NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

17 May 2013

Decisions relating to hospital medicines funding: Section H rules and NPPA policy changes

PHARMAC is pleased to announce that a decision has been made regarding Schedule rules and policies in relation to hospital medicines funding. This decision relates to a consultation letter dated 12 March 2013.

This decision establishes the framework under which the provision of hospital medicines in DHB hospitals will be managed on a day-to-day basis starting from 1 July 2013, including the use of medicines with prescribing restrictions, and the use of unlisted medicines through the NPPA policy or other exceptions provisions.

The start of July 2013 marks the first stage of a transition for DHBs to using the Schedule's Hospital Medicines List (HML) and this rules framework for all prescribing activity. You will find more information about the transition on our website alongside the rules and NPPA policy at the address below.

Details of the decision

The final rules and NPPA policy documents can be found on our website:

www.pharmac.health.nz/medicines/hospital-pharmaceuticals

Following consultation, some changes were made to the proposal. Significant changes are:

- DHBs will retain discretion over the provision of pharmaceuticals to hospital staff as part of an occupational health and safety programme, such as the provision of vaccinations.
- The exception provision covering clinical trials has been extended to include treatment following the end of the clinical trial.
- A new rule has been included to accommodate the provision of pharmaceuticals funded by other Government agencies, such as the Ministry of Health or ACC.
- The NPPA policy now requires that DHBs' decision making panels be multidisciplinary, consist of more than one person and do not involve the named patient's prescriber (refer to section 4f of the policy).
- We have included a provision in the NPPA policy that would enable PHARMAC to specify particular instances in which DHBs cannot make rapid hospital assessments decisions, even if a decision is needed in less than five days. At the moment this includes Pharmaceutical Cancer Treatments (PCTs), because these are funded from the Combined Pharmaceutical Budget (CPB) (refer section 4f of the policy).
- We have provided discretion in the NPPA policy so that DHBs can consider instances that fall outside of the two NPPA pathways, for example, where the

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pharmaceutical is less expensive to the health sector than treatments listed on the Schedule, or where the intent of the indication based restrictions, but not the technical wording, is met.

- We have amended the NPPA policy to note that PHARMAC's review process for applicants not satisfied with decisions made under the NPPA policy is also available for DHB rapid hospital assessments (refer section 4m of the policy).

Other than these changes, the decision broadly reflects what was proposed in the consultation document.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposal. The following is a summary of key issues that were raised in relation to specific aspects of the proposal:

Feedback	Discussion
Rules change	
Responders made some suggestions to the changes in the definitions section.	We have incorporated an amended definition of 'price' in the rules.
Responders sought feedback on a number of specific examples in relation to the scope of Part II of Section H.	• Vaccines and special foods are within scope, as are over the counter products, such as omega-3 fatty acids. • Standard foods are outside the scope, which would encompass commercial products such as Kiwi Crush. • Drug eluting stents and dressings are outside the scope of this work, but will be included in our on-going work with medical devices.
One responder considered that if a DHB had a need to hold stock of an unlisted product, that it should become a listed product.	We agree that regularly used products should ultimately become Schedule listings, however we consider that it may be useful to provide this flexibility.
Some DHBs noted that costs may be expected to increase as a result of coming into line with a national benchmark.	We note that financial impacts from standardising access across DHBs were inevitable, as historical funding decisions have varied across the country. We have endeavoured, however, to minimise this impact wherever possible.

Feedback	Discussion
Responders requested clarification around budgetary responsibilities and timelines; one respondent considered that budgetary responsibility should be transferred to PHARMAC as soon as possible, as this would ensure that funding constraints do not prevent access.	While we know that budget management is a goal for this project, the timing and details of this are still in development. However, the proposed rules would not permit DHBs to limit access to items on Section H for cost reasons alone.
A responder considered that DHBs should have the ability to limit access based on cost-effectiveness principles.	We consider that the application of any such restrictions should be a national decision, not one taken by individual DHBs, and we welcome feedback on the prescribing restrictions for individual products.
A responder queried if a pharmaceutical could be used for any indication if no prescribing restriction existed.	Unrestricted pharmaceuticals would be able to be used for any indication a clinician deemed appropriate, regardless of the therapeutic group it is listed under, and regardless of its registered indications.
A responder asked if PHARMAC would develop dispensing forms (similar to Special Authority forms) for DHBs to use.	We intend to assist DHBs with the development of dispensing forms, which DHBs would be able to use if they choose. In the future, electronic prescribing in hospitals may incorporate these restrictions within the prescribing system.
Responders noted that hospitals will be able to dispense pharmaceuticals for use into the community, and asked if there was an obligation to dispense community pharmaceuticals under this rule.	The proposed rules provide a capacity to dispense pharmaceuticals for use in the community, but not an obligation. Where the pharmaceutical is subsidised in the community, it is likely that patients would be provided with a discharge prescription.
Responders sought clarification as to whether the 30 day limitation for community dispensing is for a total treatment length, or length of each dispensing.	This limit relates to each dispensing. DHB hospitals would be able to provide longer term treatment in this way, but each dispensing would be up to 30 days, or longer if they had a dispensing for discharge policy.
Responders noted that long-stay mental health patients are currently provided a number of ‘over the counter’ products that might not be included in the list.	We consider it best for such items to be managed through inclusion on the list rather than providing open access to particular populations through a rule. We note that it would be possible restrict certain items to such patients if necessary, and we will be working with DHBs to review the particular needs of these patients. In the meantime, existing patients would be able to continue to receive current treatments under the ‘pre-existing patients’ rule.

