Medicines New Zealand

Submission on the PHARMAC consultation -

Hospital Pharmaceuticals: Schedule Rules and Policy Changes

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Executive Summary

Medicines New Zealand supports the expansion of PHARMAC's role into the funding of hospital medicines. We believe that the stated principle of ensuring equity of access to hospital medicines across the country is a means of improving peoples' health outcomes and should be kept paramount when implementing the changes.

It is important also to ensure that the system strives to offer timely access to new treatments that offer further health benefits; and that equity of access is not provided at a slower pace than that which DHBs could previously implement. To achieve appropriate early access to new medicines, it is important that the system of PHARMAC applications be further streamlined, has clear timelines and takes into account stakeholder (industry, patient and clinician) views on the funding of new medicines. We will continue to work with patient representatives and PHARMAC to identify the optimal application process in the PHARMAC OPP review.

There should be a clear indication of the budgetary aspects of the hospital medicines funding, with timeframes and the components that will be included in PHARMAC's budget for the new arrangements. Aspects such as whether PHARMAC is assuming responsibility for only the medicines component of the budget or including any logistics costs should be explicit. With PHARMAC's role growing and changing, it is important for the boundaries of responsibility between PHARMAC, the DHBs and other agencies to remain clear for accountability purposes. We also recommend that the move towards PHARMAC holding the entire pharmaceuticals budget be made as soon as possible, and by a specified date, to prevent transition practices becoming entrenched.

We support the binding nature of the list of medicines in Section H as a mechanism to ensure that "post code prescribing" is something of the past. The flexibility in implementing the changes and in allowing DHBs to ensure access without necessarily holding their own stock of certain products should mean that the system is able to accommodate the differing service configurations across the country.

However, we consider that the system of prescribing restrictions is likely to need further clarification and supporting information during implementation to ensure that any restrictions are appropriate and do not become obstacles to achieving equity of access.

We have some concerns about the scope and exemptions and would like to see these defined in a way that does not create barriers to access schemes such as patient familiarisation programmes and compassionate supply arrangements.

We recommend that PHARMAC work with industry to develop both Familiarisation Programs and Compassionate Supply opportunities so that they can be implemented in a consistent manner that ensures appropriate access.

The exemption allowing PHARMAC to use a medicine on a trial basis, while assessing whether it should be included on the hospital medicines list, should be limited to uses that are approved by Medsafe or other international regulators. For any unapproved uses, there would clearly be a requirement to apply to the appropriate scientific and ethics committees.

Scope of Section H

It would be useful to have a clear definition of what attributes of a medicine define its potential inclusion in Section H or its inclusion as a "Hospital Medicine". In many instances it may be self evident, but where companies and other stakeholders are developing an application, and are not certain of whether the medicines would be a community or hospital medicine, there should be a definition to refer to. Such a definition would also facilitate reporting and policy research efforts in the future. Currently the scope appears to be defined by examples of the exclusions from Section H.

Interface between hospital and community funding

We support hospitals being able to supply community medicines; and being able to supply hospital medicines in the community. However, we note that the proposed limit on community use of hospital medicines (to a period in line with individual discharge policies) may constrain use of products that are currently listed on the Discretionary Community Supply (DCS) list for "indefinite supply" (e.g. tobramycin, trimethoprim etc) and those where an initial treatment period is defined but subject to review which may indicate continued use for longer (e.g. amikacin, aztreonam, penicillin G etc). With PHARMAC bearing the responsibility for listing of, and ultimately budget for both of these categories, any restriction would be unnecessary and likely to cause inefficiencies in pharmacy service delivery and patient access.

Prescribing restrictions

Prescribing restrictions should not undermine the equity of access principle on which the new PHARMAC responsibility for funding hospital medicines is based.

Where prescribing restrictions are set by DHBs there needs to be a clear process for establishing these, with evidence being provided by clinicians, patient representatives and industry. Such a process will ensure that the restrictions are well targeted at the patients that will most benefit and that any enforcement of them will be worth the administrative burden. Ideally, the process for developing prescribing restrictions should be either a shared process between similar DHBs or a similar process within separate DHBs, which would facilitate appropriate levels of industry input as well as clinician and patient consultation.

We support the restrictions not being based on cost constraint alone, as the only group with comprehensive information about the actual costs after risk sharing agreements and rebates defined in the supply contracts is PHARMAC. We also stress the importance of the need to maintain confidentiality around commercial contractual arrangements and that disclosure is limited to only those levels of staff that are essential. We however do not consider that the proposed rules around Local Restrictions go far enough towards protecting the commercial interests of suppliers. A decision to fund a medicine may not adequately reflect the intended access and/or risk-share arrangements that underpin that listing. Local Restrictions could remain in keeping of the broad decision to fund a medicine but limit use such that the commercial arrangements are undermined. We therefore recommend that the wording of the clause be changed to better reflect the contracting obligations between companies and PHARMAC. It should read:

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 or any commercial arrangements in place for PHARMAC funding of that Hospital Pharmaceutical.

