

**National  
Hospital Pharmaceutical  
Strategy**

**Final Version**

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*PHARMAC's overall objective, as outlined in Section 47 of the New Zealand Public Health and Disability Act 2000, is to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.*

## Executive Summary

In response to authorisation to perform a new function given by the Minister of Health in September 2001, PHARMAC, in conjunction with representatives of the District Health Boards (DHBs), developed a strategy for nationwide purchasing of hospital pharmaceuticals (the "Strategy"), and undertook consultation with DHBs (CEOs, relevant managers, and provider units), clinical groups, pharmaceutical suppliers, and those other interested parties with whom PHARMAC usually consults. A summary of those responses and PHARMAC's response to them is attached as Appendix 2. This second and final version of the Strategy will be presented to the Minister of Health in February 2002 with recommendations reflecting the views of PHARMAC and DHB CEOs.

Changes to the scope of the draft Strategy, in terms of the way it is proposed PHARMAC would be involved in assessment of New Pharmaceuticals, revisions to the proposed structure and function of Section H of the Pharmaceutical Schedule, and policy details pertaining to national sole and/or preferred supplier arrangements, should be noted. It is also proposed that the Strategy be reviewed in 2 years time.

The key objectives of the Strategy are to:

- (a) obtain the best possible value for money spent by DHBs on Pharmaceuticals used in hospitals;
- (b) improve national consistency of access to Pharmaceuticals used in hospitals; and
- (c) establish a co-operative purchasing framework by collaboration between the DHBs.

Consultation has highlighted that many stakeholders believe improved health outcomes should also be an objective of the Strategy. While this fits well with PHARMAC's current legislative objective, it is likely to be difficult to monitor and measure in the hospital sector without extensive research and monitoring. However, the welfare of patients will be a key consideration in any decision criteria PHARMAC adopts under this Strategy. The fiscally oriented objectives of the Strategy will need to be balanced against the needs of the DHBs' patients and clinicians, with consideration of any adverse impact on clinical outcomes. Consultation has highlighted some of the areas where PHARMAC's ability to achieve this balance has been noted as a concern. Those areas are addressed in this version of the Strategy.

It is acknowledged that initiatives to reduce price, and manage the costs/utilisation of Pharmaceuticals used in hospitals, are already in place in most DHBs. This Strategy aims to build on these initiatives, through a process of co-operation and collaboration between PHARMAC and the DHBs, in order to improve patient outcomes, and ensure maximum value for money from current and future investment in pharmaceutical technology used in hospitals. A constructive relationship between pharmaceutical suppliers and PHARMAC will also be helpful to the success of the Strategy.

Key features of the proposed Strategy, once fully functional, would include:

- Management of hospital and community expenditure on Pharmaceuticals according to a joint national target (a notional figure set with reference to monies held by

DHBs/hospitals). It is not intended that PHARMAC would actually purchase the Pharmaceuticals.

- Nationally consistent pricing policies covering 90% of DHB's spending on Pharmaceuticals used in hospitals (with provision for choice within the limits defined in contractual "Discretionary Variance" clauses for any patients whose health needs fall outside any contractually derived policy boundaries PHARMAC might set).
- The establishment of a new section of the existing Pharmaceutical Schedule ("Section H"), containing the list of Pharmaceuticals used in hospitals for which PHARMAC has negotiated national contracts on behalf of the DHBs. Section H may also list those pharmaceuticals affected by national arrangements (such as products within a therapeutic sub-group affected by preferred supplier arrangements and alternative brands of chemicals under sole supply arrangements which could only be used within DV provisions). It is likely that Section H would be published separately from, but would legally form part of, the existing Pharmaceutical Schedule.
- Full compliance with any national pricing contracts (where such compliance would permit DHBs to purchase other Pharmaceuticals within the contractually agreed Discretionary Variance limits), once existing supply contracts held by DHBs have expired or been terminated. DHBs could still choose to purchase outside the DV limits but would be exposed to losing financial incentives or incurring financial penalties. No DHB would be able to enter into any contract which would compromise a national pricing contract.
- A centralised assessment process run by PHARMAC to appraise the clinical benefits and cost-effectiveness of New Pharmaceuticals. This process would assist DHBs to ensure that access to New Pharmaceuticals in their hospitals was consistent, where appropriate, with access in other DHBs. It is proposed that, over the first two years, this national process would run in parallel with, and augment, assessment processes that would [continue to] be undertaken by each individual DHB.
- Information systems that mesh full national hospital utilisation and clinical data, where possible, in a format that is consistent with similar data collected in the primary care setting.
- A national programme aimed at improving quality in the use of medicines by promoting best practice in the use of Pharmaceuticals within hospitals, and at the hospital/primary care interface.

The Strategy was originally developed to focus initially on the purchase of:

- (a) Pharmaceuticals;
- (b) X-ray contrast media; and
- (c) IV fluids.

However, it is now proposed that inclusion of X-ray contrast media and IV fluids within the scope of the Strategy should wait until the proposed mechanisms for national contracting have been established for Pharmaceuticals.

PHARMAC proposes that the Strategy should initially include the following elements as a minimum:

- (a) price management; and
- (b) assessment of New Pharmaceuticals; and
- (c) promotion of quality in the use of medicines (QUM).

It is also proposed that logistics management be further investigated for possible inclusion within the scope of the Strategy.

It is acknowledged that inclusion of assessment of New Pharmaceuticals and QUM brings a wider focus to the Strategy than indicated by its current title. For this reason, it is proposed that the Strategy should more correctly be referred to as the "National Hospital Pharmaceutical Strategy."

Some of the initiatives proposed by PHARMAC to manage DHB expenditure on Pharmaceuticals used in hospitals are likely to be similar to those used in the community setting, but there are some notable differences. The application of reference pricing is not proposed, procedures for managing proposals would more closely involve representatives of the DHBs (including hospital based clinicians), and implementation of sole supply arrangements would be more flexible (refer to section 5.0). An initial request for proposals process, commencing in mid-2002 is proposed. However, subject to specific caveats, PHARMAC and the DHBs would consider proposals submitted by suppliers outside of that process at any time.

Key features of the Strategy would be process transparency and consideration of clinical concerns. Clinical issues would be discussed by PHARMAC, the clinical advisory committee(s), and HPAC before changes are implemented. Choice in the range of pharmaceuticals available within therapeutic groups would be maintained although the number of brands of particular chemicals, where generic competition exists, could be limited via contractual arrangements. Discretionary Variance provisions would provide flexibility to meet the needs of small numbers of patients who may fall outside the provisions of national contractual arrangements.

The Strategy provides for national co-ordination and collaborative extension of many of the current systems already in place within individual DHBs. These include systems for assessing, and contracting for the supply of pharmaceuticals, processes for assessing new Pharmaceuticals and initiatives aimed at promoting best clinical practice where Pharmaceuticals are utilised in the care of patients.

Implementation of the Strategy would require consideration of existing and/or new supply contracts entered into by DHBs individually and prompt resolution of current data issues that have to date, prevented PHARMAC from compiling or accessing a national dataset of pharmaceutical utilisation and expenditure for the hospital sector. The approach to these issues we have recommended is likely to require the input of resources, as well as co-operation, from DHBs (refer to sections 6.3 and 7.1).

Based on specific feedback invited on what assessment criteria should be applied to the assessment of New Pharmaceuticals and of commercial proposals arising from the strategy, PHARMAC proposes to adopt its current criteria with the addition on a hospital-specific criterion (refer to section 6.4).

The anticipated benefits of the Strategy are:

- gradually improved consistency of prices for and access to Pharmaceuticals throughout New Zealand;
- increased dialogue and co-operation on pharmaceutical issues facing all DHBs' provider arms;
- a more co-ordinated approach to Pharmaceutical use across primary and secondary care;
- greater impetus to establish a national dataset for Pharmaceuticals used in hospitals;
- a modest reduction in the prices paid for Pharmaceuticals used in hospitals (which would not necessarily result in an overall fall in total Pharmaceutical expenditure);
- greater co-ordination of efforts to promote cost-effective utilisation of Pharmaceuticals; and
- better utilisation of DHBs' pharmacy and/or pharmaceutical procurement resources.

## 1.0 Introduction

In July 2001, the Minister of Health, the Honourable Annette King, announced her intention to authorise PHARMAC to lead a strategy for nationwide hospital pharmaceuticals purchasing (the "Strategy"). The new function issued by the Minister, which was published in the *New Zealand Gazette* in September 2001 (copy attached as Appendix 1), fits within the context of PHARMAC's overall objective - to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

The specific, key objectives of the Strategy are to:

- (a) obtain the best possible value for money spent by DHBs on Pharmaceuticals used in hospitals;
- (b) improve national consistency of access to pharmaceuticals used in hospitals; and
- (c) establish a co-operative purchasing framework by collaboration between the DHBs.

Implicit in these objectives is the presumption that the overall health status of New Zealanders should not be compromised as a consequence of this Strategy and, where possible, should be improved. It is acknowledged that the fiscally oriented objectives of the Strategy and constraints on VoteHealth will need to be balanced against the needs of the DHBs' patients and clinicians, in terms of clinical outcomes.

PHARMAC has developed, in consultation with advisors from the DHBs via the Hospital Pharmaceuticals Advisory Committee (HPAC), a Strategy document and has conducted extensive consultation with DHBs, hospital clinicians and the pharmaceutical industry. Revisions have been made following consultation and this final Strategy document will be presented to the Minister of Health with a recommendation from PHARMAC staff in February 2002.

In developing the Strategy, HPAC concluded that, in order to ensure continued gains from the Strategy in the longer term, consideration would need to be given to the manner in which Pharmaceuticals are utilised within hospitals, in addition to their price and availability. It acknowledged that, as a consequence of the inclusion of these concepts, the scope of the Strategy is wider than indicated by its current title. For this reason, it is proposed that the Strategy should more correctly be referred to as the "National Hospital Pharmaceutical Strategy."

The Strategy document sets out:

- A detailed plan and objectives for the Strategy.
- Proposed initiatives, milestones and a timeline for implementation of a two year programme beginning during the current financial year.

- Details of any transitional arrangements necessary to enable PHARMAC to manage the purchasing of some Pharmaceuticals on behalf of DHBs.
- A definition of roles for all parties to be involved in the implementation of the Strategy.
- Assessment of the costs, risks and benefits of the Strategy.
- Proposed key performance indicators.

## **2.0 Current Market Overview**

### **2.1 Current purchasing arrangements**

Although some DHBs have already entered into joint arrangements, purchasing of pharmaceuticals for use in hospitals is in most cases currently managed by each individual DHB. Most DHBs purchase the bulk of their hospital-only pharmaceuticals via contracts with pharmaceutical suppliers. Many of these contracts are described as “bundled deals” where DHBs negotiate prices across a range of pharmaceuticals, obtaining lower prices on some products in exchange for acceptance of higher prices than they might otherwise achieve on others. Some hospitals (Auckland and Christchurch) have achieved savings by running competitive tender processes.

Where the DHBs have no contracts with suppliers, pharmaceuticals are purchased at the suppliers’ hospital list prices. Where such products are available on the Pharmaceutical Schedule, the prices (ex manufacturer) paid by DHBs may be the same as the subsidy set by PHARMAC.

### **2.2 Range of pharmaceuticals purchased**

The range of products purchased by DHBs within the existing “pharmaceutical” purchasing arrangements varies from hospital to hospital. In addition to what are conventionally considered to be pharmaceuticals, some hospitals include such things as X-ray contrast media, IV fluids, total parenteral nutrition or special foods within this function, whereas others manage some or all of these other purchases separately. A number of unapproved and/or “orphan” pharmaceuticals may also be included. This variation contributes to the difficulties associated with comparing pharmaceutical expenditure between DHBs.

### **2.3 Data collection and analysis**

No national price database exists to enable a comparison of prices paid across the sector. Hospitals currently use a variety of computer systems to record information about their pharmaceutical purchasing and utilisation. Issues of confidentiality, and a lack of consistency in the way each hospital records and/or codes data are both barriers to the compilation of a national dataset. However, work on this issue done by Counties-Manukau last year suggests that there are price disparities across the DHBs, and that no individual DHB is consistently achieving the lowest prices across the entire range of commonly used pharmaceuticals. Some of this variation may be explained by differences in the timing of contract negotiations between hospitals and the complexities associated with prices negotiated for “bundles” of pharmaceuticals. However, the fact that some suppliers have insisted that the pricing information contained in their contracts be kept confidential, supports the notion that some hospitals pay more for their pharmaceuticals than others.

Hospitals are beginning to develop systems which enable them to track pharmaceutical utilisation at an individual patient level. Automated drug distribution systems in place in some areas are capable of tracking up to 95% of use to an individual patient level. However, most DHBs can still only track use at a patient level to a limited degree, and pharmaceutical utilisation is not yet fully trackable within any hospital. From the limited data available, it seems likely that there is variability in the needs, and therefore

demand, for pharmaceuticals within each hospital. For example, those hospitals that provide specialists services are more likely to have a greater demand for pharmaceuticals related to that speciality. However, universally the key therapeutic groups contributing to pharmaceutical expenditure include:

- antibiotics;
- cardiovascular drugs;
- psychiatric medicines;
- anaesthetic agents; and
- cancer treatments.

#### **2.4 Management of access to pharmaceuticals**

Systems for determining which pharmaceuticals can be used in each hospital, and processes for assessing New Pharmaceuticals before they are made available in hospitals, are in place within all DHBs. Most hospitals also manage some type of formulary or preferred medicines list (PML). Although the degree to which adherence to these lists is enforced varies, it is widely held that the input of local clinicians into such formularies is a factor in their acceptance and effectiveness. Where guidelines for use and/or restrictions on access to certain pharmaceuticals exist, it is acknowledged that clinician compliance with such rules is dependent on the breadth of range of pharmaceuticals available within the hospital, and degree of clinician input into the selection of this range. Making changes to the range of agents listed on a PML or formulary can also be difficult when preferences for certain brands or products become established.

Some DHBs impose restrictions on access to pharmaceuticals by exclusively stocking one product. In many cases, the continued availability of an alternative product relies on another DHB contracting for its supply. There is currently little or no conscious co-ordination of this approach.

Many hospitals undertake drug utilisation reviews to ensure “best clinical practice” in the use of them and have demonstrated an ability to indirectly produce savings in pharmaceutical expenditure via this method. Most appear to endeavour to manage expenditure on New Pharmaceuticals by subjecting them to a multi-disciplinary clinical assessment process involving clinicians, and pharmacists. Where clinical budget holding exists, service manager approval may be required before a product can be added to a PML or formulary. These processes appear to work quite well at a local level because they ensure clinicians have had input into the decisions made. However, the process can create tensions between speciality groups. Use of New Pharmaceuticals and/or existing pharmaceuticals for new indications sometimes precedes formal assessment, and internal budgeting arrangements can be an incentive for the approval of new medicines.

