition of text by the Prescriber or Pharmacist for Subsidy.

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 for the Community Pharmaceutical in the Pharmaceutical Schedule. Where the Prescriber writes "Certified Condition" as the Endorsement, he/she is making a declaration that the patient meets the Subsidy criteria as set out in Section B of the Pharmaceutical Schedule.

ii. 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 following confirmation from the Prescriber if required; and
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.
c. the Annotation should clearly differentiate the information added by the Pharmacist from that written by the Prescriber

2d. **Special Authority.** Special Authority means that the Community Pharmaceutical or t is only eligible for Subsidy or additional Subsidy for a named person if an application meeting the criteria specified in the Pharmaceutical Schedule has been approved, and the valid Special Authority number is present on the Prescription

i) Special Authority applications are approved or declined via an application process in which a Prescriber requests Subsidy on a Community Pharmaceutical for a named person.
ii) Special Authority approvals may be valid for a defined period, or without further renewal unless notified of a change.
iii) 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 Pharmaceutical Schedule.
iv) Special Authority approvals are not retrospective. The Subsidy applies from the date of receipt of a valid application form at the Ministry of Health.
v) Only Doctors, Dietitians, Nurse Practitioners and Optometrists are eligible to apply for Special Authority approvals (initial or renewal).

Part 3 – Dispensing and Giving

3a. **Subsidies and Contractors.** Subsidies are only payable for Community Pharmaceuticals where the Contractor has the appropriate agreement with the Funder**.**

i. **Community pharmacies.** Contractors with the base Community Pharmacy Services Agreement 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 specifications.
ii. **DHB Hospital Contractors.** Contactors with an agreement to claim DHB Hospital Pharmaceutical Cancer Treatments t can dispense and claim for Community Pharmaceuticals marked as "PCT" or "PCT only".
iii. **Other Contractors.** Other Contractors can claim as specified in their agreement with the Funder.

3b. Repeat dispensing.

i. A Prescription, or part thereof, will be eligible for Subsidy, if it is fulfilled within:
   a. in the case of a Prescription for the total supply of between one to three Months, three Months from the date the Community Pharmaceutical was first dispensed; or
   b. in any other case, one Month from the date the Community Pharmaceutical was first dispensed.

ii. Only that part of any Prescription that is dispensed within the time frames specified above in rule 3b(i) and 3b(ii) are eligible for Subsidy.

3c. Oral Contraceptives. A Prescription for an Oral Contraceptive, or part thereof, will only be eligible for Subsidy, if it is fulfilled within:

i. three Months from the date the Prescription was written; or
ii. six Months from the date the Oral Contraceptive was first dispensed if the quantity was dispensed in repeat dispensing.

3d. Dispensing variation. There are certain circumstances where a Contractor may dispense at variance to what has been prescribed and receive subsidy. They are:

i. Substitution:
   a. 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 Contractor may dispense and claim the fully Subsidised Community Pharmaceutical).

ii. Alteration to presentation of pharmaceutical dispensed:
   a. when it is not practicable to dispense the requested presentation, a Contractor 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.
   b. if the change will result in additional cost to the Funder s, then Annotation of the Prescription by the Contractor must occur. t.

3e. Community supply of Hospital Pharmaceuticals from DHB Hospitals.

i. Except where otherwise specified in Section H of the Pharmaceutical Schedule, DHB Hospitals may Give any Hospital Pharmaceutical, including a Medical Device, to a patient for use in the Community, provided that:
   a. the quantity dispensed at any one time does not exceed the amount sufficient for up to 30 days' treatment, unless:
      I. it would be inappropriate to provide less than the amount in an original pack; or
      II. the relevant DHB Hospital has a policy covering dispensing for discharge and the quantity dispensed is in accordance with that policy; and
   b. the Hospital Pharmaceutical is supplied consistent with any applicable Section H restrictions (includes Indication Restrictions, Local Restrictions and Prescriber Restrictions).

