CONSULTATION

PHARMAC
Pharmaceutical Management Agency

9 July 2012

Consultation on Potential Pharmaceutical Schedule Rules for Hospital Pharmaceuticals

PHARMAC is seeking feedback on a broad outline of policies and rules that would relate to hospital pharmaceuticals from 1 July 2013, at which point PHARMAC intends to implement a nationally-consistent approach to the funding of these products.

This document provides a high level overview of a possible approach to managing these products, and is intended to promote discussion of the approach, rather than represent the particular way in which the rules would be worded.

We will consult further, at a more detailed level, on these issues after we have considered the feedback from this process.

The proposed policies and rules are separated into three categories: changes to Section H, prescribing and dispensing restrictions and exceptions.

Background

Following a Government decision that PHARMAC should have a greater level of responsibility for funding decisions for hospital pharmaceuticals, we have been working to create a nationally-consistent list of pharmaceuticals that would be funded in all DHB hospitals, which would be published in Section H of the Pharmaceutical Schedule from July 2013. We have also been considering the development of a framework of rules that would apply to the day-to-day operation of that list, and we are now seeking external input into the development of these rules.

The broad direction outlined in this document has many similarities to the Pharmaceutical Schedule rules that relate to the funding of community pharmaceuticals, although there are some key areas where we have endeavoured to account for the differences between the hospital and community sectors. In several cases this has been the result of incorporating policies from existing DHB formularies, and in other cases from discussions doctors and pharmacists working in DHB hospitals.

Future consultations

This will be the first in a series of consultation documents relating to PHARMAC assuming greater responsibility for hospital pharmaceuticals. Over the next 12 months we expect to be distributing a number of similar documents, some of which will relate to policies and schedule rules, and some will relate to the inclusion and exclusion of products from Section H.

We expect that the first consultation document relating to particular products to be included in Section H will be released later this month.

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Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 31 August 2012** to:

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All feedback received before the closing date will be considered as part of our on-going work in developing these rules. We are interested in your feedback on any of the points raised in this document, however we would particularly appreciate your thoughts on the following:

In relation to section H changes:

- If the proposed new structure and format of section H of the Pharmaceutical Schedule is suitable, or whether an alternative approach would be preferable.
- Whether the scope of Part II of Section H should be different to that proposed and, if so, why you consider that certain products should be included or excluded.

In relation to prescribing and dispensing restrictions:

- Whether the proposed approach to managing indication and prescriber restrictions is appropriate and practical.
- If there would be benefit in moving to standardise the use of extemporaneously compounded preparations in DHB hospitals.
- Whether the proposed changes in relation to community dispensing are likely to be practical, and if not, which criteria or restrictions (other than product-by-product restrictions) could be implemented to make this more workable.

In relation to exceptions:

- Whether a local or regional capacity for considering applications should apply to both the Unusual Clinical Circumstances pathway and to the Urgent Assessment pathway, or whether you consider that there is a difference between these that would make it appropriate or necessary for local capacity to extend to only one pathway.
- Whether there are any features of the Hospital Pharmaceuticals in the Community (HPC) pathway that should be retained, and if so, whether this should continue to relate solely to community dispensing, or also to use within the hospital.
- Whether the threshold for determining whether the decision is a local/regional or national one should be based on cost, duration of therapy, some other factor, or a combination of these.
- What information and level of additional support would PHARMAC need to provide to DHBs in order for DHBs to operate in this way, and how do you consider that we could improve the consistency of decision-making between different decision-makers?

Changes to Section H

Section H of the Pharmaceutical Schedule relates to PHARMAC's involvement in hospital pharmaceuticals, and is published separately to sections A-G which focus on the funding of community pharmaceuticals and pharmaceutical cancer treatments. The structure and role of Section H has changed over the course of the last decade, with sections relating to cancer treatments and pharmacoeconomic assessments having been removed, and the focus put more squarely on PHARMAC's national contracting role.

As PHARMAC moves towards being responsible for managing a closed formulary for DHB hospitals, Section H will become a much larger publication, with significantly more information. We are considering how it should change to account for a new level of involvement by PHARMAC in DHB hospitals' pharmaceutical management.

Structure of Section H

Section H of the Pharmaceutical Schedule is currently divided into three parts:

- **Part I: General Rules for Hospital Pharmaceuticals** outlines the rules relating to the purchasing and funding of pharmaceuticals by DHB Hospitals.
- **Part II: Pharmaceuticals under National Contract** provides information on any national contracts for hospital pharmaceuticals, including which products have Hospital Supply Status (exclusive contracts).
- **Part III: Discretionary Community Supply (DCS) Pharmaceuticals** lists the products that DHB hospitals may provide to patients in the community, and the indications for which each product can be used.