While hospital managers tend to consider access to subsidies for new agents in the community, the criteria against which they assess new treatments vary. The rigor of the analysis, and the degree to which cost-effectiveness is considered when determining whether pharmaceuticals should be used within each hospital also appears to be quite variable. Some cost analysis is undertaken by most hospitals prior to introduction of New Pharmaceuticals. However, cost-benefit analysis is currently rarely performed, due

in part to the limited availability of reliable and meaningful costing data relevant to the sector.

Differences in the assessment processes and criteria may partly account for the fact that New Pharmaceuticals (or existing pharmaceuticals for new indications) are sometimes funded within some hospitals but not in others or, where funded universally, are subject to different caveats. In these cases, problems can arise when patients transfer from one hospital or DHB to another. However, this may be more of an issue when patients transfer from tertiary or quaternary services to secondary care or where they transfer to the care of a clinician who does not normally practice in the same speciality.

### **2.5 *The primary/secondary care interface***

Patients who require on-going pharmaceutical treatment after hospitalisation are often discharged with a prescription reflecting the pharmaceutical treatment administered during their stay or prescribed treatment in an out-patient setting. However, patients are rarely discharged from hospitals with supplies of the pharmaceuticals they require. Their discharge prescriptions, like prescriptions for out-patients, may not reflect the availability of pharmaceuticals in the primary care sector. In certain cases, hospitals explicitly fund pharmaceuticals because they are not available on the Pharmaceutical Schedule. The scope for improved patient care via better communication between the primary and secondary care sector, and consistency of access to pharmaceuticals in both areas is widely acknowledged.

### **2.6 *Distribution systems***

There is variation between DHBs in the way pharmaceuticals are distributed. Pharmaceuticals purchased directly from Health Support Services (HSL) in some areas, may account for 50% of the volume of pharmaceuticals nationally. HSL provides a range of services to DHBs including logistics, purchasing, and inventory management. Some DHBs utilise only the logistics services offered by HSL, while others rely on HSL to negotiate prices for some pharmaceuticals on their behalf, and purchase on consignment from HSL also. Other DHBs purchase their pharmaceuticals through other wholesalers or directly from pharmaceutical suppliers. Some have direct-to-ward delivery arrangements with such organisations.

### **3.0 Features and Objectives of a Strategy for Nationwide Hospital Pharmaceutical Purchasing**

The broad objectives of the Strategy already outlined, are aimed at achieving the best possible value for money spent by DHBs on Pharmaceuticals used in hospitals, and to improve nationally consistency of access to Pharmaceuticals across all DHBs where appropriate. It is acknowledged that the need for Pharmaceuticals in hospitals depends to some extent on the range of services provided by the hospital. However, there have been notable areas of common care where access to Pharmaceuticals has been inconsistent. The Strategy aims to focus on areas such as these.

Opportunity exists within the broader scope of the Strategy, to maximise patient outcomes from DHBs' investments in New Pharmaceuticals. The range of initiatives proposed in respect of price and access to Pharmaceuticals, may at times affect choice in order to create a commercial environment that is conducive to obtaining better value for money. Where this is likely, fiscal gains would be balanced against consideration of the effect on patient care. However, in acknowledgement of concerns about the long-term impact of such initiatives on health outcomes, continuation of the Strategy will be reviewed 2 years post-implementation.

Since DHBs are responsible for all expenditure on pharmaceuticals, it is proposed that the success of the Strategy would be measured, in conjunction with the impact of PHARMAC's initiatives in the community setting, against a nominal expenditure target for both areas. No budget transference is, however, proposed. There would be no change to the DHBs' funding payments to hospitals, which currently provide for their pharmaceutical use, and funding for pharmaceuticals used in primary care would remain with the DHBs.

Given the range of Pharmaceuticals used in hospitals, including a larger number of unapproved and/or "orphan" pharmaceuticals than are used in the primary care setting, it is probably not possible to put national contracts in place for all Pharmaceuticals included within the scope of the Strategy. Therefore, PHARMAC's aim would be to ultimately put in place national supply contracts for about 90% of the value of Pharmaceuticals used in hospitals. This would account for a much smaller proportion (about 10%) of the entire range of Pharmaceuticals used in hospitals. These contracts would ideally confer a net clinical and/or commercial advantage (including net savings) against the current arrangements, if not for every individual DHB, then at least across all DHBs. It is possible that some hospitals would pay more for some Pharmaceuticals but it is expected that the additional costs of those pharmaceuticals would be more than offset by savings made on others.

A key objective of the Strategy would be to ensure the compliance of all DHBs with any national arrangements PHARMAC may put in place. It is proposed that hospitals would be able (and ultimately obliged) to purchase those Pharmaceuticals that are the subject of a national contract, at a single, national price negotiated by PHARMAC. Where there were no national arrangements, hospitals would be able to secure their own purchase arrangements.

Compliance with national arrangements is likely to be closely linked with the fiscal and clinical acceptability of national arrangements. Therefore, key features of the Strategy would be process transparency and consideration of clinical concerns. Clinical issues

would be discussed by PHARMAC, the clinical advisory committee(s), and HPAC before changes are implemented. Particular consideration would be given to the level of choice in the range of Pharmaceuticals available that would need to be maintained. It is also anticipated that clinicians would need some ability to prescribe outside of the restrictions imposed by national arrangements in order to meet the needs of any patients whose health needs are not met by preferred or sole supplier products. This ability would be made available under “Discretionary Variance” (DV) provisions defined in individual supply contracts.

DV provisions would be used within sole supply and preferred supplier agreements to define an allowable limit (either in terms of volume, percentage of total volume, geographic area, or group of patients by indication) up to which DHB would be permitted to purchase non-sole supply/preferred supplier products of the same class or chemical. For example, a sole supply contract for a generic market such as propranolol might allow a small percentage variance or nominal volume (as agreed with the relevant supplier) usage of brands of propranolol other than the sole supply brand nationally. This would mean that any hospital could purchase and use other brands of propranolol provided that the volume of other brands used did not exceed the specified percentage of the total volume of propranolol used by the particular hospital. Alternatively, a sole supply agreement might define sole supply as 100% use of the relevant product for those DHBs who do not wish to make an alternative available but include DV limits for others (thus defining DV limits by geographic area).

Supply contracts might contain penalties or incentives to encourage adherence to the DV limits. For example, a supplier might choose to hold back part of a price concession as a rebate which would be allocated to DHBs according to their proportion of total usage and their compliance with any DV limits. Alternatively, contracts could contain financial penalties to the DHB (payable to the supplier). Penalties could potentially also be enforced via deductions from unrelated rebates and/or other Government payments to DHBs. DHBs could choose to accommodate a higher level of DV than permitted within the contract but, by doing so, would miss out on the financial incentives or incur the financial penalties accorded within the requirements of the contract. DHBs would not be permitted to enter into alternative supply contracts for Pharmaceuticals under sole supply or preferred supplier arrangements.

PHARMAC would not require any formal approval process for use of the non-sole supply brand but DHBs might choose to implement their own approval processes either to prevent exceeding the DV limits or to address non-compliance if the limits are exceeded by their hospital(s).

A similar system could be applied in non-generic markets where preferred supplier contracts (or similar) were in place. It is envisaged that where a contract for a chemical limited access to other chemicals within the same therapeutic category, the DV limits would potentially need to be wider than those that might apply in a generic market.

DV provisions could be monitored by PHARMAC via audit of the reports hospitals would provide in contribution to a national dataset (refer to section 7.1). However, it is envisaged that the onus would be on DHBs and suppliers to ensure compliance with supply contracts.

Key information concerning the rationale for changes made by PHARMAC, including, where appropriate, material submitted to PHARMAC's Board and advisory committee meeting minutes, would be available to DHBs.

An expected benefit of national commercial processes and negotiations being led by a single agency, PHARMAC, is a reduction in the administrative workload and legal costs of similar work duplicated in multiple centres on individual DHBs. While those DHBs that do not currently run extensive commercial processes may consider the need to provide advice to PHARMAC on proposals linked to the strategy to be an additional burden, it is likely that savings will outweigh the impact of such demands. However, it would be important to manage the administrative burden on DHBs, and hospital managers in particular, associated with compliance with restrictions on pharmaceutical use imposed by national contracts.

Key features of the proposed Strategy, once fully functional, would include (but would not necessarily be limited to):

- Management of hospital and community expenditure on Pharmaceuticals according to a joint national target (a notional budget set with reference to monies held by DHBs/hospitals). It is not intended that PHARMAC would actually purchase the Pharmaceuticals.
- Nationally consistent pricing policies covering 90% of DHB's spending on Pharmaceuticals used in hospitals (with provision for choice within the limits defined in contractual "Discretionary Variance" clauses for those patients whose health needs fall outside any contractually derived policy boundaries PHARMAC might set).
- The establishment of a new section of the existing Pharmaceutical Schedule ("Section H"), containing the list of Pharmaceuticals used in hospitals for which PHARMAC has negotiated national contracts on behalf of the DHBs. Section H may also list those pharmaceuticals affected by such arrangements (such as products within a therapeutic sub-group affected by preferred supplier arrangements and alternative brands of chemicals under sole supply arrangements which could only be used within DV provisions). It is likely that Section H would be published separately from, but would legally form part of, the existing Pharmaceutical Schedule.
- Full compliance with any national pricing contracts (where such compliance would permit DHBs to purchase other Pharmaceuticals within the contractually agreed Discretionary Variance limits), once existing contracts have expired or been terminated.
- A centralised assessment process run by PHARMAC to appraise the clinical benefits and cost-effectiveness of New Pharmaceuticals. This process would assist DHBs to ensure that access to new Pharmaceuticals in their hospitals was consistent, where appropriate, with access in other DHBs. It is proposed that, over the first two years, this national process would run in parallel with and augment assessment processes that would [continue to] be undertaken by each individual DHB.

- Information systems that mesh full national hospital utilisation and clinical data in a format that is, where possible, consistent with similar data collected in the primary care setting.
- A national programme aimed at improving quality in the use of medicines by promoting best practice in the use of Pharmaceuticals within hospitals, and the hospital/primary care interface to help to consolidate gains from the Strategy in the long-term. PHARMAC's role might that of co-ordination of the development and implementation of such a programme rather than the undertaking of the initiatives that arise from it.

## **4.0 Strategy Scope**

### **4.1 Range of product-types included**

It is proposed that Strategy should initially be focused on the purchase of Pharmaceuticals.

X-ray contrast media and IV fluids will be included within the scope of the Strategy once the proposed mechanisms for national contracting have been established for Pharmaceuticals. It is also envisaged that processes adopted under this Strategy could also be applied in future to areas such as medical devices, total parenteral nutrition, and special foods. While these areas are more likely to form part of the scope of a longer-term Strategy, proposals involving such products might be considered by DHBs/PHARMAC if offered sooner.

### **4.2 Range of initiatives to be applied**

PHARMAC proposes that the Strategy should initially include the following elements as a minimum:

- (a) price management;
- (b) assessment of new Pharmaceuticals; and
- (c) promotion of quality in the use of medicines (QUM).

While it is acknowledged that the original brief of the Strategy was to develop national purchasing arrangements, assessment of New Pharmaceuticals and promotion of quality in the use of medicines are regarded as pivotal to the longer-term management of expenditure on Pharmaceuticals and to obtain the maximum benefit for patients from the investment in Pharmaceuticals and to obtain the maximum benefit for patients from the investment in Pharmaceuticals. It is also proposed that logistics management be further investigated for possible inclusion within the scope of the Strategy.

#### **4.2.1 Price management**

Any price management strategies adopted by PHARMAC (which are covered in more detail later) would be likely to revolve mainly around requests for proposals (RFP), tendering, and alternative commercial proposals (including cross therapeutic deals, rebate arrangements etc). These strategies would be aimed at securing the best possible price for Pharmaceuticals in current use within hospitals whilst accommodating clinical issues and maintaining access to an appropriate level of choice of Pharmaceutical treatments.

It is proposed that a list of all Pharmaceuticals used in hospitals that were subject to a national contract would be published as a new section of the Pharmaceutical Schedule ("Section H"). For practical purposes, Section H would be published separately to the rest of the Pharmaceutical Schedule, and some of the rules applicable to Section H would differ from the rules that apply to the rest of the Schedule.

The prices and any relevant restrictions on the use of that or similar products agreed under the contracts, would be listed alongside those Pharmaceuticals. DHBs would be expected to purchase such [products at the listed prices and adhere to any applicable

purchasing restrictions. Such purchasing restrictions could include sole supply arrangements, although it is envisaged that the range of restrictions applied would largely be unique to the hospital setting (as opposed to those applied to pharmaceuticals currently listed on the Pharmaceutical Schedule). Any DV provisions in the relevant contracts would be identified in Section H so that such variance could be reconciled with the obligations of DHBs to comply with the Pharmaceutical Schedule (including Section H).

PHARMAC-negotiated price contracts would eventually cover the top 90% of Pharmaceuticals by expenditure. New Pharmaceuticals that have undergone or were undergoing assessment as per the process outlined under section 4.2.2 below would be listed in Section H under a separate sub-section ("National Assessment of New Pharmaceuticals) but, where volumes were low, might potentially never be the subject of national contracts negotiated by PHARMAC.

It is proposed that hospitals could still run their own PMLs or formularies, independent of Section H of the Pharmaceutical Schedule and would update these PMLs from time to time to reflect relevant national policies.

#### **4.2.2 Assessment of New Pharmaceuticals**

It is proposed that a national assessment processes for New Pharmaceuticals be established by PHARMAC, to run alongside existing processes within some DHBs for a trial period of 2 years. New Pharmaceuticals would be those recently (i.e. within the last 18 months) approved for use in New Zealand that would currently be considered by hospitals' medical committees before being introduced for routine use within a hospital. The national assessment process would involve the establishment of committees of clinicians whose brief would be similar to that of the Pharmacology and Therapeutics Advisory Committee (PTAC). Transparency and appropriate representation of hospital specialists on advisory committees would be key considerations in the formation and operation of such committees (refer to section 6.1).