3f. Community supply of Medical Devices that are Community Pharmaceuticals from DHB Hospitals.

i. Medical Devices for use in DHB hospitals are listed in the Addendum to Part 3 of Section H of the Schedule. However, there are also Medical Devices that are Community Pharmaceuticals in Section B of the Schedule for which the following rules apply:
   a. Where a Medical Device is a Community Pharmaceutical, if supplying for use in the Community then the DHB Hospital must supply:

I. the brand of Medical Device that is listed in Section B of the Schedule; and
II. only supply that Medical Device to patients who meet the funding eligibility criteria set out in Section B of the Schedule.

b. 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(f)(i)(a).e.,

3g. Supply of Medical Device consumables from DHB Hospitals

i. 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; and
   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.

ii. DHB Hospitals may also continue to fund consumable products, in accordance with 3(e), 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

4a. Long Term Conditions (LTC) registered patients. LTC patients, as defined in the Community Pharmacy Services Agreement, can have dispensing as often as the dispensing Pharmacist deems appropriate to meet that LTC patient's compliance and adherence needs.

4b. Community Pharmaceuticals identified in the Pharmaceutical Schedule with the ⁜ symbol.

i. Default dispensing is a single Lot, generally 90 days but 180 days for an oral contraceptive.

ii. 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.

4c. Community Pharmaceuticals identified in the Pharmaceutical Schedule with the ▲ symbol (Certified Exemption).

i. 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 medicine 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 on the medicine and will continue to take the medicine as prescribed.

4d. Community Pharmaceuticals identified in the Pharmaceutical Schedule without the ❋ or ▲ symbols

i. 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.

ii. A Community Pharmaceutical may be dispensed in one Lot in the following circumstances:

a. a patient or their representative signs the back of the Prescription to qualify for single Lot dispensing. In signing the Prescription, the patient or his or her nominated representative must certify which of the following criteria they meet:

I. they have limited physical mobility; or

II. they live and work more than 30 minutes from the nearest pharmacy by their normal form of transport; or

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 4d(ii).

iii. Community Pharmaceuticals identified in the Pharmaceutical Schedule without the ❋ symbol (where default dispensing is Monthly Lots) and prescribed in a quantity sufficient to provide treatment for more than one 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. 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.

5a. Unstable medicines. Where a Community Pharmaceutical is stable for a limited period only, the quantity dispensed at a time may be modified and will remain eligible for Subsidy if:

i. the Prescriber has Endorsed or Pharmacist has Annotated the Prescription with the words "unstable medicine"; and

ii. has specified the maximum quantity that may be dispensed at any one time.

5b. Residential care. Community Pharmaceuticals may be dispensed in modified dispensing quantities on the request of the person, their agent or caregiver in the following circumstances:

i. 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

a. the quantity or period of supply to be dispensed at any one time must not be less than:

I. 7 days' supply for a Class B Controlled Drug; or

II. 7 days' supply for clozapine in accordance with a Clozapine Dispensing Protocol; or

III. 28 days' supply for any other Community Pharmaceutical (except under conditions outlined in rule 5(c))

b. the Prescriber or dispensing Pharmacist must:

I. include the name of the patient's residential placement or facility on the Prescription; and

II. include the patient's National Health Index (NHI) number on the Prescription; and

III. specify the maximum quantity or period of supply to be dispensed at any one time.

ii. Any person meeting rule 5(b) who is being initiated onto a new medicine or having their dose changed may have their medicine dispensed in accordance with rule 5(c).

5c. Trial Periods. Community Pharmaceuticals may be dispensed in modified dispensing quantities to a patient who requires close monitoring in the following circumstances:

i. recent initiation onto a Community Pharmaceutical; or

ii. dose change (applicable to the patient's first changed Prescription only)

a. the prescriber must:

I. Endorse each Community Pharmaceutical on the Prescription clearly with the words “Trial Period”, or “Trial”; and

II. specify the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.

iii. Patients who reside in Prisons are not eligible for Trial Periods.

5d. Safety and co-prescribed medicines.

i. A Community Pharmaceutical identified in the Pharmaceutical 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(b); 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.

ii. A Community Pharmaceutical that is co-prescribed with a Safety Medicine, which meets the criteria in 5(d)(i), may be dispensed at the same frequency as the Safety Medicine, if deemed appropriate by the pharmacist:

a. The Pharmacist must Annotate the Prescription with the amended dispensing quantity and frequency.

