

Attachment One: Schedule Rules Changes

An overview of some of the key proposals is presented below, as well as a copy of the draft Schedule rules. If you are intending to provide feedback on these points, we encourage you to read the relevant sections of the Schedule rules.

Hospital Pharmaceuticals

Part II of Section H of the Pharmaceutical Schedule is to contain the list of “Hospital Pharmaceuticals” that are to be funded for use within all DHB Hospitals. Not every medicine that is currently used by DHB Hospitals would fall within the scope of this list, and so DHBs would retain discretion on their use. These include dialysis fluids, human-blood derived products (which are managed by the New Zealand Blood Service) and radiopharmaceuticals.

We are proposing to temporarily exempt parenteral nutrition from this scope, as we have not yet completed our review of this area; however it is our intention to assume responsibility for managing parenteral nutrition within 12 months.

Hospital Medical Supplies

Part III of Section H would contain a list of national contracts for products that are not within scope of a “Hospital Pharmaceutical”, and so for which DHBs would retain discretion around their use (although national contracting obligations may apply).

Hospital-Community Interface

DHB hospitals are currently limited in which pharmaceuticals can be dispensed to patients for use in the community. For pharmaceuticals that are not funded through the community Schedule, there are three situations in which this can occur:

- Items on the Discretionary Community Supply list can be provided, subject to applicable restrictions. The majority of these are IV antimicrobial agents and older unregistered products, supplied under section 29 of the Medicines Act.
- Any pharmaceutical can be supplied for use in the 24 hours leading up to a hospital procedure – for example bowel-cleansing preparations prior to colonoscopy or oral contrast media taken before a radiology appointment.
- Any other pharmaceutical can be considered under the NPPA policy.

DHB hospitals are also prevented from administering community-funded medicines, which can create a misalignment of funding for medicines and services.

The community Schedule contains a number of medicines that have specialist administration requirements, or are associated with services that are regularly delivered in an outpatient setting. While these medicines can be, and regularly are, delivered in the community, it may be that for a particular patient the best outcome is that administration occurs in a hospital. The current rules require that hospitals pay for all medicines in this situation out of their outpatient budgets, which may be unaffordable.

We propose to remove both of these restrictions. This would mean that:

- DHB hospitals would be able to dispense any Hospital Pharmaceutical in Part II of Section H to a patient for use in the community (removing the need for a separate DCS list), and
- DHB hospitals would also be able to administer subsidised pharmaceuticals that are dispensed by a community pharmacy, such as depot antipsychotic agents, zoledronic acid and erythropoietin.

By doing so, DHB hospitals should be better able to determine the optimal setting for administration of a funded pharmaceutical to a patient, without funding silos creating barriers to access.

Prescribing Restrictions

Some hospital medicines will have prescribing restrictions. For some, this will be in the form of indication-based restrictions, which have the same effect as Special Authority restrictions do in the community. Use outside of these restrictions will require approval under the NPPA policy (proposed changes to which are outlined in Part B).

Unlike community Special Authority forms, we do not intend to require that forms be filled out before treatment can commence. Instead, DHBs would be able to determine how best to ensure that these restrictions are adhered to. Some DHBs may require that their own Special Authority-style ‘dispensing forms’ be used, others may require regular audits of use.

Other products will have prescriber-based restrictions. Where such a restriction applies, other prescribers would still be able to prescribe that medicine, but would not have unrestricted access to it. They would be able to prescribe the agent either on the basis of a recommendation by the specified prescriber for use in that patient, or pursuant to a protocol or guideline that has been endorsed for use within that DHB (such protocols or guidelines may be written for that DHB, or may be adopted from those in use by another DHB).

As an example, if a particular product was listed in Section H with a restriction of ‘intensivist’ then it could be prescribed as follows:



Hospital protocols and guidelines, such as antimicrobial guidelines, would therefore be important in the day-to-day operation of Section H. We note that under this approach, there may be a need for new protocols or guidelines to be written, and also for some to be amended.

DHB hospitals would also have the ability to implement their own prescriber-level restrictions if they considered that doing so would be necessary to ensure good clinical practice; these would not be able to be implemented for cost reasons alone.

Exemptions

In addition to the NPPA policy (refer to attachment two), there would be other mechanisms available for patients to be prescribed medicines outside of Part II of Section H.