Pharmaceutical suppliers would be required to submit applications for listing of their pharmaceuticals in Section H of the Pharmaceutical Schedule to PHARMAC. DHBs would also be expected to bring to PHARMAC's attention any New Pharmaceuticals being considered for introductory routine use in their hospital(s) or specific departments. However, DHBs could chose to fund those Pharmaceuticals on the basis of their own assessment before PHARMAC's assessment was complete. The process would be as follows:

- (1) Applications for the use of New Pharmaceuticals would continue to be made to hospitals in addition to PHARMAC.
- (2) Hospitals would refer all applications they receive to PHARMAC for "national assessment" but could choose whether or not to review the application locally (via their own therapeutic advisory committees) before doing so.
- (3) Hospitals could commence funding of the Pharmaceutical immediately (subject to their own approval processes) if they choose to undertake a local review and their therapeutic advisory committee(s) recommend access. Hospitals would still be expected to refer the application to PHARMAC and advise PHARMAC of their recommendations and access policies, and the reasons behind these decisions

so that this could be taken into account when any national recommendations and/or decisions were made. While DHBs might wish to enter into contractual arrangements for the supply of New Pharmaceuticals, such arrangements could not be delimited by fixed terms or exclusivity unless such provisions could be overridden without penalty by a subsequent national contract.

- (4) Irrespective of whether New Pharmaceuticals had been assessed at a local level or not, PHARMAC would assess them (as quickly as possible) and promulgate the resulting recommendations to hospitals. DHBs would not be obliged to comply with recommendations made by PHARMAC during the trial period but would be expected to advise PHARMAC of their rationale for any different policy maintained.
- (5) PHARMAC would maintain a list of new Pharmaceuticals that were under national assessment or had been assessed by PHARMAC in Section H of the Pharmaceutical Schedule. The purpose of that list would not be to impose any restrictions on access to the pharmaceuticals listed there, but to raise awareness of the fact that a recommendation had or was about to be made by PHARMAC.
- (6) PHARMAC might seek to secure national supply contracts for New Pharmaceuticals once they had undergone national assessment (for instance, when usage reached a commercially significant level). National contractual arrangements would need to accommodate regional differences in access policies resulting from local reviews that could be justified on clinical grounds. Once under a national contract, the New Pharmaceutical would become listed in the main body of Section H (as opposed to the separate section for New Pharmaceuticals under national assessment).

It is acknowledged the voluntary nature of the assessment processes proposed for New Pharmaceuticals above may not ensure national consistency of access. However, the proposed process should facilitate the introduction of cost-utility analysis into assessments for Pharmaceuticals used in hospitals, promote dialogue on clinical and fiscal issues, and gradually build confidence in a system aimed at ultimately achieving national consistency of access to all Pharmaceuticals. An additional benefit of a concurrent national assessment process is that it would facilitate review by a number of experts where hospitals may only have one relevant specialist with the expertise to assess Pharmaceuticals in certain therapeutic areas.

Given the problems associated with a lack of nationally consistent access to treatments for cancers and the recommendations of the NZ Cancer Treatments Working Party, the above process will not apply to new cancer treatments. While the assessment process for these agents will be consistent with that proposed for other New Pharmaceuticals, it will be mandatory for all new pharmaceutical treatments for cancer to be reviewed by PTAC, a specialist sub-committee, and assessed by PHARMAC *before* being funded by any DHB. The sub-committee at the end of the assessment process, but before a decision is made by PHARMAC, would again review any restrictions on access to these agents to ensure that they are appropriate. Under this process, it is envisaged that allocation of funding will be contingent on:

- (a) the costs and benefits of the assessed New Pharmaceutical exceeding those of other pharmaceuticals, in any therapeutic area, awaiting funding; and

- (b) the availability of sufficient funding either from within the budget(s) managed by PHARMAC or from additional money allocated by the Ministry of Health/DHBs.

While the reasons for this difference relate exclusively to the specific issues that have been associated with access to cancer treatments, the effectiveness of this alternative process may be relevant to the review of the assessment processes proposed for New Pharmaceuticals at the end of the two years trial period.

#### **4.2.3 Promotion of quality in the use of medicines.**

While many hospitals undertake initiatives to promote quality in the use of medicines, these efforts are not co-ordinated across DHBs, nor does New Zealand have any Government-recognised national standard for clinical pharmacy practice. Given developments of this nature in overseas countries, and the greater potential for such initiatives to help improve health outcomes and achieve better value for money spent on pharmaceuticals, this is considered to be a deficiency. HPAC has recommended that the Government should establish a steering group to develop a quality in the use of medicines (QUM) strategy for New Zealand. While it is acknowledged that PHARMAC does not currently have specific expertise in this area, it is noted that such a strategy would be consistent with PHARMAC's legislative objective to promote the responsible use of pharmaceuticals. Given PHARMAC's interest and expertise in the use of pharmaceuticals, and proposed involvement in procurement and assessment of Pharmaceuticals used in hospitals, it is logical for PHARMAC to establish and co-ordinate a QUM steering group as part of this Strategy.

It is proposed that PHARMAC would establish the QUM steering group as a sub-committee of HPAC, with representatives from HPAC and a mixture of clinicians and specialist pharmacists with an interest in this area. This would facilitate links between the QUM strategy and PHARMAC's proposed procurement strategies via HPAC. In developing the strategy, it would be appropriate for the sub-committee group to consider the role of drug utilisation review (DUR), education, compliance monitoring, reporting of adverse events from pharmaceutical interventions, guidelines on the use of medicines, clinical pharmacy standards and the hospital/primary sector interface. It would be useful to examine QUM systems and programmes in use overseas. The role of the sub-committee would be to develop a project plan and programme of activities using a combination of these and any other initiatives it considered appropriate.

It is proposed that any national programme of QUM initiatives recommended by the sub-committee would rely mainly on, and utilise the expertise of the resources that already exist within hospitals. Activities might include the development of educational material, and/or organisation of visits from experts aimed at addressing medication-related therapeutic issues either in the hospital setting or those that span both hospital and community.

If DUR is considered by the sub-committee to be a useful tool in promoting quality use of medicines PHARMAC might be able to assist by providing better co-ordination of such initiatives and/or information sharing. It is clear that the information and expertise required to conduct such reviews is concentrated within the hospital sector and that it would, therefore, be more appropriate for such analysis to be undertaken at a local rather than national level. However, the effectiveness of DUR within hospitals could be enhanced by some form of national co-ordination. This likely to be of most assistance to

those smaller DHBs for whom the resources available to undertake such analysis are limited. It is possible that:

- (1) PHARMAC could establish, in consultation with DHBs, a programme of areas on which DHBs would be encouraged to focus their DUR activities within a given period.
- (2) DHBs would be asked to provide input as to what should be included in the programme.
- (3) Community-based organisations with an interest in DUR, such as BPAC and PreMec, could also be invited to contribute to the programme.
- (4) The programme would be voluntary (i.e. DHBs could undertake activities in some, all or none of the areas identified in the programme.)
- (5) PHARMAC could collate a national database of the results of DURs conducted in participating hospitals and promulgate this information to all DHBs for use in the development of local or national guidelines.

Alternatively, the co-ordination role could be taken up or let as a service to an independent organisation. Responses to consultation indicate that this option may be preferred by hospital managers.

#### **4.2.4 Logistics management**

Subject to a detailed assessment of the current distribution arrangements and costs, PHARMAC might include a request for proposals for distribution arrangements within the scope of the Strategy. The main objective of such an initiative would be to facilitate the collection of a national data set although it is possible that it might also provide savings for DHBs.

Given the diversity of existing arrangements which have been adopted to address issues including locality and capacity, it is likely that DHBs would want to maintain the key services provided to hospitals under current distribution arrangements. While it may be difficult to achieve this under a single national distribution arrangement, it may be possible to improve distribution arrangements and facilitate data collection without increasing the overall costs of distribution to DHBs, under multiple new arrangements via an RFP.

## **5.0 Proposed Pricing Strategy Initiatives**

While some of the initiatives adopted by PHARMAC in order to manage DHB expenditure on Pharmaceuticals used in hospitals would be similar to those used in the community setting, there are some important points of difference, which are noted below:

### **5.1 Application of reference pricing**

PHARMAC does not propose to utilise reference pricing in the hospital sector at this time. However, the concept of therapeutic sub-groups might be applied elsewhere, such as when considering whether products are suitable for sole supply arrangements.

### **5.2 Initial Request for Proposals**

PHARMAC proposes to commence implementation of the Strategy with an invitation to suppliers to submit pricing proposals for those products already purchased by hospitals (the "Initial Request for Proposals" or "Initial RFP"). It is envisaged that PHARMAC would first work with DHBs to develop a list of Pharmaceuticals in respect of which proposals would be invited (the "Initial RFP List"). Initial development work may include identification of those products, which would not be suitable for sole supply arrangements, those therapeutic groups where availability of a range of chemicals is desirable, and any pack-size, presentation or labeling issues that might need to be considered. However, clinical and continuity of supply issues are also likely to arise, and would be considered, during any consultation on the list and/or when assessing proposals. The proposals received would be evaluated on a number of criteria, not just price. For example, consideration would be given to the impact of each decision on costs elsewhere in the health sector, and quality issues such as packsize, labeling, ease of use to ensure that overall, the best value for money is obtained. Comment is invited on the exact assessment criteria to be adopted (refer to section 6.5).

Unlike the tenders PHARMAC runs for pharmaceuticals used in the primary care setting, it is likely that alternative commercial proposals would not be sought prior to finalising the list of pharmaceuticals for the Initial RFP. Instead, suppliers would be asked to submit pricing proposals by individual line-items and could submit prices associated with a composite proposal concurrently if they so wished.

This process is expected to take 6-8 months from development of the Initial RFP list to assessment of proposals. Therefore, it is envisaged that the first national contracts resulting from the Initial RFP would be implemented sometime in quarter 2 of the next financial year (2002/03).

RFPs would become a regular feature of PHARMAC's price management strategies – either to replace expired or terminated national contracts or to secure arrangements in respect of new pharmaceuticals (i.e. those previously not available in hospitals).

PHARMAC would maintain an "open-door" policy for suppliers to put forward proposals outside of the RFP processes, but would not accept proposals involving exclusive or sole supply arrangements that were not subject to a competitive process.

### **5.3 *Alternative Commercial Proposals***

PHARMAC might also consider alternative composite proposals (“ACPs”) offered, without specific invitation, by suppliers before the issue of the Initial RFP or any subsequent RFP. Such proposals could not involve exclusive or sole supply arrangements.

Arrangements covered by composite proposals offered via the Initial RFP, other RFPs or ACPs might include cross-deals, rebates, market caps, preferred access, tender protection, two-part pricing, extension of existing contractual arrangements with PHARMAC from the community setting to include supply to hospitals, etc.

### **5.4 *Sole supply and Preferred supply arrangements***

Sole supply arrangements are likely to be used by PHARMAC in markets where generic competition exists. While such arrangements would result in there being only one brand of a particular chemical listed in Section H of the Pharmaceutical Schedule, it is not proposed that sole supply tenders would be run for therapeutic groups (e.g. a class of pharmaceuticals such as proton pump inhibitors). However, it is possible that PHARMAC would agree preferred supplier status for some chemicals in exchange for price concessions, affecting access to related pharmaceuticals within the same therapeutic group. Both sole and preferred supplier contracts would contain provision for use of other agents within agreed DV limits, which may be based on volume, percentage of total volume, geographic area, or group of patients by indication. Availability of a range of pharmaceuticals and/or arrangements for back-up supply may be necessary in some cases where sole supply arrangements were put in place.

## **6.0 Implementation of a Nationwide Pharmaceutical Pricing Policy**

Implementation of a nationwide pharmaceutical pricing policy for hospitals centers around four key issues:

- (a) Consultation with hospital managers and clinicians.
- (b) Communication of national prices.
- (c) Transitional arrangements.
- (d) Assessment criteria.

### **6.1 *Consultation with hospital managers and clinicians.***

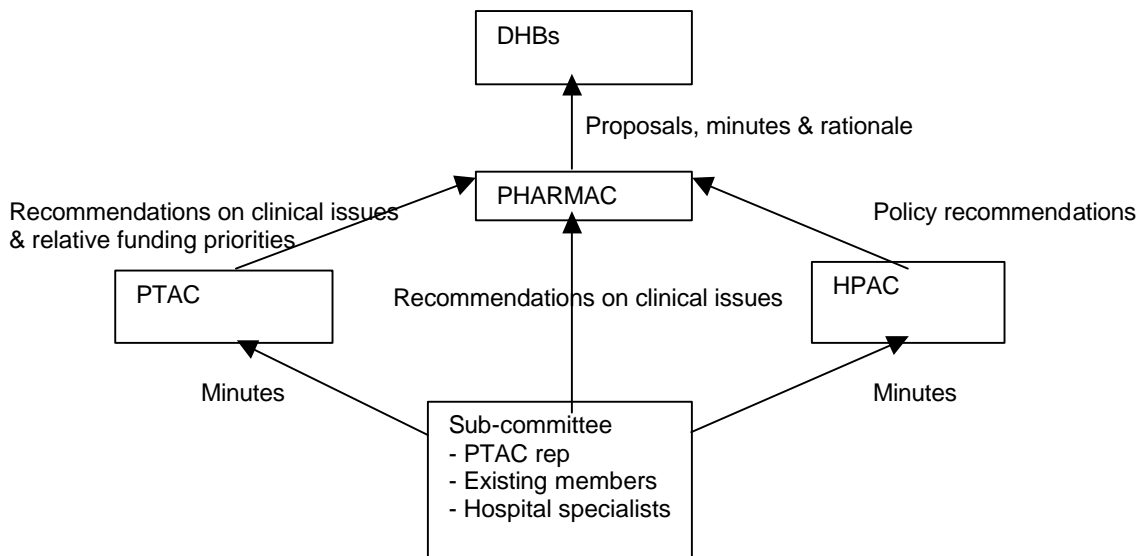
It is proposed that PHARMAC would base its clinical assessment of hospital pharmaceuticals on the existing PTAC system, utilising its sub-committees with additional representation from hospital specialists. The current sub-committees of PTAC generally consist of one or two representatives of PTAC, and a mix of specialists and GPs with interest/expertise in the relevant specialty.

It is proposed that an appropriate number of hospital specialists would join the existing sub-committees whenever hospital pharmaceuticals were considered (i.e. sub-committees would meet to consider a range of hospitals and/or the community pharmaceuticals. Hospital representatives need not participate in discussions about community-only medicines and, where appropriate, would replace the appointed general practitioners on the sub-committee for discussions relating to hospital-only medicines). For specialties for which there is no relevant PTAC sub-committee currently in existence, PHARMAC would establish a new sub-committee within similar PTAC/hospital representation, when the need arises.