5e. Pharmaceutical Supply Management. PHARMAC may activate this rule allowing more frequent dispensing to manage stock supply issues or emergency situations

i. Pharmacists may dispense more frequently than the Schedule would otherwise allow when all of the following conditions are met:

a. 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;

b. the Pharmacist has:

I. clearly Annotated each of the approved Community Pharmaceuticals that appear on the Prescription with the words “out of stock” or “OOS”;

II. initialled the Annotation in their own handwriting; and

III. complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

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

Part 6 – Funding

6a. Subsidies for Community Pharmaceuticals.

i. 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.

ii. A Community Pharmaceutical listed with “Hospital Pharmacy” is only eligible for Subsidy if it is supplied by a hospital or pharmacy contracted by the Funder to dispense as a Hospital Pharmacy.

6b. Cost, Brand, Source of Supply (CBS).

i. Where the Subsidy for a Community Pharmaceutical Schedule is listed as “CBS” in the Price column in the Pharmaceutical 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:
   a. the purchase Price (GST exclusive), brand and source of supply of the Community Pharmaceutical Annotated on the Prescription; or
   b. a copy of the invoice for the purchase of the Community Pharmaceutical attached to the Prescription

6c. Multiples. The Pharmaceutical 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.

6d. 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.

i. 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% (eg; 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.

ii. 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);
   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 Pharmaceutical Schedule.

iii. Any 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.

iv. At the time of dispensing, the Pharmacist must keep a record of the quantity discarded if wastage is claimed.

6e. Wastage and DHB Hospital Contractors. Wastage may be claimed by DHB Hospital Contractors as it applies to Pharmaceutical Cancer Treatment ~~on any line~~, and the claim does not have to be linked to a specific patient dispensing.

6f. 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:

i. identified as an OP in the Schedule; and
ii. is packed in a container from which it is not practicable to dispense lesser amounts.

6g. DHB Hospital funding. 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. The default funding arrangement for Pharmaceuticals administered, provided or dispensed by DHB Hospitals is that they are to be funded by the relevant DHB Hospital from its own budget, with the exception of:

i. Pharmaceutical Cancer Treatments which are funded through a Subsidy claim;
ii. Community Pharmaceuticals that have been brought to the DHB Hospital by the patient who is being treated by outpatient services or who is admitted as an inpatient;
iii. Community Pharmaceuticals that have been dispensed to a mental health day clinic under a Practitioner's Supply Order;
iv. Unlisted Pharmaceuticals that have been brought to the DHB Hospital by the patient who is admitted as an inpatient,
v. Non-seasonal vaccines, and
vi. Haemophilia treatments.

Part 7 – Compounds and Mixtures

7a. Combinations. Some Community Pharmaceuticals have Subsidy restrictions conditional on whether they are prescribed or combined with or without another Subsidised Pharmaceutical.

i. A Community Pharmaceutical identified as "In Combination" is only Subsidised when prescribed in combination with another Subsidised Pharmaceutical, as specified in Section B or C of the Pharmaceutical Schedule.
ii. A Community Pharmaceutical identified as "Not In Combination" is only Subsidised when it is not combined with other Community Pharmaceutical ingredients unless the particular combination of ingredients is separately specified in Section B of the Pharmaceutical Schedule, and then only to the extent specified.

7b. Extemporaneously Compounded Preparations (ECP). For an Extemporaneously Compounded Preparation to be Subsidised, it must contain two or more Subsidised component pharmaceuticals listed in the Pharmaceutical Schedule. The following ECPs are eligible for Subsidy:

i. the Standard Formulae;
ii. oral liquid mixtures for patients unable to swallow Subsidised solid dose oral formulations;
iii. the preparation of syringe drivers G; and
iv. 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.

7c. **Oral liquid mixtures.** An oral liquid mixture will be eligible for Subsidy if all the requirements of the Pharmaceutical Schedule applicable to the Pharmaceutical(s) are met.

However following will not be Subsidised:

i. where a Standard Formula exists in the Pharmaceutical 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;
ii. mixing one or more proprietary oral liquids (eg an antihistamine with pholcodine linctus);
iii. extemporaneously compounding an oral liquid with more than one solid dose form;
iv. mixing more than one extemporaneously compounded oral liquid mixture;
v. mixing one or more extemporaneously compounded oral liquid mixtures with one or more proprietary oral liquids; or
vi. the addition of a chemical, powder, agent, or solution to a proprietary oral liquid or extemporaneously compounded oral mixture.