Any budget holding that DHBs would continue to be responsible for should be clearly defined as this would clarify any incentives for enforcing cost based (versus clinical based) restrictions. The need for DHB pharmacies to hold pharmaceutical budgets locally and report on these through their DHBs should be reduced and removed rapidly to reduce any risk of confusion about accountability for this budget. The appropriate route of accountability for the pharmaceuticals budget should clearly lie with PHARMAC.

Exemptions from part II of Section H

Companies currently provide early access to medicines in patient access programmes, such as patient familiarisation programmes and the proposed exemptions do not appear to make provision for these. Similarly there appears to be no provision for and compassionate supply programmes. Simultaneously DHBs are increasingly requiring these initiatives to supply the medicines through DHB pharmacies. We recommend that an exemption be made for companies to provide medicines for familiarisation and compassionate supply programmes through DHB pharmacies.

The exemption allowing PHARMAC "*to permit use of a medicine in a DHB hospital for specified purposes*" should be limited to such purposes, indications and dosages as are registered with Medsafe or major international regulators.

Specific clauses in the Rules

3.4 This clause appears to prevent DHBs participating in patient familiarisation and compassionate supply programmes and should be altered to make provision for the supply of medicines under these programmes with the appropriate information provided to patients and clinicians to support their appropriate implementation.

4. The requirement for hospital pharmacies to fund (and budget for) *Hospital Pharmaceuticals* or *Optional Pharmaceuticals* appears to be a transitional budgetary arrangement. The ultimate funding and budgetary arrangement should be clarified and the timeframes for transition to PHARMAC taking responsibility for these budgets outlined.

6.3 For medicines that have a restriction "for continuation only" there should be additional clarification that (6.3.c) changing the patient to an alternative hospital pharmaceutical would pose unacceptable clinical risks to the patient.

We recommend that the portion of 6.3(b) be deleted from "*and the prescriber has explained …not fully subsidised in the Community* " as this is superfluous if the patient is already receiving, and presumably paying for, the treatment.

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12.1 Points 12 a, b and c should be alternatives and not require all to be present before a hospital may continue the supply of that Hospital Pharmaceutical. The points should therefore read (a) and/or (b) and/or (c).

16 PHARMAC should not use the exemption under point 16 to provide experimental use of medicines that are not approved by Medsafe.

As discussed above, provision should be made for DHBs to "give" medicines to patients participating in patient access programmes provided by the industry.

22 PHARMAC should generally not be funding or promoting the use of medicines or indications that do not hold New Zealand regulatory approval. Although the PHARMAC schedule has been deemed not to be an advertisement of a medicine, it has the potential to promote the inappropriate use of unapproved medicines and indications. Recognising there may be a few isolated instances where unapproved medicines are listed out of necessity, PHARMAC should state a prerequisite requirement that prescribers use approved alternatives before resorting to unapproved ones. Such a stated position would go some way towards discouraging the inappropriate use of unapproved medicines. The current disclaimer about PHARMAC not making representations about the approval status of a medicine is an abrogation of PHARMAC's responsibility in this regard.

NPPA Policy changes

We support the move to ensure the NPPA system works effectively for community and hospital medicines.

As hospital medicines will now be assessed for cost effectiveness in the context of the community pharmaceuticals list there is no further need for the "Hospital Pharmaceuticals in the Community" HPC component of the NPPA.

We believe there should be explicit timeframes within which NPPA decisions are made and communicated to the applicants.

Page 6 of Attachment Two: To allow better targeted applications under the UCC component, please specify a financial threshold below which applications may be made, or define what a "*limited direct financial impact on DHBs*" would be.

Specific questions posed:

- *Should there be only one NPPA policy that applies to both hospital and community pharmaceuticals, rather than two individual policies?*

Yes

- *Are there any features of the HPC pathway that need to be retained?*

None identified

- *Are there any other ways in which the hospital setting requires a different approach?*

None identified, as the "Acute" assessment process within DHBs appears to resolve the issue of PHARMAC not being able to make such decisions in a timely manner.

- *Should the review process (refer section 4m of the policy document) be extended to include NPPA decisions taken by DHBs?*

Yes, all NPPA decisions should be subject to review to ensure equitable and appropriate decision making.

- *Who within the DHB should be made ultimately responsible for the acute assessments (assuming that the responsible body or individual will delegate this authority to a panel, but will be held responsible for the performance of that panel) – DHB Board, Board DHB Chair, CE or someone at the hospital level?*

No opinion

- *What support will DHBs need to implement a process for acute assessments?*

Appropriate levels of evidence supplied by stakeholders such as industry, patient representative groups and clinicians should be provided.

Where SOPs are developed for this process, these should be developed centrally to ensure DHBs make consistent decisions where possible.

- *Should the general discretion (refer to section 1 of the policy document) provided for in the NPPA policy, to consider applications that do not meet the criteria for UA or UCC, also be extended to DHB acute application decisions?*

Yes, initially it is not possible to be certain of all of the types of application the DHB acute application process is likely to have to make decisions on. Thus a more inclusive approach is preferable, at least until the system is running and any problematic aspects can be identified.

Thank you for the opportunity to comment on these proposals.

Yours sincerely

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