All sub-committees would report to PHARMAC and PTAC (whose role would be to put the recommendations of the specialist sub-committees in the context of the wider priorities for spending on pharmaceuticals and to provide a link with assessments for pharmaceuticals used in the community). Their minutes would be made available to clinicians and managers within the DHBs and specifically considered by HPAC when it provided advice to PHARMAC on particular proposals.

PHARMAC would seek nominations for appointments to particular sub-committees from relevant colleges and clinical groups. Each DHB would then vote for their choice of non-PTAC appointments. Inclusion of HPAC members on the clinical sub-committees of PTAC will be considered.

The consultation process would operate as shown:



## 6.2 Communication of national prices.

PHARMAC proposes that adherence to a national pricing policy for pharmaceuticals used in hospitals be enforced via the current legislative requirement (Section 23(7) of the New Zealand Public Health and Disability Act, 2000) for DHBs to comply with the Pharmaceutical Schedule. Accordingly PHARMAC proposes the following:

- A new section of the existing Pharmaceutical Schedule (“Section H”), containing the list of those Pharmaceuticals used in hospitals which were subject to national contracts is likely to be published separately from, but would legally form part of, the existing Pharmaceutical Schedule.
- Section H would set the ex manufacturer prices (as opposed to subsidies) at which, subject to the cost of distribution, DHBs would be able to purchase listed Pharmaceuticals.
- Some of the rules applicable to Section H would differ from the rules that apply to the rest of the Pharmaceutical Schedule.
- DHBs would be obliged to comply with those prices and agreements when purchasing pharmaceuticals. Initially, this requirement might need to be subject to existing contracts, until such contracts were terminated or expired.
- Where national contracts had been negotiated, it is envisaged that DHBs would not subsequently enter into their own individual contracts.
- Purchasing restrictions (such as sole supply arrangements or limitations on access to a wider selection of brands and/or chemicals) as required under national contracts negotiated by PHARMAC, would be associated with some Pharmaceuticals listed in Section H. There would be consultation on proposals with DHBs and clinical groups prior to the implementation of such purchasing restrictions. Where such restrictions

applied, DHBs would be required to comply with them within defined limits of variation.

- Where sole supply arrangements are in place, only the sole supply brand of a particular chemical would be listed in Section H (although other brands would be used within DV limits and this use would need to be reported/monitored).
- Where preferred supplier arrangements are in place, the relevant sub-section of Section H would show all the products available within the relevant therapeutic category and the conditions of access for each product.
- Section H would indicate which products were also listed in other sections of the Pharmaceutical Schedule, and which are fully subsidised there.
- New pharmaceuticals could be used before they were listed in Section H. However, the intention is that such new products would eventually end up listed in a special sub-section for new products undergoing national assessment or in the main body of Section H.

Issues such as how often the Section H would need to be published and how to accommodate hospital-specific pack-size and/or presentation requirements, which may differ from those used in the community, would be dealt with as the needs arise.

### **6.3 Transitional arrangements**

Implementation of the Strategy, and the introduction of national contracts would require co-ordination to ensure continuity of supply and price stability as existing pharmaceutical supply contracts held by DHBs are replaced.

The first national contracts, which are expected to arise out of the Initial RFP process, are likely to be put in place in or around September 2002. While this may coincide with the natural expiry or optional renewal of some existing contracts, it is likely that others will fall due for renegotiation before then or may not expire until some time after that date. Where contracts fall due before national contracts are in place, DHBs will be faced with the issue of finding interim supply arrangements. Where possible, and where they are aware of pending national contracts, they should seek to roll existing contracts over for a short period of time. However, where this is not possible or where it would be fiscally imprudent, DHBs might need to enter into short-term interim supply agreements.

PHARMAC proposes that DHBs would include clauses to the effect of (a) and (b) below in any new contracts entered into with suppliers from now on (and, where possible, any renewed contracts) to enable those contracts to be superceded by any national arrangements PHARMAC subsequently implements and to facilitate future data collection:

- (a) This Agreement Superceded by PHARMAC Agreement

Both parties acknowledge that the Minister of Health has authorised PHARMAC, as one of its statutory functions under the New Zealand Public Health and Disability Act 2000, to manage the purchasing of any or all hospital

pharmaceuticals, whether used in a hospital or outside it, on behalf of district health boards ("**DHBs**").

Both parties agree that where PHARMAC enters into [, or has entered into,] an agreement with a supplier for the national purchase of a pharmaceutical or pharmaceuticals covered by this Agreement (the "**PHARMAC Agreement**"), then this Agreement or, as applicable, parts of this Agreement, will be deemed to be superceded by the PHARMAC Agreement in respect of such pharmaceutical or pharmaceuticals to the maximum extent necessary to give full effect to the PHARMAC Agreement. Where there is any conflict between this clause and any other provisions in this Agreement, this clause will take precedence.

(b) Access by PHARMAC to Price and Volume Data

Both parties acknowledge that PHARMAC may require access to price and volume data [held by us] in respect of pharmaceuticals covered by this Agreement to assist PHARMAC to carry out its statutory function in relation to managing the purchasing of hospital pharmaceuticals on behalf of DHBs.

Notwithstanding any other provisions in this Agreement, including clause[s] [ ] regarding confidential information, both parties agree that where the circumstances in this clause apply, we may [, following prior written notice to you,] provide PHARMAC with any price and volume data [held by us] in respect of any pharmaceuticals covered by this Agreement.

Given that PHARMAC does not have access to the particular contracts that the clauses are to be included in, it is possible that these issues could alternatively be dealt with by amending other provisions in each DHB Contract.

In any event, clauses (a) and (b) would need to be reviewed against relevant provisions in each DHB Contract to determine whether they should be grafted on to existing clauses or if their drafting should be modified for consistency with existing clauses (including definitions) in the DHB Contract and may need to be tailored to avoid or clarify the position in respect of any conflict with other provisions in the DHB Contracts.

Those contracts that are already in existence, which may not contain such a clause, may need to remain in force until they expire. However, it is proposed that where such contracts contain a right of renewal or provision for earlier termination, the merits, limitations and/or penalties associated with exercising those provisions would be jointly assessed by PHARMAC and the DHB(s) concerned on a case-by-case basis as the need arises.

Agreement between PHARMAC and the DHBs to work within the framework described above might need to be reflected in our service level agreements.

#### **6.4 Assessment criteria**

It is proposed that following criteria should be used by the PHARMAC Board, PTAC and its sub-committees for the assessment of new Pharmaceuticals used in hospitals and of commercial proposals arising from the Strategy:

PHARMAC, PTAC and HPAC use the criteria set out below, where applicable and giving such weight to each criterion as PHARMAC. PTAC or HPAC considers appropriate, to makes decisions or recommendations (as applicable) relating to the listing and price of hospital pharmaceuticals in Section H of the Pharmaceutical Schedule. These criteria will be used, in place of the decision criteria in PHARMAC's Operating Policies and Procedures, where pharmaceuticals for use in hospitals are concerned.

Where there are factors listed under a particular criterion, PHARMAC, PTAC or HPAC will consider those factors, where applicable and giving such weight to each factor as it considers appropriate, in the course of applying that criterion. In doing so, PHARMAC, PTAC or HPAC will seek or use such supporting information as it considers appropriate.

The criteria are as follows:

- (i) the health needs of all eligible people within New Zealand;
- (ii) the particular health needs of Maori and Pacific peoples;
- (iii) the availability and suitability of existing medicines, therapeutic medical devices and related products and related things, having regard to (without limitation) to:
  - other interventions (existing pharmaceuticals, medical/surgical interventions, therapeutic medical devices etc) currently available to meet the health needs that would be met by this pharmaceutical;
  - other interventions this pharmaceutical be used in addition to or instead of;
  - evidence that this pharmaceutical is more efficacious, safer and/or clinically more acceptable to patients than the other interventions currently available to meet these health needs;
  - the clinical significance of any advantages identified above;
- (iv) the availability and suitability of this pharmaceutical for use in hospitals, having regard (without limitation) to:
  - the importance of uninterrupted supply of this pharmaceutical;
  - the reliability of the supplier of this pharmaceutical in ensuring its availability;
  - other pharmaceuticals or other interventions that could be used in the event that this pharmaceutical was unavailable;
  - the suitability of the packaging and/or proposed packsize for this pharmaceutical;
  - the impact, if any, that this proposal would have on existing DHB supply contracts;

- (v) the clinical benefits and risks of pharmaceuticals;
- (vi) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, having regard (without limitation) to:
  - the cost-effectiveness of this pharmaceutical
  - the effect that the use of this pharmaceutical would have on:
    - (a) the total cost of pharmaceuticals used in hospitals and/or the community;
    - (b) the total cost of non-pharmaceutical hospital acquisitions;
    - (c) staff costs in hospitals; and
    - (d) other costs to DHB.
- (vi) the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule, having regard (without limitation) to:
  - the impact this proposal has on total expenditure on pharmaceuticals;
- (vii) the direct cost to health service users;
- (viii) the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- (ix) such other criteria as PHARMAC thinks fit

## **7.0 Monitoring and Measuring the Impact of the Strategy**

The future direction of the Strategy beyond its two-year review will depend largely on assessment of the fiscal and clinical impact it has had on the hospital sector. Achievement of the fiscal objectives of the Strategy and quantitative assessment of the effectiveness of the Strategy is highly dependent on the establishment of national Pharmaceutical utilisation and price dataset (refer to section 7.1). It is proposed that the Strategy would be assessed against the following quantitative indicators:

- annual expenditure targets (refer to section 7.2);
- the cost of pharmaceuticals per occupied bed day per hospital per annum;
- the impact of national contracts on costs of pharmaceuticals (refer to section 7.3); and
- NZ prices compared with overseas prices (refer to section 7.4).

Health outcomes may be more difficult to measure in the absence of reliable baseline data and systems, which enable interventions to be accurately traced at an individual patient level. However, it may be possible for an independent researcher to study the clinical impact of the Strategy by following key interventions in particular therapeutic areas. In addition, the Strategy will be assessed against the following qualitative indicators:

- the number of QUM activities undertaken (e.g. DUR's conducted, education campaigns undertaken etc);
- the effect of the Strategy on the administrative workload in hospitals; and
- the impact on consistency of supply of pharmaceuticals.

### **7.1 Monitoring and analysis.**

Development of RFP documentation, assessment of proposals, monitoring of DHB compliance with Section H of the Pharmaceutical Schedule, and contract monitoring (i.e. for supplier rebates etc) would be based on the data collected by hospitals or their wholesalers.

In the absence of other suitable arrangements for the collation of a national dataset of Pharmaceutical utilisation in hospitals from records held by each DHB, PHARMAC proposes that DHBs should be required to submit regular (monthly) data returns to PHARMAC. These returns would initially contain only volume data and any pricing data able to be disclosed. However, as existing contracts expire, they would eventually contain comprehensive price and expenditure data.

In order to facilitate compilation of a national dataset from these returns, DHBs would need to submit returns using pharmacodes or some other common coding system such as the European Article Number system (EAN). Pharmacodes are issued by the Pharmacy Guild and can be applied to all pharmaceuticals to enable their identification at a pack-size level, but other systems exist. It is acknowledged that some DHBs would need to undertake a considerable amount of work, possibly in conjunction with wholesalers and/or software vendors in order to enable their hospitals to provide

Pharmaceutical utilisation returns using a common code. While a formal assessment of the costs of this work have not been assessed, it is possible that the IT requirements would require an initial investment in excess of \$200,000.

It may ultimately be possible to facilitate data collection via distributors or via the introduction of nationally consistent IT programmes into hospitals. Although the latter is likely to fall outside the scope of this Strategy, it is an issue that merits further investigation.

Until a national dataset is established, PHARMAC proposes to assess the financial impact of any proposals it might put forward by asking DHBs to individually provide their own assessments, including detailed, substantiated feedback on the acceptability of such proposals.

## **7.2 Setting of expenditure targets**

PHARMAC proposes to set expenditure targets for hospital Pharmaceutical expenditure, and to manage pharmaceutical expenditure within a nominal joint expenditure target for Pharmaceuticals used in hospitals and pharmaceuticals used in the community. Funding for Pharmaceuticals would remain within the individual hospital budgets. It is envisaged that managing to a single national expenditure target would enable PHARMAC to negotiate agreements that span both sectors. A single budget would reduce the risk of cost shifting from one budget to another.

It will be necessary to index expenditure targets to another variable such as hospital admissions or occupied bed days in order to offset the effect of changes in demand on overall expenditure.

It is proposed that the national expenditure target for hospital pharmaceuticals would be forecast from a national dataset of hospitals' expenditure on Pharmaceuticals over the last 5 years (collated by PHARMAC), and added to the annual budget set for pharmaceuticals used in the community (i.e. PHARMAC's current budget). As with the current community budget, distribution costs would be excluded for the purposes of this exercise and would be considered separately (with respect to hospitals only) if logistics ultimately formed part of the scope of the Strategy.

## **7.3 The impact of national contracts on costs of pharmaceuticals.**

It is envisaged that the financial impact of national contracts on Pharmaceutical costs could be measured in terms of costs avoided, by comparing actual expenditure against the value of actual volumes purchased at pre-contract prices. The limitations of this method are:

- volumes could increase in excess of the value of price reductions (thus the "savings" would not be realised);
- the value of savings could be artificially inflated by increased volumes; and
- the comparison assumes that the counterfactual is the old price (when the counterfactual may have been a price increase or a price reduction that was equal to or greater than that achieved under a national contract).

These same issues of performance measurement have also been faced by PHARMAC in the past.

#### **7.4 *NZ prices compared with overseas prices***

A useful measure of the effectiveness of the Strategy would be to conduct a comparison of then-current NZ prices and price changes with prices and price changes for equivalent products in overseas markets such as Australia, Canada and the United Kingdom.

## **8.0 Roles and Responsibilities**

### **8.1 *PHARMAC and Members of PHARMAC's Board***

- Collating a national dataset (or negotiating contracts for its collation).
- Managing competitive processes.
- Analysing proposals.
- Negotiating national price contracts.
- Managing the Pharmaceutical Schedule (including Section H).
- Appointing, and managing HPAC and its QUM sub-committee.
- Appointing and co-ordinating PTAC sub-committees.
- Consulting on proposals, restrictions on use of pharmaceuticals and guidelines.
- Decision-making (and providing information to DHBs about the decision process).
- Managing the assessment process for New Pharmaceuticals.
- Co-ordinating activities included in the QUM strategy.