7d. Standard formulae. A list of Standard Formulae is contained in Section C). Note that:

i. All ingredients associated with a Standard Formulae preparation will be eligible for Subsidy if all relevant requirements are met.
ii. Prescribers may prescribe, or Pharmacists may add, extra non-Subsidised ingredients to the Standard Formulae preparation, 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.

7e. Dermatological Preparations. In relation to dermatological preparations:

i. proprietary topical corticosteroid preparations may be diluted with a Dermatological Base from the Barrier Creams and Emollients section of the Pharmaceutical Schedule and will be eligible for Subsidy;
ii. one or more Dermatological Galenicals may be added to a Dermatological Base (including proprietary topical corticosteroid preparations) and will be eligible for Subsidy;
iii. 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
iv. the addition of Dermatological Galenicals to diluted proprietary Topical Corticosteroids-Plain will not be Subsidised.

7f. 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:

i. all of the component Pharmaceuticals of the ECP are Hospital Pharmaceuticals; and
ii. the ECP is supplied consistent with any applicable rules or restrictions for its component Hospital Pharmaceuticals.

Part 8 – Funding Exceptions

8a. General Exceptions. The Schedule describes the situations under which a Subsidy is payable and/or a product can be used in a DHB Hospital.

i. In general, a DHB Hospital may not Give:
   a. an Unlisted Pharmaceutical; or
   b. a Hospital Pharmaceutical outside of any relevant DHB Restrictions.
ii. Two exceptions to 8(a)(i) are:

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

8b. Hospital-specific exceptions. In the case of Giving in a DHB Hospital, the additional exceptions also apply:

i. **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; and
   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.
ii. **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.
iii. **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.
iv. **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.
v. **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 and 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

9a. Hospital Pharmaceutical Contracts.

i) 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; and
   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.

ii) 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.

9b. National Contract Pharmaceuticals.

i. 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.

ii. 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).

iii. 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.

iv. 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.

9c. Hospital Supply Status (HSS).

i. 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; and
   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; and
   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 9(c)(iii) ;
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.

ii. 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.

iii. PHARMAC may, in 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.

iv. 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;
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; and
c. in addition to the steps taken by PHARMAC in accordance with 9(c)(iv) to address any issues of non-compliance by any individual DHB or DHB Hospital with a DV Limit, the relevant Pharmaceutical supplier may require, in its discretion, financial compensation from the relevant DHB or DHB Hospital:
I. 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
II. 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 (I) and (II) within the number of business days specified in the notice from the Pharmaceutical supplier requiring such payment to be made.

v. The terms and conditions of a National Contract shall apply for a National Contract Pharmaceutical which has HSS for a Medical Device. In the event 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.

9d. Price and Volume Data.

i. 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.

ii. All Price and volume data provided to PHARMAC under i) above should identify the relevant Hospital Pharmaceutical by using a Pharmacode or some other unique numerical identifier, and the date (Month and year) on which the DHB Hospital incurred a cost for the purchase of that Hospital Pharmaceutical. Volume is to be measured in units (that being the smallest possible whole unit – e.g. a capsule, a vial, a millilitre etc).

9e. Hospital Pharmaceuticals without contracts.

i. 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

▲ three Months' supply may be dispensed at one time if the exempted medicine is endorsed 'Certified Exemption' by the Practitioner or Pharmacist;

❋ three Months' supply dispensed all-at-once or, in the case of oral contraceptives, six 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;

"**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;

"Annotation" means text written by a Pharmacist on a Prescription, and "Annotated" has a corresponding meaning;

"Armed Forces" has the meaning given in the Defence Act 1990;

"**Authorised Prescriber**" means a a nurse practitioner; or an optometrist; or a practitioner; or a registered midwife; or a designated prescriber as defined in the Medicines Act 1981;

"Bulk Supply Order" 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;

"Certified Condition" means text written on a Prescription by a Prescriber to fulfil Subsidy by Endorsement criteria;

"Certified Exemption" means text written on a Prescription by a Prescriber or Pharmacist to fulfil dispensing quantity Subsidy criteria for Community Pharmaceuticals identified in the as eligible in the Schedule;

"Clozapine Dispensing Protocol" has the meaning given in the Community Pharmacy Services Agreement;