We are considering reshaping Section H to be more aligned with the new functions for PHARMAC, namely hospital pharmaceuticals and medical devices. In this regard, we are proposing that that:

- **Part I: General Rules for Hospital Pharmaceuticals** would have an unchanged function.
- **Part II: Hospital Medicines** would indicate which pharmaceuticals are funded in DHB hospitals as well as detailing any national prescribing restrictions or national contracts for these products.
- **Part III: Medical Supplies** would include details of any national contracts for hospital medical devices and consumables entered into by PHARMAC on behalf of DHBs.

Note that this would remove the section relating to the DCS list. This is discussed in further detail below in the 'Community Dispensing' section on page 8.

Scope of Section H

Any pharmaceutical could be included in Section H, and would be defined as either Hospital Medicines or Medical Supplies, and therefore could be listed in either Part II or Part III. We propose that the split between these two would be as follows:

> ***Part II: Hospital Medicines*** would include most medicines, including intravenous fluids, recombinant blood products, irrigation fluids, in-vivo diagnostic products, specialised nutritional products and vaccines.
>
> ***Part III: Medical Supplies*** would encompass any pharmaceutical not covered by Part II, such as medical devices, ex-vivo diagnostic products, whole and fractionated human blood products, dialysis fluids, nuclear medicine products, disinfectant agents and any other medical consumables.

Please note that:

- A number of products that are currently the subject of national contracts (and therefore currently in Part II of Section H), such as diabetes equipment, spacer devices and pregnancy tests, would shift to Part III under this proposal.
- The function and size of Part III of Section H would likely change as PHARMAC's medical devices management role develops. We would consult widely before making any changes.
- The boundary between Part II and Part III may be amended over time, if it is decided that there would be benefits from the scope of Part II being expanded. We would consult widely before making any such change.

Community Pharmaceuticals and Pharmaceutical Cancer Treatments

We propose that every pharmaceutical that is listed in Sections B-D of the Pharmaceutical Schedule would be included in Part II of Section H, with the exception of those that are Medical Supplies, such as pregnancy tests (and would therefore be included in Part III of Section H.

In most cases the Special Authority or Endorsement criteria that apply in the community (including PCTs) would also apply in DHB hospitals. It is likely that some products with Special Authority or Endorsement criteria to access funding in the community would have either wider criteria or no criteria for prescribing in DHB hospitals.

Some products that are partially subsidised in Sections B-D may be limited to use for on-going treatment only, and not for initiation. We would specifically consult on any such restrictions.

Funding Requirements

DHBs would be required to fund all pharmaceuticals listed in Part II of Section H, and not to fund any that are not listed in Part II of Section H, other than through a specific exemption (discussed further on page 9).

The obligation to fund would not mean that hospital pharmacies would need to hold stocks everything on the list, nor would it mean that DHBs would be compelled to purchase any capital equipment related to the delivery of a pharmaceutical.

Where DHBs have contracts with other providers (such as community trust hospitals) to provide hospital services, DHBs would need to ensure that these providers act in a manner that is consistent with the funding rules for pharmaceuticals outlined in Part II of Section H. That is, DHBs should not use such contracts to fund other pharmaceuticals.

Brands

We are not proposing any changes at a brand level at this stage - Part II of Section H would only specify products to a chemical and formulation level, but would provide information on any national contracts that exist. DHB hospitals would remain able to choose brands and pack sizes unless Hospital Supply Status (exclusivity) had been awarded.

For example, diclofenac sodium may appear in Part II of Section H as follows:

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)			
DICLOFENAC SODIUM			
Tab EC 25 mg			
Tab EC 50 mg			
Tab 50 mg dispersible			
Tab long-acting 75 mg	3.10	30	Diclax
Tab long-acting 100 mg			
Suppos 12.5 mg – **1% DV Sep-11 to 2014**	1.85	10	**Voltaren**
Suppos 25 mg – **1% DV Sep-11 to 2014**	2.22	10	**Voltaren**
Suppos 50 mg – **1% DV Sep-11 to 2014**	3.84	10	**Voltaren**
Suppos 100 mg – **1% DV Sep-11 to 2014**	6.36	10	**Voltaren**
Inj 25 mg per ml, 3 ml – **1% DV Sep-11 to 2014**	12.00	5	**Voltaren**

In this example the Voltaren brand has been awarded Hospital Supply Status for the injection and suppositories, so DHBs are required to purchase only that brand (other than under the 1% Discretionary Variance allowance). DHBs would be free to use any brand of the tablets, even though a national contract exists for the 75 mg presentation.