### **8.2 *Hospital Pharmaceuticals Advisory Committee (HPAC)***

- Providing to PHARMAC of technical advice and policy direction on strategies for nationwide purchasing of hospital pharmaceuticals.
- Assisting with preparation of lists for RFPs.
- Evaluating individual commercial proposals and clinical advice provided by the clinical advisory committee(s).
- Representing the views of all DHBs (where possible), liaising with PHARMAC on behalf of other DHBs where requested to, and considering the welfare of the whole sector when making recommendations to PHARMAC.
- Assisting in the development and implementation of QUM strategy via participation on the QUM sub-committee.
- Possible participation on relevant sub-committees of PTAC.

### **8.3 *DHBNZ***

- Assisting PHARMAC on communication of issues to DHBs.
- Facilitating the responses from DHBs on certain issues, as required.
- Providing/ facilitating the provision of feedback from DHBs to PHARMAC on strategic issues relating to the nationwide purchasing of hospital pharmaceuticals.

### **8.4 *District Health Board's Chairs and CEOs***

- Ensuring compliance with data provision requirements.
- Ensuring compliance with national contracts and Section H of the Pharmaceutical Schedule.
- Providing resources (i.e. membership) to HPAC.
- Responding to consultation on strategic issues relating to hospital pharmaceutical expenditure.

### **8.5 Hospital Managers**

- Compiling and providing data in the required format.
- Responding to consultation on proposals, restrictions on use of pharmaceuticals and guidelines.
- Providing assessments of proposals, where required.
- Purchasing pharmaceuticals in accordance with national contracts and Section H of the Pharmaceutical Schedule.
- Advising PHARMAC of new pharmaceuticals.
- Co-ordinating (where applicable) activities that fall out from the QUM strategy.

### **8.6 Ministry of Health**

- Monitoring the performance of DHBs and PHARMAC with respect to the strategy for nationwide purchasing of hospital pharmaceuticals.
- Enabling PHARMAC to bid, on behalf of the DHBs for funding for new pharmaceuticals assessed via its technology assessment processes.
- Assisting PHARMAC on communication of issues.
- Facilitating responses from DHBs on certain issues, as required.
- Monitoring compliance with key performance measures associated with the Strategy.

### **8.7 Hospital Clinicians**

- Providing input into clinical advisory committee(s) if required.
- Participating in local drug utilisation reviews or activities that fall out from the QUM strategy within their hospitals.
- Responding to consultation on proposals, restrictions on use of pharmaceuticals and guidelines.
- Complying with Section H of the Pharmaceutical Schedule and any national guidelines.

### **8.8 PTAC/Clinical advisory committee(s)**

- Assessing the evidence in support of new pharmaceuticals.
- Making recommendations to PHARMAC regarding the listing of new pharmaceuticals in Section H of the Pharmaceutical Schedule.
- Making recommendations to PHARMAC regarding any guidelines for use that should be applied to new pharmaceuticals listed in Section H of the Pharmaceutical Schedule and other national guidelines such as those resulting from local drug utilisation reviews.
- Providing feedback to PHARMAC on developed proposals relating to new pharmaceuticals.
- Advising PHARMAC on clinical issues relating to any pharmaceutical listed in Section H of the Pharmaceutical Schedule.
- Assisting in the development and implementation of the QUM Strategy.

## 9.0 Proposed Timelines and Milestones

MILESTONE	TARGET DATE
<p><b>Expected annualised value of reduction in the cost of Pharmaceuticals attributable to national contracts implemented in the hospital sector</b></p> <ul style="list-style-type: none"> <li>• \$3 million</li> <li>• \$6 million</li> <li>• \$10 million</li> </ul>	<p>31 December 2002 31 December 2003 31 December 2004</p>
<p><b>First joint hospital/community pharmaceutical expenditure target set</b></p>	<p>31 July 2003</p>
<p><b>Full national price/volume dataset for hospital pharmaceuticals established.</b></p> <ul style="list-style-type: none"> <li>• IT requirements scoped</li> <li>• Full volume dataset compiled by PHARMAC</li> <li>• Regular returns being submitted by 100% of hospitals</li> </ul>	<p>Subject to existing contracts being superseded</p> <p>30 April 2002 1 June 2002 1 July 2002</p>
<p><b>National hospital pharmaceutical schedule established</b></p> <ul style="list-style-type: none"> <li>• National prices set for top 50% of hospital expenditure on pharmaceuticals</li> <li>• National prices set for top 90% of hospital expenditure on pharmaceuticals</li> </ul>	<p>Would co-incide with first national contract.</p> <p>31 December 2003 31 December 2004</p>
<p><b>Initial Request for Proposals (RFP)</b></p> <ul style="list-style-type: none"> <li>• List of pharmaceuticals compiled by HPAC/PHARMAC</li> <li>• First national contracts from Initial RFP implemented</li> </ul>	<p>1 April 2002 31 September 2002</p>
<p><b>All individual DHB pharmaceutical supply contracts include new clause enabling replacement with national contracts</b></p>	<p>Subject to existing contracts being superseded</p>
<p><b>Assessment process for new Pharmaceuticals established</b></p> <ul style="list-style-type: none"> <li>• All applications for New Pharmaceuticals to be sent to DHBs and PHARMAC concurrently.</li> <li>• PHARMAC to call for nominations for clinical advisory committee</li> <li>• Appointments made by PHARMAC Board</li> </ul>	<p>1 March 2002</p> <p>As required</p>
<p><b>Development of QUM Strategy</b></p> <ul style="list-style-type: none"> <li>• Establishment of HPAC sub-committee (QUM Steering group)</li> <li>• QUM Strategy finalised</li> </ul>	<p>31 March 2002 31 July 2002</p>

## 10.0 Summary of proposed strategy for specific issues

Strategy Issues	Short-term	Medium-term	Long-term
Lack of nationally consistent use of coding system	<p>PHARMAC to assess coding systems and provide all DHBs with a list of the chosen code for hospital pharmaceuticals.</p> <p>DHBs to upgrade or develop systems to enable reporting by the chosen code.</p>	<p>Suppliers to get codes assigned to all new products.</p> <p>All new pharmaceuticals to be input into DHBs' systems by a common code.</p>	Possible management of data collation by wholesalers.
National dataset - market analysis/contract monitoring	<p>DHBs to verify/provide financial assessment of individual proposals as PHARMAC consults on them</p> <p>and</p> <p>DHBs to regularly provide volume data and any price data able to be disclosed to PHARMAC.</p> <p>or</p> <p>PHARMAC to subscribe to IMS Health data if possible.</p>	<p>PHARMAC to subscribe to IMS Health data if possible.</p> <p>and/or</p> <p>PHARMAC to run a RFP for logistics management (including data collection) if appropriate.</p> <p>and/or</p> <p>DHBs to continue to submit regular returns containing volume data and any pricing data able to be disclosed to PHARMAC.</p>	<p>Possible collection of data via logistics manager.</p> <p>or</p> <p>Possible development of nationally compatible IT systems (outside scope of strategy).</p>
Budget configuration	<p>Budgets stay within hospitals.</p> <p>Strategy monitored in terms of total savings from transactions only.</p>	<p>PHARMAC and DHBs to set a nominal national expenditure target for pharmaceuticals used in hospitals and the community</p> <p>Monies to remain with current budgets.</p>	No change from medium term approach.

Issues \ Strategy	Short-term	Medium-term	Long-term
Price setting	<p>DHBs purchase pharmaceuticals at PHARMAC -negotiated prices (where they exist) unless they have a current contract of their own.</p> <p>All new contracts negotiated by hospitals to include provision for replacement with a national contract.</p>	<p>Continuance of short-term strategy until current contracts expire.</p> <p>Expansion of national contracts via RFPs and ACPs.</p>	<p>Full replacement of individual contracts with national contracts.</p> <p>National prices for top 90% of pharmaceuticals used in hospitals (by value).</p>
Logistics	Hospitals to continue under current arrangements.	Hospitals to comply with results of any RFP.	Possible continuation of medium-term strategy
New technology assessment	<p>DHBs to advise PHARMAC of new pharmaceuticals not yet available within hospitals. PHARMAC to conduct assessment. DHBs able to use new pharmaceuticals in the interim.</p>	Subject to outcomes of assessment of any transitional arrangement implemented.	Subject to outcomes of assessment of any transitional arrangement implemented.

## **11.0 Other considerations**

Implementation of the Strategy is expected to confer a range of benefits across the health sector. For the DHBs, the benefits are likely include greater buying power, improved value from expenditure on Pharmaceuticals, and a reduction in the resources committed to pharmaceutical procurement. Benefits for patients are also anticipated as greater consistency of access to Pharmaceuticals between hospitals is achieved over time. Closer alignment of pharmaceutical pricing and access policies between the primary and secondary care sectors is also likely to promote more seamless care, and ultimately improve patient outcomes. It is also possible that the Strategy could have positive spin-offs for the New Zealand pharmaceutical market, such as encouraging new suppliers into the market. However, the potential risks and issues associated with the Strategy are acknowledged.

### ***11.1 Long-term impact on pharmaceutical market***

It is acknowledged that the application of the initiatives outlined to manage DHB's expenditure on pharmaceuticals used in hospitals, in conjunction with those policies already in existence in the primary care setting, could impact on the range of pharmaceuticals and/or number of pharmaceutical suppliers in the New Zealand market. It is possible that competition in markets for hospital Pharmaceuticals might encourage the entry of new generic suppliers into New Zealand. Equally, there is concern that suppliers who are unsuccessful securing exclusive supply arrangements might leave the market. Provided any potential adverse effects on the market are specifically taken into account and reasonable steps taken to ensure that the market remains viable and competitive, the long-term impact on the pharmaceutical market is not considered to be a strong reason not to pursue a nationwide purchasing strategy for hospital pharmaceuticals as proposed.

### ***11.2 Effect on pharmaceutical research***

The proposed nationwide purchasing strategy for hospital pharmaceuticals, if successful, could potentially become a factor in the amount of research into pharmaceuticals being conducted in New Zealand. The subject of investment into pharmaceutical research has already being discussed outside the scope of this strategy but is an issue that needs to be considered. Consideration would also need to be given to the impact of the Strategy on locally funded trials currently undertaken within hospitals.

### ***11.3 Effect on opportunities for clinical education***

It is acknowledged that many clinicians derive benefit from travel allowances, conference attendances etc sponsored by pharmaceutical companies. It is possible that such opportunities may diminish as a consequence of the success of this nationwide purchasing strategy for hospital pharmaceuticals. However, it may be appropriate for some of the money being spent in this area to be redistributed via pricing for the more direct benefit of patients and it is likely that parts of the New Zealand pharmaceutical market would still be able to afford to support these initiatives to some degree. Sponsorship of clinicians is unlikely to disappear entirely as a consequence of the proposed strategy.

#### **11.4 National data systems**

Immediate commencement of the development of a national hospital sector data collection strategy designed to provide information systems to capture appropriate pharmaceutical utilisation and clinical data in a format that meshes is consistent with similar data collected in the primary sector is recommended. However, it is acknowledged that such a strategy would involve additional resources and would fall outside the scope of this Strategy. It is also acknowledged that, because hospitals do not issue all pharmaceuticals at a patient level, it may never be possible, even with improved systems, to track all utilisation at that level.

#### **11.5 “Orphan” and Section 29 medicines**

A range of medicines, not commercially available, is supplied by pharmaceutical companies on compassionate grounds. These products include medicines required specifically for an individual or small group of patients and special formulations such as those for paediatric use. Concern has been expressed that the Strategy may result in pharmaceutical companies reducing this service to the detriment of a small number of patients, who may derive significant benefit from these medicines. While there is theoretically some risk of this and some pharmaceutical companies have indicated that this may be the outcome of the Strategy, the availability of such medicines is likely to be influenced as much by other factors within the pharmaceutical industry. The Strategy may facilitate the improved availability of orphan and section 29 medicines through a nationally coordinated focus and purchase arrangements.

#### **11.6 Potential mutual benefits for primary and hospital sector**

Implementation of a hospital-focused Strategy in conjunction with PHARMAC is likely to facilitate greater liaison between the hospital sector and the primary care sector. In addition to the potential benefits for patients that would result from improved consistency between the two sectors in terms of pharmaceutical policy, there are opportunities to address known issues in a collaborative manner. Such issues might include the impact of global rationalisation by pharmaceutical companies on supply of essential medicines with small markets in New Zealand and funding of pharmaceutical treatments that are not listed on the Pharmaceutical Schedule for patients who are not hospitalised.

## **12.0 Risks, Benefits and Costs of the Strategy**

### **12.2 Risks associated with the Strategy**

- (1) Adverse effects on health outcomes. There is no easy way to assess the likely impact of the Strategy on health outcomes – positive or negative.
- (2) Adverse effects on pharmaceutical industry – The responses of clinicians and DHBs indicate that any reduction in the presence of the pharmaceutical industry in New Zealand – office closures, withdrawal of products, failure to launch new products, stock shortages, withdrawn education support and/or sponsorship and/or reduced research – would be regarded as a consequence of the Strategy, whether or not this was the case.

### **12.2 Costs and Benefits of the Strategy**

PHARMAC's assessment of the anticipated benefits of the Strategy, as they relate to its stated objectives, is as follows:

- (1) National consistency of access to pharmaceuticals: – The proposed two-year trial of voluntary processes for assessing New Pharmaceuticals mean that disparities in access to pharmaceuticals could still occur for the time being. The fact that the New Zealand Cancer Treatments Working Party has recommended a mandatory PHARMAC-review for pharmaceuticals used to treat cancers should prevent a repeat of the problem in this particular market. We would also expect national consistency to gradually improve if DHBs accept PHARMAC's recommendations during the trial period.
- (2) A co-operative purchasing framework by collaboration between DHBs: – The development of the Strategy has already shown the potential benefits in this regard. There is now a strong joint focus on the issues relating to pharmaceutical management where previous attempts by the DHBs to collaborate in this area fell short. Many of the responses received in response to consultation suggest that DHBs consider the framework to be applicable (and potentially more effective) in other areas.
- (3) A more co-ordinated approach to pharmaceutical use across primary and secondary care (refer to section 11.5).
- (4) Improved information systems and availability to Government of data about utilisation of Pharmaceuticals in the hospital sector: - the current lack of a national dataset is a key barrier to more cost-effective utilisation of Pharmaceuticals used in hospitals for a number of reasons. Without a national dataset that is available to DHBs, there is no practical way to compare the effectiveness of existing pharmaceutical management Strategies. The development of a national dataset will enable DHBs to assess whether a national approach to hospital pharmaceutical management is more effective than current arrangements. More importantly, if it is determined after two years that a national approach is not optimal, DHBs would be in a better position than they are currently to assess their alternative options.