"Community Pharmaceutical" means a Pharmaceutical listed in Sections B to G or I of the Schedule that is Subsidised by the Funder from the Combined Pharmaceutical Budget and includes Pharmaceutical Cancer Treatments;

"Community Pharmacy Services Agreement" means the contract between individual DHBs and each individual pharmacy throughout New Zealand for the provision of pharmacy services

"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;

"Dermatological Base" means a standard medicinal preparation used topically that may have a Dermatological Galenical added. For the purposes of the Pharmaceutical Schedule, Dermatological Bases are identified within Section B of the Schedule and include the Proprietary Topical Corticosteroid-Plain preparations;

"Dermatological Galenical" means an ingredient identified in the Pharmaceutical Schedule as a Dermatological Galenical, and Subsidised for use in a topical extemporaneously compounded product;

"**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" means a designated prescriber as that term is defined 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 claim DHB Hospital Pharmaceutical Cancer Treatments who can 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" has the meaning given in the Medicines Act 1981;

"Doctor" means a Medical Practitioner as defined in the Medicines Act 1981;

"**DV Limit**" means, for a particular National Contract Pharmaceutical with HSS, the National DV Limit or the Individual DV Limit;

"**DV Pharmaceutical**" means a "discretionary variance" Pharmaceutical that does not have HSS 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. 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 NZPHD Act, and "eligible person" has a corresponding meaning;

"Endorsement" means text written by the Prescriber on a Prescription to either gain 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 New Zealand Public Health and Disability 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 and before HSS 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 Sale Medicines" has the meaning given in 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" 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;

"Hospital Supply Status 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 Pharmaceutical 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

"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 the Medicines Act 1981

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

"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 Pharmaceutical 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 Pharmaceutical Schedule, i.e. nicotine patches, gum and lozenges

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

"Optional Pharmaceuticals" means the list of National Contract Pharmaceuticals set out in Section H Part III of the Schedule e.g. devices;

"**Original Pack"** means a Community Pharmaceutical identified by the designation "OP" in the Schedule

"**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 only" is a designation which, when applied to a specific Community Pharmaceutical, means a Pharmaceutical Cancer Treatment 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;

"Pharmaceutical Cancer Treatment" means a Pharmaceutical for the treatment of cancer, listed in Section B of the Pharmaceutical Schedule and identified therein as a "PCT" or "PCT only" Pharmaceutical;

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

"Pharmacist" has the meaning given in the Medicines Act 1981

"Pharmacist Prescriber" has the meaning given in regulations made under the Medicines Act 1981;

"Pharmacy Only Medicine" has the meaning given in 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 Pharmaceutical Schedule;

"Practitioner's Supply Order" 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 Doctor, a Dentist, a Dietitian, a 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 a quantity of a Community Pharmaceutical prescribed for a named person on a document signed by a Prescriber;

"Prescription Medicine" has the meaning given in the Medicines Act 1981

"**Price**" means the standard national Price for a National Contract Pharmaceutical in Section H of the Pharmaceutical 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;

"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 this 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 Nurse" means a nurse meeting the registration and practice requirements specified by the Nursing Council of New Zealand;

"Registered Nurse Prescriber" has the meaning given in regulations made under the Medicines Act 1981;

"**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 the Medicines Act 1981

"Rheumatic Fever Prevention Programme" means a programme so designated by the Ministry of Health

"Safety Medicine" means a Community Pharmaceutical identified in the Pharmaceutical 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;

"Sole Subsidised Supply" means in relation to a Community Pharmaceutical, the status of being the Sole Subsidised Supplier of a particular item for the Sole Supply Period, and "Supplier" has corresponding meaning;

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

a. the Doctor is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the Heath Practitioners Competence Assurance Act 2003 and has written the Prescription in the course of practising in that area of medicine;
b. the Doctor 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 Doctor 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;
d. the doctor 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 Doctor who satisfies any of the criteria set out in the paragraphs below:

a. the Doctor is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the Heath Practitioners Competence Assurance Act 2003 and has written the Prescription in the course of practising in that area of medicine;

b. the Doctor 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 Doctor 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 Approval" means an approval relating to an application which meets the criteria specified in the Pharmaceutical Schedule

"Standard Formulae" means a list of formulae for extemporaneously compounded products 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;

"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 specified circumstances

"**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.