- Use of medicines in clinical trials will be permitted, provided that funding for unfunded medicines is provided as part of the trial.
- Patients who have been stabilised on treatment prior to 1 July would be able to continue on treatment.
- DHB hospitals would be able to continue an unfunded medicine for an inpatient, if the patient's own supplies are unavailable.
- The exemption that applies to use of pharmaceutical cancer treatments (PCTs) in paediatrics would continue for now. We are reviewing this exemption, but are not proposing to remove it from 1 July.
- PHARMAC would be able to permit use of a medicine in a DHB hospital for specified purposes, where doing so would assist with PHARMAC's process of assessing that pharmaceutical (or that indication) for inclusion in the Schedule.

Medical Devices

There would be a constraint on the ability of DHBs to provide certain medical devices for use in the community – if such a device is funded through the community Schedule, DHBs must act consistently with the community decision, which means that:

- they should not provide the device to patients who do not meet the Special Authority criteria, if the product is restricted; and
- they should provide the same device that is listed in the community Schedule.

Background

We issued a discussion document in June 2012 relating to the high-level approach that we were considering when developing these rules. There were a few key issues that were raised by multiple respondents:

- It was noted that the enforcement of the Schedule rules was proposed to be the responsibility of individual DHBs, and that in practice this would fall to the pharmacy departments, which may result in additional workload for hospital pharmacy staff.
- There were some concerns raised about the proposal to allow DHBs to overlay their own prescriber-level restrictions on top of the national restrictions, and that this may result in the undermining of national funding decisions. We consider that this provision would be a useful mechanism for transitioning towards a national system, however we will monitor this issue over time, and would be able to refine or remove it in the future if necessary.

There were also some concerns about the changes to the outpatient dispensing rules for hospital pharmaceuticals, both in terms of workload for pharmacy staff and for the potential for geographic inequities. The proposed rule is a permissive one, not a requirement, so hospital pharmacies should not feel compelled to dispense three-monthly prescriptions for medicines that are available from community pharmacies. We do not consider that there is a

significant risk of geographical inequities through this provision, however we will monitor it over time and will act to remedy this if necessary.

PROPOSED NEW SCHEDULE RULES IN SECTION H

INTRODUCTION

Section H contains general rules that apply, and other information relating, to Hospital Pharmaceuticals and Optional Pharmaceuticals.

Where relevant, Section H shows the Price at which a Pharmaceutical can be purchased directly from the pharmaceutical supplier by DHBs, providers of logistics services, wholesalers or other such distributors, or Contract Manufacturers.

The Price is determined via contractual arrangements between PHARMAC and the relevant pharmaceutical supplier. Where a Pharmaceutical is listed in Part II of Section H, 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.

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.

INTERPRETATION AND DEFINITIONS

1 Interpretations

1.1 In this Schedule, unless the context otherwise requires:

“**Act**” means the New Zealand Public Health and Disability Act 2000.

“**Combined Pharmaceutical Budget**” means the pharmaceutical budget set for PHARMAC by the Crown for the subsidised supply of Community Pharmaceuticals and Pharmaceutical Cancer Treatments including for named patients in exceptional circumstances.

“**Community**” means any setting outside of a DHB Hospital.

“**Community Pharmaceutical**” means a Pharmaceutical listed in Sections A to G or I of the Pharmaceutical Schedule that is subsidised by the Funder from the Combined Pharmaceutical Budget and, for the purposes of this Section H, includes Pharmaceutical Cancer Treatments (PCTs).

“**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.

“**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.

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

"DHB Hospital" means a hospital (including community trust hospitals) and/or an associated health service that is funded by a DHB including (but not limited to) district nursing services and child dental services.

"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 Hospital Pharmaceutical.

"Extemporaneously Compounded Product" means a Pharmaceutical that is compounded from two or more Pharmaceuticals, for the purposes of reconstitution, dilution or otherwise.

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

"Funder" means the body or bodies responsible, pursuant to the Act, 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.

"Give" means to administer, provide or dispense a Pharmaceutical, or to arrange for the administration, provision or dispensing of a Pharmaceutical.

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

"HSS" stands for hospital supply status, which 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. Pharmaceuticals with HSS are listed in Section H in bold text.

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

"Individual DV Limit" means, for a particular National Contract Pharmaceutical with HSS and a particular DHB Hospital, the discretionary variance limit, being the specified percentage of that DHB Hospital's Total Market Volume up to which that DHB Hospital may purchase DV Pharmaceuticals of that National Contract Pharmaceutical.