(5) Financial benefits: - PHARMAC expects only a modest reduction in the costs of pharmaceuticals used in hospitals (which, given demand driven growth, would not necessarily result in an overall fall in total pharmaceutical expenditure). We consider it unlikely that the maximum value of any reductions obtained would exceed \$10 million per year, and anticipate that data issues will continue to be a barrier to optimal effectiveness of any pricing strategy for up to two years.

- Without a national dataset, it is impossible to quantify the potential for price reductions. In the absence of national price and volume data, PHARMAC cannot easily identify opportunities for price, plan or implement commercial activities or monitor any pricing strategy. Optimal effectiveness of any pricing strategy adopted could be limited by the availability of consistently coded price and volume data.
- It is likely that PHARMAC could obtain volume data from DHBs. However, those data would need to be reported according to a common coding system in order for PHARMAC to collate them. This is likely to require an upgrade of IT systems within many hospitals which could cost as much as \$200,000. The costs and benefits of such work and the proposed reporting requirements need to be assessed.
- Access to volume data would enable PHARMAC to operate a rudimentary RFP process in which it would have to rely on the DHBs' own assessment of the commercial value of any bids or proposals received.

(6) Better utilisation of DHBs' resources: - It is more likely that DHB would utilise the staff resources they current have assigned to pharmaceutical purchasing in other areas rather than reducing staff levels. PHARMAC estimates that implementation of the Strategy in the form now proposed would require the following resources within PHARMAC:

- a full-time senior manager (to manage commercial transactions and relationship issues);
- an advisor (to conduct and co-ordinate commercial analysis and transactions);
- and
- at least one additional analyst (dedicated to assessment of New Pharmaceuticals);

In addition to these human resources (estimated value \$250,000 per year) it is likely that PHARMAC would need to take legal advice (mainly to ensure procedural correctness for competitive processes and contracting) to the value of \$150,000 per year or more. However, these legal costs are likely to be more than off-set by savings from the reduced need for DHBs to take legal advice individually. Provided DHBs do not have to increase their own resources in order to respond to implementation and monitoring requirements associated with the Strategy, the potential to increase administrative costs is small.

(7) Greater co-ordination of efforts to promote quality use of pharmaceuticals (refer to section 4.2.3).

## **Glossary of terms and abbreviations**

For the purposes of this document, the term(s):

“ACP” stands for Alternative Commercial Proposals.

“cost” or “price” where used in the context of pharmaceuticals is intended to mean cost or price “ex manufacturer excluding rebates and distribution costs” unless otherwise stated.

“cross-deal” means any proposal from a single supplier involving more than one Pharmaceutical where a price reduction on one or more Pharmaceutical has been used to off-set or partially off-set additional costs associated with another.

“DHB” stands for District Health Board.

“drug utilisation reviews” means initiatives within hospitals under which prescribing practices with respect to particular drug groups or disease states are assessed against the relevant published evidence, and modified where appropriate using guidelines.

“Discretionary Variance” refers to polices to be defined, which would enable DHBs to depart, within limits and for patients whose exceptional clinical needs require it, from restrictions imposed by PHARMAC on the use of Pharmaceuticals listed in Section H of the Pharmaceutical Schedule. DV limits could be set with reference to volume, percentage of total volume, geographic area, or group of patients by indication.

“HPAC” stands for the Hospital Pharmaceutical Advisory Committee.

“HSL” stands for Health Support Limited.

“hospital managers” should generally be interpreted as meaning pharmacy managers, clinical services managers, funding and purchasing managers or any manager responsible for the procurement or use of pharmaceuticals in their particular hospital.

“logistics” and “distribution” are used interchangeably. Both terms are intended to be inclusive of any purchasing, inventory management and/or direct-to-ward delivery arrangements offered by pharmaceutical wholesalers.

“market caps” or “cap” are maximum expenditure limits on either a group of Pharmaceuticals (a market) or a single Pharmaceutical defined in contracts between PHARMAC and a pharmaceutical supplier, above which the DHB would not bear 100% of the cost of Pharmaceuticals covered by that cap that are purchased and used by a hospital.

“mix” where used in the context of influence on pharmaceutical expenditure means prescribing trends that cause increased uptake of old or new technology in exchange for a decline in use of new or old technology (as applicable).

“New Pharmaceuticals” means those Pharmaceuticals recently (i.e. within the last 18 months) approved for use in New Zealand that would currently be considered by

hospitals' medical committees before being introduced for routine use within a hospital or specific department.

“orphan pharmaceuticals” are Pharmaceuticals of which use is extremely low, though often essential for a small group of patients, where there is only one supplier either internationally or willing to supply the New Zealand market.

“Pharmaceutical” where spelt with a capital ‘P’ other than at the start of a sentence or in the term “Pharmaceutical Schedule” means pharmaceuticals (as conventionally defined).

“Pharmaceutical Schedule” has the same meaning as given in the New Zealand Public Health and Disability Act, 2000.

“pharmacode” means the unique code allocated by the Pharmacy Guild of New Zealand to pharmaceuticals sold in New Zealand.

“primary care setting” and “community” are used interchangeably and both refer to the current coverage of the Pharmaceutical Schedule.

“PML” stands for Preferred Medicines List.

“PTAC” stands for the Pharmacology and Therapeutics Advisory Committee.

“QUM” stands for quality use of medicines.

“rebate” means any supplier paid reimbursement, for the costs incurred by DHBs in purchasing Pharmaceutical(s), required under contract with PHARMAC.

“reference pricing” has the same meaning as set out in section 3.3 of PHARMAC’s operating policies and procedures.

“RFP” stands for Request for Proposals.

“sole supply arrangement” means a contractual arrangement, which grants to a single supplier, exclusive or near exclusive (where exceptions are defined) rights to supply a particular Pharmaceutical to DHBs via their hospitals.

“therapeutic sub-group” has the same meaning as set out in section 3.3 of PHARMAC’s operating policies and procedures.

“two-part pricing” has the same meaning as set out in section 3.3 of PHARMAC’s operating policies and procedures.

“unapproved pharmaceutical” means a Pharmaceutical distributed in New Zealand without consent by Medsafe under the Medicines Act.

## **Appendix 1**

### **Authorisation to PHARMAC from the Minister of Health**

## **New Zealand Public Health and Disability Act 2000**

### **Authorisation of PHARMAC to perform an additional function – August 2001**

Under section 48(e) of the New Zealand Public Health and Disability Act 2000, after consulting with the Board of PHARMAC in accordance with the requirements of that section, I authorise PHARMAC to perform the function specified in the Schedule to this authorisation.

This authorisation is effective from the date of signing and shall remain in force until it is revoked by the Minister of Health.

Dated at Wellington this 4<sup>th</sup> day of September 2001.

ANNETTE FAYE KING, Minister of Health.

### **SCHEDULE**

PHARMAC is authorised to manage the purchasing of any or all pharmaceuticals, whether used either in a hospital or outside it, on behalf of DHBs.

In carrying out this function PHARMAC will need to address, at a minimum, the following factors:

- (i) developing a management strategy;
- (ii) consulting and communicating with DHBs and other interested parties as PHARMAC considers appropriate;
- (iii) amending PHARMAC planning, funding, and policy documents to the extent appropriate;
- (iv) compiling and analysing information from DHBs on pharmaceutical volumes, expenditure, and contractual arrangements;
- (v) adjusting the pharmaceutical schedule as necessary; and
- (vi) carrying out purchasing on behalf of DHBs.

## **Appendix 2**

### **Summarised consultation responses**

Section 49(a) of the New Zealand Public Health and Disability Act, 2000 requires PHARMAC to consult, when it considers appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by decisions on those matters. Accordingly, consultation documents were circulated on 10 November 2001 and 12 December 2001 to all suppliers and other parties that, in the view of PHARMAC, may be affected by the Strategy. Summaries of what PHARMAC staff believe are the significant matters raised in these responses are provided below. The full responses are available.

### Submissions from District Health Boards (CEOs and provider units)

#### *Submissions received*

DHB	Author(s)	Title/position/capacity
Northland	Fred Quin	None provided with email
Waitamata	Robin Skeggs Vaughan Matthews	COO On behalf of healthAlliance
Auckland	Neil Woodhams Fiona Ritsma Peter Black	COO GM, Clinical Support Services Chair, Hospital Medicines Committee
Counties-Manukau	Brian Rousseau Vaughan Matthews	COO Group Manager, Commercial - on behalf of healthAlliance
Bay of Plenty	Peter Cooke  Claire Stott	On behalf clinical directorate Pharmacy Manager (on behalf of Medicines Review Committee)
Taranaki	John O'Neill	CEO
Mid-Central	Jeff Small  Barbara O'Driscoll	Group Manager, Commercial Support Services Professional Advisor, Pharmacy
Wairarapa	Joel George	CEO
Capital and Coast	Julie Yee Tim Maling	On behalf of hospital pharmacists On behalf of Pharmaceutical Expenditure Working Group
Nelson-Marlborough	David Smith	Service Manager, Community Rehabilitation & Clinical Support
Canterbury	Rachel Wilson & Janelle Kennedy Nigel Dean  Kathryn Snook	Department of Clinical Pharmacology Pharmacy department  On behalf of Ashburton Drug & Therapeutics Committee Senior Pharmacist, Burwood Hospital
Otago	Bill Adam	CEO

### *Summary of main points from DHBs and provider units*

Most of the DHBs that responded to consultation were supportive of national purchasing arrangements of some type for pharmaceuticals used in hospitals, provided patient care was not compromised. That is not to say they were all fully supportive of PHARMAC's involvement. Many of the respondents were concerned about the level of restriction PHARMAC might impose on prescribing choice and were doubtful that level of savings achievable from a national pharmaceutical purchasing strategy for hospitals would be significant. Smaller hospitals were more inclined to the view that savings could be made, whereas the general view of the larger hospitals was that their current strategies are already effective, and PHARMAC's proposed Strategy could result in increased costs for them.

A commonly raised concern was that the objectives of the Strategy were too cost-focused. Many respondents suggested that an additional objective should be to improve patient outcomes. There was universal agreement that the welfare of patients should not be compromised as a consequence of the Strategy.

It was clear that DHBs would seek transparency and the close involvement of their clinicians in any decisions made by PHARMAC. This came through particularly in comments about possible restrictions on access to pharmaceuticals. Some DHBs expressed concerns about the proposed use of advisory committees – specifically that PHARMAC could potentially ignore or override recommendations made by such committees. It was suggested that PHARMAC should be obliged to follow the recommendations of advisory committees.

Many respondents expressed the view that PHARMAC-style restrictions on access to pharmaceuticals were likely to be less effective in helping to manage hospitals' pharmaceutical expenditure than locally developed guidelines supported with local drug-utilisation reviews. Many of the DHBs have already developed their own Preferred Medicines Lists (PML) and advocated retention of these – in some cases, instead of the proposed Section H. They claimed that clinicians would be more likely to comply with a locally developed PML than with a PHARMAC imposed restrictive list of pharmaceuticals and/or guidelines. Concerns were also raised by hospital pharmacists about the amount of work that would be required explaining and “policing” Section H. Some respondents considered it likely that the costs of the administrative burden PHARMAC's Strategy would impose would outweigh the benefits of Strategy and any savings.

A few respondents considered that PHARMAC's target of national contracts for 90% of hospital pharmaceuticals (by expenditure) was too high. They considered that PHARMAC should focus its efforts on the top 10-20 agents. However, there was general support for the proposed scope of the Strategy, albeit qualified support for the proposed processes for assessing New Pharmaceuticals and drug utilisation programme (for which there was greater support after the 12 December revisions).

Smaller hospitals appeared more inclined to support the proposed nationally co-ordinated DUR programme whereas those with DUR programmes already in place tended to question PHARMAC's expertise in this area (compared with the expertise of hospital pharmacists). The 12 December clarification of PHARMAC's proposal does not appear to have alleviated all of the issues raised. Concerns about resources, and the costs of improving information systems appeared to remain especially among the

smaller hospitals. While most DHBs agreed that the revised proposal was more practicable, some of the larger hospitals still considered that local initiatives with a focus on optimal use of pharmaceuticals rather than cost-containment, without PHARMAC's involvement would be more effective.

Many DHBs considered that new pharmaceuticals, which potentially reduce hospital costs in other areas, should be introduced into hospitals without delay. Smaller hospitals noted that access to some new pharmaceuticals was important because surgical services were unavailable. Before PHARMAC revised its proposal around processes for assessing New Pharmaceuticals, most DHBs were concerned that rate at which new pharmaceuticals could be introduced into hospitals would be too slow. It was clear that unfavourable impressions about PHARMAC's current assessment processes for new community pharmaceuticals contributed to this view. However, there appears to be greater support for the proposed non-mandatory assessment process with some DHBs acknowledging that a national overview would be useful.

While there was general support for the objective of improving national consistency of access to pharmaceuticals used in hospitals, support for a hospital Schedule (Section H) was less widespread. Some DHBs were concerned that, in aiming to achieve national consistency, PHARMAC would have to restrict access to "the lowest common denominator" by default. Many were concerned that Section H would give rise to "the type of problems encountered in the community". Where support for Section H was indicated, the need for Section H to accommodate the needs of small groups of patients was raised consistently. Some DHBs did not support inclusion of Section 29 drugs in Section H and/or within the scope of the Strategy – although the reasons for this may have related to misunderstanding about how these pharmaceuticals would be treated under the processes for assessing New Pharmaceuticals originally proposed.

A key issue raised was the fact that Section H would establish an anomaly between hospital and community based patients. It was noted that, while patients in the community have the option of paying for an unlisted pharmaceutical themselves, hospitals are unable to pass charges on to patients so Section H would truly restrict the range pharmaceutical treatments available to hospitalised patients.

A number of DHBs acknowledged the need to improve the interface between primary and secondary care. While not all respondents considered that the Strategy would assist in this regard, some considered that the availability in hospitals of all pharmaceuticals listed on the Pharmaceutical Schedule was imperative.

A number of submissions raised questions about how access restrictions would be imposed, and the proposed discretionary variance provisions would be administered and monitored. Many of these questions were addressed in PHARMAC's 12 December letter although later submissions suggest further clarification may be required. Some DHBs noted that they would have to upgrade their IT systems in order to provide the reports PHARMAC requires for monitoring using a national code – thus incurring costs.