Feedback	Discussion
Respondents considered that 'compassionate supply' and 'patient familiarisation' programmes should be permitted under the rules.	Supply of free stock to patients under these programmes would still be possible under these rules, however this would be bound by the exceptions framework that we have put in place (rules 11 to 17). The particular circumstance would need to meet one of these rules. We consider that this will help ensure that long-term funding for patients will be more certain, and that patients with similar circumstances will be treated in a more equitable manner.
A responder questioned whether NPPA approval would be required for patients who are treated under the 'pre-existing patients' rule.	We do not expect NPPA applications for these patients, but will ask DHBs to provide us with a summary of patients who access treatment under this provision on a long-term basis.
Responders noted that the rule relating to clinical trials should permit on-going supply following the end of the trial.	We have amended the proposed rule to ensure that such on-going supply can be provided.
Some pharmaceutical suppliers considered that the Schedule rules should provide some clarity around the confidentiality of rebates in national contracts, but that at the same time PHARMAC should endeavour to inform clinicians which products have confidential rebates (but without revealing their magnitude).	We agree that continued confidentiality is important, but are not certain that the Schedule rules are the best place to manage this issue. We are happy to have further discussions with suppliers on this issue in the coming months.
Responders considered that there should be tighter constraints on the ability of DHBs to implement local prescriber restrictions, and that these should be contestable and consistent with any commercial arrangements that are in place.	We consider that such wording would be ambiguous for DHBs to interpret and difficult for PHARMAC to monitor. We consider that prescribers or suppliers should bring to PHARMAC's attention any restrictions that they consider have been improperly implemented under this provision. We note that we expect that most of the local restrictions that will be put in place post-July will reflect the current prescribing restrictions in DHB hospitals.
Some responders considered that PHARMAC should use the rules to limit the circumstances under which an unregistered medicine would be listed in Section H.	We note that it is PHARMAC's preference that medicines listed in the Pharmaceutical Schedule have regulatory approval, however consider that it is appropriate to retain a flexible approach to this issue.
A responder questioned whether there would be an explicit timeline for a review of the rules and policies.	We do not have a fixed timeline for such a review. We intend to work through individual matters as they arise, and will be working with DHBs to highlight issues from July onwards.

Feedback	Discussion
Some DHB respondents noted that the implementation of the list and the on-going management of it will result in additional work for DHB staff.	We acknowledge that this will result in additional workload for pharmacy and other hospital staff. We are providing flexibility in how DHBs ensure that prescribing restrictions are adhered to, so the overall workload will be able to be adjusted by each DHB. As hospitals gradually move to new electronic systems, such as with e-prescribing, we expect that the workloads will reduce over time.
A responder noted that there may be unintended consequences from the introduction of new prescribing restrictions.	We note that while we have consulted widely on all restrictions, it is possible that some current and appropriate uses will be missed from some restrictions. Accordingly, we are working to ensure that such gaps will be able to be highlighted to us as soon as they are noticed, and we will be working to make appropriate changes to Section H in a timely manner.
DHBs noted that changing or developing protocols or guidelines to adapt to the new funding decisions will take time, and may be associated with additional costs. Some responders noted that the development of national guidelines to support this work would be of benefit.	We note that in many cases such changes may not be necessary, however we will be working with DHBs to manage this transition. We note that DHBs would be able to adopt guidelines or protocols from other DHBs, rather than developing their own. We agree that there would be benefits from establishing national guidelines in some areas, and note that we have started to discuss the development of national antibiotic guidelines with a number of stakeholders.
NPPA policy changes	
A responder considered that explicit timeframes for NPPA decisions should be made and communicated to applicants.	We note that it is necessary to balance the need for quick decision-making with the need for careful analysis, and that these needs will differ across applications. We have not included explicit timeframes for NPPA decisions, to ensure that PHARMAC (and DHBs) have the flexibility to triage applications based on clinical urgency, and to manage each application within a clinically appropriate timeframe.
Several respondents considered that the name for the new NPPA process ‘acute assessments’ is too similar to the name of the Urgent Assessment pathway, and that this could cause confusion.	We have changed the name of the acute assessment process to ‘rapid hospital assessments’.

Feedback	Discussion
DHB responders queried what would happen if a DHB approved a rapid hospital assessment, and then the patient transferred to another DHB hospital.	We have clarified in the policy that the DHB who makes the original decision is responsible for on-going funding until the other DHB agrees to pay for treatment (refer 4f of the policy).
The policy wording regarding the Unusual Clinical Circumstances (UCC) pathway in the consultation document included the following: *"This pathway is for named patients whose clinical circumstances are so unusual that the time and resource required for consideration of a Schedule listing is not warranted given the limited impact on the Combined Pharmaceutical Budget due to the relatively rarity of the unusual clinical circumstances".* A respondent requested that PHARMAC specify a financial threshold below which applications would be defined as having a *"limited impact on the Combined Pharmaceutical Budget"*.	We note that there is no financial threshold for UCC applications, therefore we have removed the reference to 'limited impact on the Combined Pharmaceutical Budget', to reflect the original intent of the policy (refer section 4a of the policy).
The wording of the Urgent Assessment (UA) pathway in the consultation document included the following: *"If, however, PHARMAC decided to decline to fund that treatment on the Schedule, the UA pathway will not be available for named patient applications received after this decision, even if they are for the same clinical circumstances".* A responder considered that the word 'even' may imply that new applications would always be declined for a pharmaceutical that has been the subject of a UA decline, whether or not the clinical circumstances were different, or if new evidence has become available.	We have removed the word 'even' from this sentence, to clarify that this exclusion only applies to applicants that have the same clinical circumstances (refer 4a of the policy).

More information

Further information on decisions relating to PHARMAC's work with hospital medicines can be found on our website at:

www.pharmac.health.nz/medicines/hospital-pharmaceuticals

If you have any questions about these decisions, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.