“Local Restriction” means a restriction on the use of Pharmaceutical in specific DHB Hospitals on the basis of prescriber type that is implemented by the relevant DHB in accordance with rule 7.

“Medical Device” has the meaning set out in the Medicines Act 1981.

“Named Patient Pharmaceutical Assessment Advisory Panel” means the panel of clinicians, appointed by the PHARMAC Board, that is responsible for advising PHARMAC, in accordance with its Terms of Reference, on Named Patient Pharmaceutical Assessment applications and any Exceptional Circumstances renewal applications submitted after 1 March 2012.

“National Contract Pharmaceutical” means a brand of Pharmaceutical listed in Section H, where PHARMAC has entered into contractual arrangements with the relevant pharmaceutical supplier that specify the terms and conditions of listing, including the Price. Such Pharmaceuticals are recognisable in Section H because the relevant listing identifies the brand and Price.

“National DV Limit” means, for a particular National Contract Pharmaceutical with HSS, the discretionary variance limit, being the specified percentage of the Total Market Volume up to which all DHB Hospitals may collectively purchase DV Pharmaceuticals of that National Contract Pharmaceutical.

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

“PHARMAC” means the Pharmaceutical Management Agency established by Section 46 of the Act.

“Pharmacode” means the six or seven digit identifier assigned to a Pharmaceutical by the Pharmacy Guild following application from a pharmaceutical supplier.

“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 Pharmaceuticals for the treatment of cancer, listed in Sections A to G of the Schedule and identified therein as a “PCT” or “PCT only” Pharmaceutical that DHBs must fund for use in their DHB hospitals, and/or in association with outpatient services provided by their DHB Hospitals, in relation to the treatment of cancers.

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

“Price” means the standard national price for a National Contract Pharmaceutical, 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).

“Restriction” means a limitation, put in place by PHARMAC or a DHB, restricting the funding of a Pharmaceutical and includes Indication Restrictions, Local Restrictions and Prescriber Restrictions (as defined in this Part I of Section H).

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

“Special Authority Approval” means an approval for funding of a Community Pharmaceutical that is marked in Sections B-G of the Schedule as being subject to a Special Authority restriction.

“Total Market Volume” means, for a particular Hospital Pharmaceutical with HSS in any given period, in accordance with the data available to PHARMAC, the sum of:

- a) the total number of Units of the relevant Hospital Pharmaceutical with HSS purchased by all DHB Hospitals, or by a particular DHB Hospital in the case of the Individual DV Limit; and
- b) the total number of Units of all the relevant DV Pharmaceuticals purchased by all DHB Hospitals, or by a particular DHB Hospital in the case of the Individual DV Limit.

“Unapproved Indication” means, for a Pharmaceutical, an indication for which it is not approved under the Medicines Act 1981. Clinicians prescribing Pharmaceuticals for Unapproved Indications should be aware of, and comply with, their obligations under Section 25 and/or Section 29 of the Medicines Act 1981 and as set out in rule 22.

“Unit” means an individual unit of a Pharmaceutical (e.g. a tablet, 1 ml of an oral liquid, an ampoule or a syringe).

“Unlisted Pharmaceutical” means a Pharmaceutical that is within the scope of a Hospital Pharmaceutical, but is not listed in Section H Part II.

1.2 In addition to the above interpretations and definitions, unless the content requires otherwise, a reference in the Schedule to:

- a) the singular includes the plural; and
- b) any legislation includes a modification and re-enactment of, legislation enacted in substitution for, and a regulation, Order in Council, and other instrument from time to time issued or made under, that legislation.

HOSPITAL SUPPLY OF PHARMACEUTICALS

2 Hospital Pharmaceuticals

2.1 Section H Part II contains the list of Hospital Pharmaceuticals that must be funded by DHB Hospitals. Section H Part II does not currently encompass the following categories of pharmaceuticals:

- a) Medical Devices;
- b) whole or fractionated blood products;
- c) diagnostic products which have an ex vivo use, such as pregnancy tests and reagents;
- d) disinfectants and sterilising products, except those that are to be used in or on a patient;
- e) foods and probiotics;
- f) radioactive materials;
- g) medical gases; and
- h) parenteral nutrition.

Subject to rule 2.2, the funding of pharmaceuticals identified in a) – h) above is a decision for individual DHB Hospitals.