We propose that Part II of Section H would specify brands and pack sizes of each pharmaceutical at some point in the future (whether or not a national contract existed), but that would not happen for at least two years. We would consult further on this issue before making any such changes.

Prescribing and Dispensing Restrictions

Restrictions on prescribing, either by prescriber type or by indication, are a feature of the Pharmaceutical Schedule for community pharmaceuticals and cancer medicines (Sections B-D), and a feature of many current DHB hospital formularies. The overall objective of PHARMAC taking responsibility for managing the funding of hospital medicines is greater national consistency, so it is appropriate that prescribing criteria be equivalent across DHBs. We acknowledge, however, that DHBs have different specialities on staff and different service configurations – where this does not undermine national consistency, we are proposing to retain some local flexibility in the system to account for these differences.

Prescriber Restrictions

Some pharmaceuticals in Part II of Section H would have restrictions limiting use to certain prescriber types. In this circumstance, a prescriber who is not of the type listed would still be able to prescribe that pharmaceutical, provided that either:

(a) they are using the pharmaceutical in line with a defined hospital protocol (or guideline); or

(b) use of the pharmaceutical is recommended by a clinician of the prescriber type specified.

Hospital protocols may be local, sub-regional, regional or national, but they would need to be approved or endorsed by the DHB's Hospital Medicines Committee (or equivalent) – while hospital protocols may differ between DHBs, they should be consistent throughout a hospital. Such protocols would also need to be consistent with any applicable indication restrictions.

As an example, suppose that vancomycin has a national prescriber restriction of *'Infectious Disease Physician or Clinical Microbiologist'*. Under this scenario, Infectious Disease Physicians and Clinical Microbiologists would be able to prescribe vancomycin freely, and other clinicians could prescribe vancomycin, either (a) in accordance with the DHB's antimicrobial guidelines, or (b) if an Infectious Disease Physician or a Clinical Microbiologist has recommended vancomycin for the patient.

Local Prescriber Restrictions

Taking into account the differences in staffing at DHB hospitals, we consider that it would be appropriate to provide DHBs the ability to overlay their own prescriber restrictions on access to Hospital Medicines. They would not, however, be able to add any indication-type or patient-based restrictions.

As an example, suppose that nimodipine does not have a national prescriber restriction. In this situation, DHBs may choose not to have any prescriber restrictions, to restrict prescribing to neurologists, or to restrict prescribing to Senior Medical Officers.

Indication Restrictions

Some pharmaceuticals listed in Part II of Section H would have restrictions on the clinical circumstances, and/or patient population, in which a pharmaceutical may be prescribed and funded. Any use of pharmaceuticals in the DHB hospital outside of these restrictions would require approval under an exemption provision (see page 9).

We are proposing that, initially at least, each DHB would have discretion to determine how best to ensure that these indication restrictions are adhered to in practice. A DHB may employ different methods for each pharmaceutical, which may include:

(a) regular clinical audits;

(b) dispensing forms; or

(c) oversight of individual cases by the Hospital Medicines Committee (or equivalent).

The use of Special Authority forms to seek funding approval for Pharmaceutical Cancer Treatments would not change.

Extemporaneous Compounds

Part II of Section H (Hospital Medicines) would relate to proprietary products and ingredients for compounding. DHB hospitals would be able to manufacture (or to request be manufactured) any extemporaneously compounded preparation, provided that:

(a) each ingredient is included in Part II of Section H (unless it is outside its scope); and

(b) the prescribing restrictions for each component (as applicable) are met.

We are interested in people's views as to whether there is a need, or would be benefits from, moving to create greater consistency in the use of compounded products, such as having a limited set of compounded products (other than for reconstitution or dilution).

Community Dispensing

At present, DHB hospitals are able to dispense pharmaceuticals for use in the community under a range of different mechanisms:

- items in the Discretionary Community Supply list can be supplied according to any criteria listed in Part III of Section H;
- products listed in Sections B-D can be supplied according to the community criteria;
- any pharmaceutical can be supplied for use in the 24 hours leading up to a hospital procedure; and
- for any other situation, clinicians can apply through the Hospital Pharmaceuticals in the Community (HPC) mechanism (previously Hospital Exceptional Circumstances).