Many DHBs raised concerns about the use of known strategies used by PHARMAC. Use of reference pricing was opposed. Concerns were raised about the effect of sole supply arrangements on hospitals' ability to obtain supplies of certain pharmaceuticals. Some DHBs expressed the view that a national tender could result in price increases, if not initially, then in a subsequent tender round. Concerns were also raised in some

instances about bundled deals - particularly where this could have an adverse effect on non-pharmaceutical costs elsewhere in the hospital system. For instance, it was noted that some pharmaceuticals are administered via specific equipment, the cost of which is linked with the price. Some DHBs cautioned about the risk of cost-shifting and urged PHARMAC to take such issues into consideration in any decision-making. While no DHB recommended a specific set of assessment criteria (some indicated that PHARMAC's current criteria would be acceptable), pack size issues and distribution costs were among the factors DHBs commonly considered should be assessed when making decisions about hospital pharmaceuticals. In addition, they considered that cost should not be the main or sole criteria used by PHARMAC.

Concern was commonly expressed about the potential effect of the Strategy on the pharmaceutical industry – particularly with respect to the amount of support and education provided to clinicians and pharmacists, research and implications for access to pharmaceuticals in future. Some DHBs considered that if pharmaceutical companies left NZ and/or withdrew their research funding, clinicians would follow.

Some DHBs questioned the inclusion of IV fluids and X ray contrast media within the scope of the Strategy. They claimed that the Strategy would be difficult to administer where X-ray contrast media are purchased by a different department. Some suggested that specific consideration of the clinical issues involved would need to be given before application of PHARMAC's pricing strategies to IV fluids.

#### *Other points raised by DHBs and provider units*

- The Strategy should differentiate between purchasing and procurement. What PHARMAC proposes is procurement. [PHARMAC's response – the proposed new title for this project addresses this point.]
- All savings made via the Strategy should come back to the DHBs. [PHARMAC's response – Any savings made by PHARMAC would fall within the DHBs' budgets. The question is, should savings made on hospital pharmaceuticals come back to hospitals or be made available for use anywhere in the health sector? This is a question for the DHBs, not PHARMAC.]
- Should Section H be established, it would need to indicate limitations on the availability of those pharmaceuticals for which availability was not nationally consistent previously. [PHARMAC's response – The revised proposal to list only those pharmaceuticals subject to national contracts in Section H should address this issue.]
- Would IMM status be a requirement for sole supply brands? [PHARMAC's response – This would depend on the advice of our advisory committees but we note that IMM status is not always a requirement for sole supply products in the community sector.]
- The Strategy should be piloted first. [PHARMAC's response – In a sense, the proposed two-year review is a pilot trial. It would be difficult to conduct a meaningful assessment of a national programme using a few DHBs in a smaller pilot trial.]

- Alternative Strategies should have been available for DHBs to comment on and compare PHARMAC's to. [PHARMAC's response – PHARMAC would have no objection to its Strategy being compared with other Strategies. We note that DHBs attempted to develop their own strategy last year but not all DHBs were willing to contribute to that project.]
- Assessment criteria should include compliance with any international guidelines. [PHARMAC's response – This is unrealistic. Consideration should be given to international guidelines within the context of New Zealand's economy and health budget.]
- PHARMAC should achieve its main objective (price) before attempting new technology assessment etc. [PHARMAC's response – The revised proposal to make the results of new technology assessments non-mandatory, and the deferral of PHARMAC's involvement in DUR go some way towards addressing this point.]
- The Strategy could increase the number of orphan drugs. [PHARMAC's response – This is possible but the issue of orphan drugs has also arisen internationally as a consequence of global rationalisation by pharmaceutical companies. The Strategy could provide the impetus to develop systems and procedures to deal with this issue.]

#### *PHARMAC's response to comments from DHBs*

Based on the limited information available, PHARMAC agrees with the DHBs' assessment that the value of price reductions in this market is likely to be relatively modest. It is possible, although not proven, that some DHBs, particular larger ones, are already achieving the best possible prices for the pharmaceuticals they purchase. It is likely that the price reductions PHARMAC could achieve would confer a net benefit to DHBs, if not some benefit for all DHBs. PHARMAC also agrees that these modest financial benefits should not come at the expense of patients' overall welfare. However, we also note that PHARMAC's most effective price lever to date has been its control on access to pharmaceutical markets. The savings achieved as a consequence have been used to improve health outcomes via re-investment in health. While preservation of prescribing choice would reduce the potential for adverse patient outcomes to occur as a result of pharmaceutical pricing strategies, it would also limit PHARMAC's ability to reduce prices and provide savings to the DHBs. Within an environment of limited health funding, such limitations could, in themselves, become a barrier to improving health outcomes in a wider context.

PHARMAC agrees with the principle of transparency. We note that many of the concerns raised about PHARMAC's lack of transparency reflect misunderstanding of our processes and outcomes. There are few, if any, examples where PHARMAC's Board has overridden the advice of its clinical advisors. While there are numerous examples of recommendations, which have not been acted upon, the reasons for this often relate to the availability of funding and/or competing priorities rather than any disregard for the advice received. However, we acknowledge clinicians would prefer more expedient decision-making and communication of the rationale for decisions made. We consider that this degree of transparency can be accommodated within the Strategy.

It is acknowledged that PHARMAC-style pricing policies would impose some monitoring requirements on hospitals' clinical staff. It is likely that the role of compliance monitoring would fall to hospital pharmacists. However, given that most hospitals claim to administer some form of pharmaceutical management policy already, it is possible that the work involved would simply change rather than grow, provided that the frequency of changes made by PHARMAC is kept manageable. Given that the proposed pricing policies for the hospital sector are less restrictive than those employed in the community sector, it is unlikely that monitoring of Section H would require the same degree of counseling and explanation as retail pharmacists claim to undertake. We note that recent research by the Pharmaceutical Society suggests that pharmacists spend less than 2% of their time spent on prescription interventions on matters related to PHARMAC.

PHARMAC acknowledges that buy-in from clinicians is essential to the success of any pharmaceutical management policies. It is difficult to access whether locally developed policies would achieve better compliance than those driven nationally. The responses received suggest a degree of prejudice against PHARMAC-derived policy. They also suggest a high level of satisfaction with current arrangements. Without data to support the success of local policies, it is difficult to tell whether this support should be heeded as a warning to Government that it should not attempt to fix something that is not broken or whether it simply reflects an element of patch protection. It would seem that there are pros and cons to either approach. Contentious issues that have arisen in the past because of disparity of access to pharmaceuticals are less likely to occur under a national umbrella. However, it is acknowledged that DHBs would forfeit some of their ability to respond to the unique needs of their target populations under a national approach.

It is acknowledged that the need for pharmaceuticals in hospitals depends to some extent on the range of services provided by the hospital. However, there have been notable areas of common care where access to pharmaceuticals has been inconsistent. The Strategy aims to focus on areas such as these.

PHARMAC notes that opportunities to reduce prices across the top 90% of pharmaceuticals by expenditure are relatively modest. The revisions already made to address concerns in respect of key elements of the Strategy with the proposed pricing strategies and processes for assessing New Pharmaceuticals will reduce the effectiveness of the Strategy in financial terms. Further narrowing the focus of the Strategy would probably result in it not being worth pursuing.

In view of the concerns raised about PHARMAC's proposed involvement in DUR, and in order to enable PHARMAC to concentrate its limited resources on establishing the proposed pricing strategies and assessment processes, it would seem appropriate to defer pursuit of this aspect of the Strategy at this stage. It is also possible that the notion of a nationally co-ordinated DUR programme would be more widely accepted if implemented by another agency or group.

While the eagerness of clinicians to use new pharmaceuticals is understandable, accumulating evidence about new products sometimes highlights clinical issues that were not shown in the early trials. While this does not indicate that access to new medicines should be deliberately delayed, it does suggest that a little more caution can

be prudent. The non-mandatory nature of the revised proposal around new technology assessment is a logical step given the level and nature of concerns raised. The revision will reduce the short-term effectiveness of the Strategy.

The anomaly between hospital and community based patient in terms of user charges anomaly is noted.

It is possible that PHARMAC will be able to obtain its reports via IMS without placing onerous requirements on DHBs and creating a need for IT system upgrades. However, if PHARMAC should have to rely on DHB reporting, then the cost-effectiveness of upgrading IT systems would be considered. Given that hospitals' current IT system limit the amount of monitoring they can undertake themselves, and the lack of national data, the upgrades may be considered in a wider context to be a good investment.

To some extent, the concerns raised about the likelihood that PHARMAC would take cost-offsets from other parts of the hospitals' business and/or the health sector into account when making decisions about access to pharmaceuticals also reflect a misunderstanding of factors taken into account in the analysis PHARMAC conducts. PHARMAC is likely to have more expertise than hospitals in the techniques of quantifying costs and benefits using cost-utility analysis. However, such analysis relies on the quality of inputs, and PHARMAC's lack of detailed knowledge of hospital systems has to be acknowledged as a weakness. Given the strengths and weaknesses of both parties, it is clear that a collaborative approach to analysis is more likely to be optimal.

PHARMAC's area of expertise is pharmaceuticals. We have little knowledge of the X-ray contrast media market and note that many hospitals purchase these agents differently to pharmaceuticals. While we have no data with which to assess the contribution of X-ray contrast media to hospitals' "pharmaceutical" expenditure, we consider it likely that only a small number of them would fall within the top 90% of products by expenditure. As such, we consider that X-ray contrast media should be excluded from the Strategy for the time being.

We note that our experience in the primary care sector is that the number of pharmaceutical suppliers in the market has increased as a result of tendering and, if anything, prices continue to fall in the second tenders, rather than rise as has been suggested.

## Submissions from professional bodies

### *Submissions received*

Professional Body	Author(s)	Title/position/capacity
Pharmaceutical Society	Euan Galloway	Staff Pharmacist, Practice & Legislation
Pharmacy Guild	Meena Vallabh	Pharmacy Practice Advisor
New Zealand Medical Association	Philippa Bascand	Manager Policy and Support
Council of Anesthesia Clinical Directors	Vanessa Beavis	Chairwoman
Australian and New Zealand Colleges of Anaesthetists	Dr Malcolm Futter	
The Royal Australian and New Zealand College of radiologists	Mark Osborne	Chairperson
The Thoracic Society of Australia and New Zealand	Robin Taylor	President
Paediatric Society of NZ	William Wong	Chair, Drugs and Therapeutics Committee
NZ Clinical Oncology Group	Vernon Harvey Michel Findlay Garry Forgeson	
The Cardiac Society of Australia and New Zealand	Harvey White Stewart Mann	Chairman Chairman elect
The Royal Australian and New Zealand College of psychiatrists (RANCP)	Allen Fraser	
Royal New Zealand College of GPs	Cathy Webber	Senior Policy Analyst

### *Summary of main points from professional bodies*

The key points of the submissions received from professional bodies can be summarised as follows:

1. Consensus that there is merit in bulk purchasing of pharmaceuticals used in hospitals.
2. Reservations that national consistency of access to pharmaceuticals is achievable or desirable.
3. Concern about the impact of the Strategy in the level of choice of pharmaceuticals available.
4. Satisfaction with present arrangements.
5. Concern about PHARMAC's track record and expertise in the hospital sector.

While there was agreement on the merit of bulk purchasing, not all respondents considered that a national purchasing programme run by PHARMAC would offer

significant advantages over current arrangements (under which, it was noted, that some DHBs already collaborate). Some considered that the prices currently paid by those DHBs that were already collaborating would be likely to increase under the Strategy. Most respondents considered that PHARMAC was likely to be too focused on price at the expense of patient care. Some respondents questioned whether PHARMAC/the Government would accept medico-legal responsibility for compromised patient care. It was noted that compared with the primary care sector, there is a greater ability in the hospital setting to trade off pharmaceutical expenditure against other interventions. Respondents considered that, for this reason, the Strategy should be focused on budget.

The response to the objective of achieving national consistency of access to pharmaceuticals was mixed. While some respondents considered there to be merit in this objective, many noted that this it appears to be at odds with the Governments goal of achieving locally based healthcare policy. They noted that the range of healthcare needs differs regionally and considered that policy regarding access to pharmaceuticals should mirror this variation. Others considered that national consistency was undesirable because it would degrade the ability of clinicians to exercise their professional responsibilities to choose the best therapy for their patients. While it was acknowledged that the current arrangements do lead to disparity of access, respondents considered that the disadvantages of this need to be balanced against the benefits of individualised arrangements.

Many respondents considered that secondary and tertiary sub-specialties necessitate drug therapy to be more closely tailored to the patient. While some groups were supportive of greater use of generic pharmaceuticals, the view that access to range of pharmaceuticals is critical because of the complexity of secondary and tertiary care prevailed. Many pointed out areas where PHARMAC has imposed restrictions on access to pharmaceuticals in the community sector, as examples of what would be unacceptable in the hospital setting. Comments reflected a perception that PHARMAC has sometimes downplayed clinical evidence to justify its decisions on access to some therapies. Respondents considered that hospitals must be given the ability to integrate the constantly changing evidence base into clinical practice. Some commented on the proposed scope for discretionary variance and expressed concern that the figure of 10% mentioned as an example would be insufficient to cater to the needs of all patients. Many respondents considered that savings would need to be significant to justify any restrictions placed on clinical freedom.

Some clinicians expressed a preference for adding value via their own prescribing decisions rather than as a consequence of restrictions on choice imposed by PHARMAC. Many expressed satisfaction with the way in which pharmaceutical costs are currently managed within hospitals. The professional nature and degree of collaboration between hospital pharmacists and clinicians was highlighted as a key contributor to the success of current arrangements. The expertise of hospital pharmacists in reviewing pharmaceutical utilisation was also noted. The view was expressed that this expertise should not be ignored and that PHARMAC should not attempt to duplicate this work. One respondent considered that PHARMAC's involvement in DUR was beyond the scope of the authorisation provided by the Minister of Health. Many respondents noted that success of some hospitals in reducing the prices paid for pharmaceuticals. They noted that the individualised contracts that have been negotiated often deliver excellent benefits to hospitals in terms of equipment, clinical support, training, research etc.