- 2.2 Section H Part III lists Optional Pharmaceuticals that PHARMAC and the relevant pharmaceutical supplier have entered into contractual arrangements for the purchase of, including an agreement on a national price and other obligations such as HSS. DHB Hospitals may choose whether or not to fund the Optional Pharmaceuticals listed in Part III of Section H, but if they do, they must comply with any National Contract obligations.

3 DHB Supply Obligations

- 3.1 In accordance with 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, which includes these General Rules.
- 3.2 DHB Hospitals are not required to hold stock of every Hospital Pharmaceutical listed in Section H Part II, but they must Give it within a reasonable time if it is prescribed.
- 3.3 DHB Hospitals are able to hold stock of an Unlisted Pharmaceutical if doing so is considered necessary for the DHB Hospital to be able to Give the Unlisted Pharmaceutical in a timely manner under rules 11-16 inclusive.
- 3.4 Except where permitted in accordance with rule 11, DHBs must not Give:
- a) an Unlisted Pharmaceutical; or
 - b) a Hospital Pharmaceutical outside of any relevant Restrictions.

4 Funding

- 4.1 The purchase costs of Hospital Pharmaceuticals or Optional Pharmaceuticals administered, provided or dispensed by DHB Hospitals must be funded by the relevant DHB Hospital from its own budget, with the exception of:
- a) Pharmaceutical Cancer Treatments;

- b) 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;
 - c) Community Pharmaceuticals that have been dispensed to a mental health day clinic under a Practitioner's Supply Order; and
 - d) Unlisted Pharmaceutical that have been brought to the DHB Hospital by the patient who is admitted as an inpatient.
- 4.2 For the avoidance of doubt, Pharmaceutical Cancer Treatments and Community Pharmaceuticals are funded through the Combined Pharmaceutical Budget, and Unlisted Pharmaceuticals are funded by the patient.

LIMITS ON SUPPLY

5 Prescriber Restrictions

- 5.1 A DHB Hospital may only Give a Hospital Pharmaceutical that has a Prescriber Restriction if it is prescribed:
- a) by a clinician of the type specified in the restriction for that Pharmaceutical or, subject to rule 5.2, pursuant to a recommendation from such a clinician;
 - b) in accordance with a protocol or guideline that has been endorsed by the DHB Hospital; or
 - c) in an emergency situation, provided that the prescriber has made reasonable attempts to comply with rule 5.1(a) above. If on-going treatment is required (i.e. beyond 24 hours) subsequent prescribing must comply with rule 5.1(a).
- 5.2 Where a Hospital Pharmaceutical is prescribed pursuant to a recommendation from a clinician of the type specified in the restriction for that Pharmaceutical:
- a) the prescriber must consult with a clinician 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) both the consulting clinician and the advising clinician must keep a written record of the consultation; and
 - e) the name of the advising clinician is to be recorded on the prescription/chart.

6 Indication Restrictions

- 6.1 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.
- 6.2 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.
- 6.3 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 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.

7 Local Restrictions

- 7.1 A DHB Hospital may implement a Local Restriction, provided that:
 - a) in doing so, 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 must be funded;
 - b) it provides PHARMAC with details of each Local Restriction that it implements; and
- 7.2 PHARMAC may, when it considers that a Local Restriction does not conform to rule 7.1 above, require a DHB to amend or remove that Local Restriction.

8 Community use of Hospital Pharmaceuticals

- 8.1 Except where otherwise specified in Section H, DHB Hospitals can Give any Hospital Pharmaceutical to a patient for use in the Community, provided that:
 - a) the quantity does not exceed that 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 *Dispensing for Discharge Policy* and the quantity dispensed is in accordance with that policy; and
 - b) the Hospital Pharmaceutical is supplied consistent with any applicable Restrictions.