We are considering a significant change in this area. Instead of the above system, we propose that DHB hospitals would be able to dispense any pharmaceutical listed in Part II of Section H to a patient for use in the community, provided that:

(a) this was consistent with the DHB's dispensing for discharge policy; and

(b) the use conforms with any criteria for that pharmaceutical specified in Part II of Section H, as if the patient was being administered the treatment within the hospital.

The purpose of this approach is to treat patients who are under the care of the hospital equally, whether they are admitted to hospital, or have been discharged into the community.

As an example, suppose that ivermectin is included in Part II of Section H, but is not subsidised in the community. DHB hospitals would be able to provide it to patients to take home, provided that any applicable prescribing criteria for ivermectin were met.

Because funding decisions in hospitals and the community will not be perfectly aligned, it may be necessary to restrict community dispensing for a few products, either by specifying that for a particular product:

(a) the product is not eligible for funded community dispensing; or

(b) that funded community dispensing must be in accordance with the community Special Authority or Endorsement criteria.

For example if cough suppressants, which are not subsidised in the community, were included in Part II of Section H, they could have a restriction limiting funded use to treatment within the hospital – DHB hospitals would then not be able to provide these medicines to patients to take home.

We expect that this would apply to a very small number of products.

Exceptions

Clinicians will, from time to time, wish to prescribe a pharmaceutical that is not included in Part II of Section H, or for an indication that is outside the criteria specified for it in Part II of Section H. We propose these situations would addressed by three separate mechanisms.

Pre-Existing Patients

Patients who have been initiated on a pharmaceutical in a DHB hospital, that is not included in Part II of Section H (or for an indication outside that specified) as at 30 June 2013, would be able to continue on that treatment but only if the patient cannot be switched to a clinically acceptable alternative funded treatment.

Private Treatment Continuation

Where a patient is stabilised in the community on a privately-funded pharmaceutical that is not included in Part II of Section H (or is outside the indication restrictions), DHB hospitals would be able to provide ongoing treatment for that patient during the period of hospitalisation, provided that:

(a) the patient is admitted as an in-patient;

(b) it is considered clinically necessary for the patient to continue on treatment, and delaying or ceasing treatment until the patient is discharged would result in substantial clinical harm;

(c) the patient is unable to use their own stocks while in hospital; and

(d) the patient cannot be adequately treated with alternative funded pharmaceuticals.

Other Exceptions

Most exceptions will not fall into the above scenarios, and a broader exception mechanism would be required to initiate patients on other treatments.

We are proposing that, in general, an exceptions mechanism for hospital pharmaceuticals would be essentially the same as the Named Patient Pharmaceutical Assessment (NPPA) Policy, although several features would be amended.

(a) Given the proposed approach to community dispensing described on page 8 above, we are considering the removal of the 'Hospital Pharmaceuticals in the Community' NPPA pathway.

- If a DHB hospital clinician wished to prescribe an unfunded Hospital Medicine to a patient in the community, it would need to be considered under the Unusual Clinical Circumstances (UCC) or Urgent Assessment (UA) pathways.

- This would mean that exceptions funding for patients would be considered under the same framework, whether the pharmaceutical is to be used in the hospital or in the community.

- We note that there may be features of the HPC pathway that people may wish to retain, potentially expanded to include inpatients, and we are interested in your views on this – please see the questions on page 2.

(b) We note that there are can be long-term impacts on funding where treatment has been commenced with pharmaceuticals that are supplied through sampling or other free stock programmes, and that even if stock is supplied at no cost, other resources are utilised in the administration of a product. We are therefore interested in your views as to whether NPPA approval should be required before commencing a patient on an unlisted pharmaceutical (or listed pharmaceutical used outside of specified restrictions), even if the pharmaceutical is to be initially supplied to the hospital at no cost.

- If this was the case, any use outside of the pharmaceuticals listed in Part II of Section H would be evaluated under the same decision-making framework, regardless of cost. It would also mean that, should the supply of free stock cease before a patient's course is complete, approval would already exist to pay for any necessary further doses.

(c) We propose that some decisions under the NPPA Policy would be able to be made by a DHB committee (or a regional or sub-regional committee that covered several DHBs). Applications would need to be considered under the same framework and criteria that would apply to a decision made by PHARMAC. We expect that such a capacity would provide for more rapid decision-making. As noted in the questions on page 2, we are keen to know what information and level of additional support DHBs would need to do this and what might be needed to ensure DHBs act in a nationally consistent way.

(d) As patients can often be treated at multiple hospitals (particularly transferring between a tertiary centre and their home DHB), any approval under this mechanism by one DHB would need to be continued by all other DHBs.