Most respondents lacked confidence in PHARMAC's ability to balance the needs of patients and clinicians against fiscal objectives. Concerns about the impact of sole supply arrangements implemented by PHARMAC in the community on availability of pharmaceuticals were raised repeatedly. Some respondents were also concerned that sole supply arrangements would ultimately lead to price increases. Many criticised PHARMAC always selecting the cheapest option no matter what the clinical arguments for a more expensive alternative were and for being too slow in making new treatments available. Some regarded the delays as a deliberate tactic, which would be undesirable in the hospital setting. Others considered that, while immediate access might not be possible because of funding constraints, this should be made explicit rather than resulting in interminable and unexplained delays. The need for greater transparency and explanation of PHARMAC's decisions came through as a common theme. In seeking assurance that their own specialties would be able to provide input into PHARMAC's decision making via advisory committees, some respondents raised concerns about the current appointment process for PTAC. A common concern was PHARMAC's apparent ability to ignore or override the recommendations of these committees, which respondents felt was unacceptable. Another comment criticism was that PHARMAC does not audit or monitor the clinical outcomes of its decision. It was recommended that, if the Strategy is implemented, its effect on clinical outcomes and access to cutting edge technology should be monitored and a full evaluation undertaken after two years. Some respondents considered that the cost-effectiveness of the Strategy should be researched before a decision is made to proceed.

Concern was also expressed about the effect of the Strategy on the long-term viability of the pharmaceutical industry in New Zealand with particular reference to on-going research, continued availability of a wide range of pharmaceuticals, and early access to newly developed treatments.

#### *Other points*

- Is it ethical to decide not to use a treatment on financial grounds?
- Why should access to pharmaceuticals be rationed when funding for emergency surgery is open-ended?
- If guidelines are implemented, clinicians who can justify treatment outside of them should be permitted.
- Clinicians should be informed where the savings go and savings should be utilised in a timely manner.
- A further objective of the Strategy should be to provide excellence of care.
- It would be more appropriate for decisions about access to new pharmaceuticals to be made by local medicine utilisation committees than by PHARMAC.
- Section H is unnecessary as it would duplicate existing PMLs.
- Policy regarding access to new medicines should begin and comply with international guidelines.
- The perceptions of clinicians will be important to the success of the Strategy. Restricting choice will create negative perceptions.
- Given the proposal to manage pharmaceutical expenditure to a single national target for both community and hospitals, if hospitals exceed their pharmaceutical "budgets" what impact would this have on access to pharmaceuticals in the primary care sector?

*PHARMAC's response to comments from professional bodies*

Most of the points raised by this group of respondents have already been addressed in PHARMAC's comments on points raised by the DHBs. There are some additional points:

- (1) The ethics of deciding whether to treat on the grounds of funding: This is covered by the NZMA Code of Ethics, which states that the resource implications of decisions made by doctors should be taken into account. Clearly in a resource-constrained environment, one could argue it is unethical to waste resources by not using them in the most appropriate way.
- (2) Medico-legal responsibility – PHARMAC notes that the issue of culpability in the hospital sector is the same as in the community where PHARMAC's policies have been in place for eight years
- (3) Audit of outcomes – The intention of a 2-year trial of the Strategy is that its effectiveness can be reviewed. Monitoring of clinical outcomes would require a research protocol. PHARMAC has already received expressions of interest from potential researchers. However HPAC has noted and expressed concern about the level of DHB resource required to provide information for such research.
- (4) While we note that clinicians are generally satisfied with current hospital processes, little detail about how the cost-effectiveness of medicines is currently assessed and little evidence has been provided as to the effectiveness of existing processes in managing within a budget.

## Submissions from individual clinicians

### *Submissions received*

Clinician	Title/Position/Capacity	DHB
Allen Fraser	Deputy Chair, NZ Branch, RANCP	Waitamata
Gill Hood	Acting Clinical Director, Department of Critical Care Medicine	Auckland
CB Dominy	Anaesthetist and Acting Clinical Director of the Department of Anaesthesia, Tauranga Hospital	BOP
Andrew Simpson	Consultant Medical Oncologist, Wellington Cancer Centre	Capital & Coast
Thorsten V Stanley	Senior Lecturer, Department of Paediatrics, Wellington School of Medicine	Capital & Coast
Bruce King	Specialist Physician in Internal Medicine and Nephrology	Nelson-Marlborough
Ian Crozier	Clinical Director, Cardiology	Canterbury
Ruth Spearing	Clinical Director, Haematology Department	Canterbury
Harsh Singh	Cardiothoracic Surgeon	Canterbury
	Consultant psychiatrists, Hillmorton Hospital, Christchurch School of Medicine	Canterbury
F Michael Davis	Medical Director, Hyperbaric Unit	Canterbury
Felicity Woodham	Oncology & Haematology Service Manager	Canterbury

### *Summary of main points from individual clinicians*

Many of the submissions received from individual clinicians (representing six DHBs) were sent before receipt of PHARMAC's 12 December 2001 letter. Consequently, they reflect stronger concerns about the proposed processes for assessing New Pharmaceuticals, which were subsequently revised. Otherwise the responses generally echoed the comments made by professional bodies regarding:

- the need for prescribing choice;
- reservations about PHARMAC's expertise in the hospital sector and ability to take wider costs into account;
- concerns about patient welfare given perceptions that the Strategy is too price-focused;

- the view that there is little evidence that Strategy would provide significant benefits/savings;
- perceptions that DHB collaboration without PHARMAC's involvement might be more appropriate;
- concern about the impact of the Strategy on future viability of the pharmaceutical industry in NZ;
- concern about continuity of supply particularly for critical medications; and
- concern that PHARMAC would delay or decrease the introduction of new pharmaceuticals.

A number of individual anaesthetists wrote to PHARMAC expressing the view that continued access to a range of products for their specialty was particularly important given the delicate, life-and-death nature of their work. One in particular made the point that, relative to the costs of the surgical services he supports, the costs of the pharmaceuticals he uses is already very small.

Other commonly raised points that came through more strongly in individual submissions than in the group submissions were:

- the need for clinicians to keep up-to-date with international trends in clinical practice;
- the likelihood that clinicians would leave NZ if they are unable to access new medicines;
- concerns about increased paperwork as a consequence of PHARMAC's involvement; and
- concerns about loss of pharmaceutical company sponsorship.

One respondent raised particular concerns about the amount of resources that would have to go into implementing the Strategy. He opposed PHARMAC increasing its role as a major educator on pharmaceutical use claiming that this should be undertaken by the medical schools. He also commented on the fact that advisory committees would take clinicians away from their usual clinical responsibilities.

#### *Other points*

- Who would be culpable if legal action was taken as a result of compromised patients care?

#### *PHARMAC's response to comments from individual clinicians*

Most of the points raised by this group of respondents have already been addressed in PHARMAC's comments on points raised by the DHBs and professional groups. There are four additional main points:

- (1) Concern about continuity of supply for critical medicines - Back-up supply arrangements may go some way to addressing these concerns. Contractual arrangements to disincentivise out-of-stock situations and product discontinuations are useful but cannot realistically prevent stock problems 100% of the time. There is no evidence that the introduction of sole supply arrangements in the community has increased the number of medicines that

go out of stock. If anything, the rate of stock outages appears to be lower for pharmaceuticals under sole supply contracts. Many of the stock issues hospitals and community pharmacists are currently facing are the result of global rationalisation of product ranges within larger multi-national companies. A significant number of products on which hospitals rely are sole supply already (by virtue of their application and lack of competition rather than as a consequence of any contractual arrangement). The Strategy could make it easier to address these inevitable situations (for instance by enabling a co-ordinated approach to section 29 medicines, and because the system would be conducive to setting up systems which enable these issues to be identified earlier and potentially before stock shortages arise). PHARMAC intends to work with Medsafe to address issues relating to “orphan” products (by identifying such products and discussing possible lowering of registration barriers for some products) in the near future.

- (2) Effect of Strategy on medical workforce if access to new medicines is restricted – it is difficult to assess what, if any, impact the Strategy would have on the amount of pharmaceutical research and sponsorship of clinicians currently available. Clearly, the workforce impact anticipated by these clinicians would be undesirable if it was to occur. However, there are many factors affecting the workforce in New Zealand and we are unaware of any evidence that access to medicines is one of the relevant factors. However, it is unlikely that such an effect would be immediate. This issue should be monitored.
- (3) Resources required for implementation of the Strategy – PHARMAC proposes to implement the Strategy using few additional resources. The potential financial benefits of the Strategy are likely to be sufficient to justify the addition of 2-3 PHARMAC staff. Unless hospitals expand their own workforces to accommodate the Strategy, which we do not consider would be necessary, no further additional resources should be required. It is possible that DHBs could reduce resources currently used to undertake the purchase role PHARMAC proposes to undertake.
- (4) Effect of committee participation on workforce – PHARMAC considers that participation in the proposed clinical advisory committees would be both educative and worthwhile.

## Submissions from industry (suppliers, industry representatives and wholesalers)

### *Submissions received*

Company	Author(s)	Title/position
Researched Medicines Industry (RMI)	Terrance Aschoff	General Manager
Medical Industry Association of New Zealand	Faye Sumner	CEO
Glaxo SmithKline (GSK)	Kristin Holm	Health Outcomes Manager
Pharmacia	Terrie Curran	Country President, NZ
Aventis	Alan Carter	Business Unit Manager
AstraZeneca	Lance Gravatt	Business Director, Business Strategy & Development
Baxter	Mark Russell	CEO
Biomed	Sandra Roberts	Sales & Marketing Manager
Apotex NZ Ltd	Colin Robertson	CEO
AFT Pharmaceuticals	Hartley Atkinson	
Multichem NZ Limited	Russell Jones	Managing Director
Zuellig Pharma	Peter Merton	CEO
Regional Health Limited	Donnay Tisch	Manager, Bracco Imaging

### *Summary of main points from industry*

The submissions received from suppliers who belong to the Researched Medicines Industry (RMI) were similar and the main points are captured within the RMI's submissions which is summarised as follows:

1. The intention of the NZ Public Health and Disability Act was to give DHBs the independence needed to optimize healthcare on a regional level. The DHBs statutory responsibilities for regional health needs should extend to each DHB setting its own strategy goals and objectives for the purchase of medicines, and determine for itself issues affecting newer technology. It would be more in line with the intentions of the Act if PHARMAC took a role in managing the process on behalf of the DHBs rather than making the decisions for them.
2. PHARMAC does not have the empirical expertise or the culture to assess new technology in a complex, hospital setting. This should be done by a completely independent agency with clinical as well as pharmaceutical and commercial expertise. Costs of new pharmaceuticals should be weighted by DHBs with potential savings in other areas of healthcare funded by DHBs.
3. The basic principles governing the clinical advisory committees' functions should be transparency, professional independence and public confidence in the recommendations.
4. Objective and transparent criteria should be established so that suppliers, prescribers, different health groups and the public have a realistic prospect of making PHARMAC accountable. PHARMAC's current criteria are focused on drug acquisition cost and do not adequately take into account downstream savings for DHBs in other areas.

5. The proposed 2 year interim arrangement for new technology assessment could end with stricter restrictions being imposed later. There should be no possibility that such barriers to new technology that which may be considered worthwhile in a wider context could be imposed.
6. DHBs should have the freedom to negotiate on a continuing basis with a range of suppliers where considerations such as quality of treatment and efficacy are as important as price. Sole supply arrangements would prevent this.
7. Existing contracts between suppliers and DHBs should be respected. They should not be overridden upon PHARMAC's instruction and confidentiality provisions should remain in effect for their duration.
8. New contracts should not require the provision of price and volume data.

Other points raised in submissions from suppliers were:

- An additional aim of the Strategy should be to maximize health outcomes.
- The hospital market is much smaller than the community market and the smaller markets would be destroyed by PHARMAC's interventions.
- The success of the Strategy should be measured in terms of quality and health outcomes in addition to financial results.
- A collaborative approach with DHBs and clinicians is proposed, omitting suppliers.
- The Strategy would be likely to have a very real impact on pharmaceutical company sponsorship and research. PHARMAC's policies have already had some impact in this regard.
- It would be inappropriate for PHARMAC to evaluate and list unregistered medicines. This should be left to Medsafe.

Responses were also received from a number of potential and existing generic suppliers. Existing generic suppliers noted that hospitals are already benefiting from the lower prices PHARMAC obtains via its community tender. Some questioned the need to run a separate hospital tender. It was noted that a separate tender could result in there being a different brand of product available in the hospital vs the community. Questions were raised about leakage would be prevented in such situations. An existing generic supplier expressed doubt about PHARMAC's ability to enforce preferred supplier contracts in the hospital sector given that this strategy had not been successful in the community. There was some indication that generic suppliers would hesitate to enter hospital markets where the original supplier could potentially undercut them. Concerns were expressed about the potential for the proposed discretionary variance provisions to result in undercutting. One generic supplier expressed the view that, where a generic product had been deemed by Medsafe to be interchangeable, it was inappropriate and unnecessary for PHARMAC to allow use of another brand under such provisions. Another noted that it had assisted DHBs to achieve significant savings in the past and expressed concern that sole supply arrangements could threaten its viability and ultimately result in increased costs to DHBs.

*PHARMAC's response to comments from industry*

In assessing the intention of the New Zealand Public Health and Disability Act, 2000, the industry appears to have overlooked the revision to the Act made by the Minister of Health when she authorised PHARMAC to extend its responsibilities to include hospital pharmaceuticals.

PHARMAC staff do not believe it is possible to establish a completely independent advisory body in any industry, let alone one with clinical, pharmaceutical and commercial expertise. Some bias is inevitable but can be managed procedurally. PHARMAC believes that it is a suitable agency to assess new technology because it possesses expertise in all three areas mentioned. We have endeavoured to address issues around the independence of the advisory committees on which we propose to rely via revisions to the proposed appointment processes for them and their relationship to PHARMAC, HPAC etc.

We agree in principle with the need for process transparency. We note that, while not the only factor, the confidentiality requirements of the industry are a key factor in perceived deficiencies in this regard with PHARMAC's current processes. We also note that, in its submission, the RMI both requests greater transparency and stipulates further confidentiality requirements.

We believe that the assessment criteria for this Strategy should be well thought out and transparent in order to ensure robust decision-making. The accountability of PHARMAC is surely secondary to the health needs of New Zealanders. In any case, despite numerous attempts, the industry has failed to prove that PHARMAC has been remiss in applying its decision criteria in the past.

We believe that the rest of the sector has proposed a review of the proposed, non-mandatory, processes for assessing New Pharmaceuticals after two years because it believes there is merit in the process and would wish to extend it if it is working well. The industry's position on this issue is clearly motivated by its understandable desire not to let PHARMAC obtain greater control over access to new pharmaceutical markets.

PHARMAC does not propose any actions that would be disrespectful to existing contracts. It is likely that decisions regarding early termination of existing contracts would be left to the discretion of the individual DHBs. In other words, a combination of national and individual contracts would be permissible in any transition period. We believe that, if the Strategy proceeds, it would be reasonable for DHBs to stipulate in contracts that they need to be able to provide data to PHARMAC.