9 Community use of Medical Devices

- 9.1 Subject to rules 9.2 and 9.3, DHB Hospitals may Give a Medical Device for patients for use in the Community.
- 9.2 Where a Medical Device (or a similar Medical Device) is a Community Pharmaceutical, the DHB Hospital must supply:
- a) the brand of Medical Device that is listed in Sections A-G of the Schedule; and
 - b) only to patients who meet the funding eligibility criteria set out in Sections A-G of the Schedule.
- 9.3 Where a DHB Hospital has supplied a Medical Device to a patient; and
- a) that Medical Device (or a similar Medical Device) is subsequently listed in Sections A-G of the Schedule ; and
 - b) the patient would not meet any funding eligibility criteria for the Medical Device set out in Sections A-G of the Schedule; and
 - c) the Medical Device has consumable components that need to be replaced throughout its usable life; then

DHB Hospitals may continue to fund consumable products for that patient until the end of the usable life of the Medical Device. At the end of the usable life of the device, funding for a replacement device must be consistent with the Pharmaceutical Schedule and/or in accordance with the Named Patient Pharmaceutical Assessment policy.

- 9.4 DHB Hospitals may also continue to fund consumable products, as in rule 9.3 above, in situations where the DHB has been funding consumable products but where the Medical Device was funded by the patient.

10 Extemporaneous Compounding

- 10.1 A DHB Hospital may Give any Extemporaneously Compounded Product for a patient in its care, provided that:
- a) all of the component Pharmaceuticals of the Extemporaneously Compounded Product are Hospital Pharmaceuticals; and
 - b) the Extemporaneously Compounded Product is supplied consistent with any applicable rules or Restrictions for its component Hospital Pharmaceuticals.
- 10.2 For the avoidance of doubt, this rule 10.1 applies to any Extemporaneously Compounded Product, whether it is manufactured by the DHB Hospital or by a Contract Manufacturer.

EXCEPTIONS

11 Named Patient Pharmaceutical Assessment

11.1 A DHB Hospitals may only Give:

- a) an Unlisted Pharmaceutical; or
- b) a Hospital Pharmaceutical outside of any relevant Restrictions,

in accordance with the Named Patient Pharmaceutical Assessment Policy or rules 12 – 16 inclusive.

12 Continuation

12.1 Where a patient's clinical circumstances have been stabilised via treatment in the Community with Pharmaceutical that has not been funded by the DHB Hospital, DHB or 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 pharmacy staff consider that 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.

13 Pre-Existing Use

13.1 Subject to 13.2, where a DHB Hospital has commenced funding a Pharmaceutical for a patient prior to 1 July 2013, and the Pharmaceutical:

- a) is an Unlisted Pharmaceutical; or
- b) treatment of the patient would not comply with any relevant Restrictions;

the DHB Hospital may continue to fund that Pharmaceutical if it is considered that there would be significant adverse clinical consequences from ceasing or switching treatment.

13.2 Each DHB Hospital must, by no later than 1 October 2013, provide PHARMAC with a report on Pharmaceuticals it has funded in accordance with this rule 13 where treatment has continued beyond 1 August 2013.

14 Clinical Trials

DHBs may Give any Pharmaceutical that is funded by a third party and is being used as part of a clinical trial which has Ethics Committee approval.

15 Pharmaceutical Cancer Treatments in Paediatrics

DHB Hospitals may Give any Pharmaceutical for use within a paediatric oncology/haematology service for the treatment of cancer.

16 Other Exceptions

- 16.1 PHARMAC may also approve the funding of a Pharmaceutical within a single DHB Hospital for information gathering purposes or otherwise related to PHARMAC's decision-making process for considering additions to or amendments to the Pharmaceutical Schedule.
- 16.2 Funding approvals granted under rule 16.1 will be subject to specific limitations on use as determined appropriate by PHARMAC in each circumstance, in consultation with the relevant DHB Hospital and/or DHB.

NATIONAL CONTRACTING

17 Hospital Pharmaceutical Contracts

- 17.1 A DHB Hospital may enter into a contract for the purchase of any Pharmaceutical that it is entitled to fund in accordance with this Schedule H 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 the national contract on no more than 3 months' written notice to the pharmaceutical supplier.
- 17.2 From 1 July 2013, where a DHB Hospital has a pre-existing supply contract for a particular brand of chemical entity for which there is a National Contract Pharmaceutical, the DHB may continue purchasing the chemical entity in accordance with its pre-existing supply contract however:
 - a) from the day its pre-existing supply contract expires, that DHB Hospital is to purchase the relevant National Contract Pharmaceutical listed in Section H at the Price, and is to comply with any DV Limits for the National Contract Pharmaceutical where it has HSS;

- b) if purchase of the relevant National Contract Pharmaceutical listed in Section H at the Price, where it has HSS, would not cause the relevant DHB Hospital to be in breach of its pre-existing supply contract for a particular brand of chemical entity; the DHB Hospital must purchase the National Contract Pharmaceutical.
- 17.3 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 to 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.

18 National Contract Pharmaceuticals

- 18.1 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.
- 18.2 The contractual arrangement between PHARMAC and the relevant pharmaceutical supplier of a National Contract Pharmaceutical requires it to be made available by 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).

19 Hospital Supply Status (HSS)

- 19.1 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, and may be amended from time to time.
- 19.2 If a National Contract Pharmaceutical is listed in Section H 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 (subject to rule 19.2(d)(iii) below) 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 19.3 below);
- 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.

19.3 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.

19.4 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
- 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.

19.5 In addition to the steps taken by PHARMAC under rule 19.4 above 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:

- 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.

20 Collection of rebates and payment of financial compensation

- 20.1 Following the receipt of any rebates from a pharmaceutical supplier in respect of a particular National Contract Pharmaceutical, PHARMAC will notify each relevant DHB and DHB Hospital of the amount of the rebate owing to it, being a portion of the total rebate determined by PHARMAC on the basis of that DHB Hospital's usage of that National Contract Pharmaceutical, where this is able to be determined. Where data to determine individual DHB Hospitals' usage is not available, PHARMAC will apportion rebates on the basis of an alternative method agreed between the relevant DHBs and PHARMAC.
- 20.2 PHARMAC will pay each DHB Hospital the rebate amounts (if any) owing to it, no less frequently than once each calendar quarter in respect of rebates received quarterly (or more often).

21 Price and Volume Data

- 21.1 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 Hospital Pharmaceuticals listed in Part II of Section H of the Schedule.
- 21.2 All price and volume data provided to PHARMAC under rule 21.1 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).

MISCELLANEOUS PROVISIONS

22 Unapproved Pharmaceuticals

Prescribers should, where possible, prescribe Hospital Pharmaceuticals that are approved under the Medicines Act 1981. However, the funding criteria (including Restrictions) under which a Hospital Pharmaceutical is listed in Section H of the Schedule may:

- 22.1 in some cases, explicitly permit a DHB to fund for a Pharmaceutical that is not approved under the Medicines Act 1981 or for an Unapproved Indication; or
- 22.2 not explicitly prohibit a DHB from funding a Pharmaceutical for use for an Unapproved Indication;

Accordingly, if clinicians are planning on prescribing an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication, they should:

- 22.3 be aware of and comply with their obligations under sections 25 and/or 29 of the Medicines Act 1981, as applicable, and otherwise under that Act and the Medicines Regulations 1984;
- 22.4 be aware of and comply with their obligations under the Health and Disability Commissioner's Code of Consumer Rights, including the requirement to obtain informed consent from the patient (PHARMAC recommends that clinicians obtain written consent); and
- 22.5 exercise their own skill, judgment, expertise and discretion, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication.

Clinicians should be aware that simply by listing a Pharmaceutical on the Pharmaceutical Schedule, PHARMAC makes no representations about whether that Pharmaceutical has any form of approval or consent under, or whether the supply or use of the Pharmaceutical otherwise complies with, the Medicines Act 1981. Further, the Pharmaceutical Schedule does not constitute an advertisement, advertising material or a medical advertisement as defined in the Medicines Act or otherwise.

CHANGES TO DEFINITIONS IN SECTION A

In addition to the changes in Part I of Section H of the Pharmaceutical Schedule, we propose to make some changes to the definitions section in Section A of the Pharmaceutical Schedule

Definitions to be deleted::

- **“Assessed Pharmaceuticals”**
- **“Discretionary Community Supply Pharmaceutical”**
- **“Hospital Pharmaceuticals in the Community (HPC)”**

Definitions to be amended:

- **“Community Pharmaceutical”** means a Pharmaceutical listed in Section A to G and Section I of the Pharmaceutical Schedule that it subsidised by the Funder from the Pharmaceutical Budget for use in the community.
- **“Hospital Pharmaceuticals”** means the list of Pharmaceuticals set out in Section H Part II of the Schedule which includes some National Contract Pharmaceuticals.

New definitions:

- **“Optional Pharmaceuticals”** means the list of National Contract Pharmaceuticals set out in Section H Part III of the Schedule.
- **“Unlisted Pharmaceutical”** means a Pharmaceutical that is within the scope of a Hospital Pharmaceutical, but is not listed in Section H Part II.