RATIONING OF MEDICINES

A report prepared for
the Pharmacy Guild of New Zealand

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1. Introduction

Early in 2005 The Pharmacy Guild of New Zealand (Inc) (the Guild) issued to its members *Blueprint for the Future of Community Pharmacy* (the *Blueprint*). The foreword to the *Blueprint* began with the statement:

> The Government's primary health strategy has the potential to transform community pharmacy practice in the 21st century. If we grasp the opportunity, it can open the way for many of the initiatives pharmacists have talked about for years to become reality, increasing the satisfaction we derive from day-to-day practice and allowing us to do more for our patients. We may never encounter a similar opportunity again in our professional lives.

The *Blueprint* covered a number of matters relevant to the future of community pharmacy, among them funding policy. This reflected long-standing concerns of the Guild and its members that:

- Community pharmacists are often, at least by implication, held accountable for the level of expenditure on pharmaceuticals but in practice have no influence as both the volume of pharmaceuticals dispensed by pharmacists, and the price, are determined by others.

- The traditional arrangements for the funding and delivery of primary health care services have undervalued the professional skills of pharmacists both in terms of medication management and as the primary health care professionals who, in practice, most often have contact with patients.

In the Guild's view addressing these issues needs to start with considering the basis on which New Zealanders have access to subsidised pharmaceuticals. This includes the extent to which pharmacists or other primary health care workers (other than authorised prescribers) should have input into decisions on the use and management of medication, and on monitoring aspects of the health status of individuals where testing can conveniently be carried out in a pharmacy environment.

The funding policy section of the *Blueprint* set out the Guild's concerns and preferred approach in the following terms:

1. Pharmacists do not determine the pattern of growth in prescription volumes. Prescribers and policymakers are accountable for the growth trends along with funders who are setting service rationing criteria.

2. Rationing of access to medicine sits at the heart of the Pharmaceutical Schedule and its rules and procedures. The Guild has considered possible

new approaches to rationing of access to determine if there are more effective ways to match the available revenue to peoples' needs.

3. Rationing of medicines sits alongside other demand side interventions currently within the system. Options for medicine rationing include:

Clinical rationing	Setting clinical criteria for access to medicines for a disease state where demand for funding exceeds available resources.
Financial rationing	A variation on clinical rationing of making some medicines fully subsidised for certain clinical criteria, partly subsidised at another clinical point, with remaining patients paying the full cost.
Geographic rationing	Certain medicine categories are unavailable in some areas or communities or only available in priority areas matching particular assessed needs of a priority population.
Disease state rationing	Patients with specified diseases of defined severity get full access at low cost.

4. The Guild accepts that medicine rationing is fraught with issues, problems of equity access, and introduces hidden policy operating costs. Debate is likely to raise serious health questions about access and affordability as well as health outcomes.

5. Rationing of access to medicine is akin to rationing any elective health service. DHBs already ration access based on set criteria. If funding is under pressure then the access point is lifted and more rationing occurs. As with other health services, DHBs must make explicit decisions to ration essential pharmacy services. If they do not, they are obliged to fund natural volume growth.

6. The referred services management strategy will assist in identifying the causal factors driving prescription volume growth. To the extent better information is available to manage prescribing patterns, then some control on growth at the point of prescribing is possible. Quality improvements in terms of medicines used and outcomes are also facilitated. However, we note there is an inevitable tension between the objectives of the referred services management strategy and those of the program reducing barriers to care. Community pharmacy is able and willing to contribute to the management of this tension at the patient and community levels.

7. Community pharmacy can greatly assist in the success of the referred services strategy if local pharmacists are properly engaged and involved from the

outset. Alignment of incentives for performance will have a key bearing on the outcome.

8. As stated earlier, confidence to invest in new and existing pharmacy services requires clarity and equity in government funding policy and greater understanding of trends. Regular release of information on key trends will develop the understanding needed for the evolution of smarter practices.

The Guild invited McKinlay Douglas Ltd (MDL) to prepare a report for it exploring options for rationing of medicine consistent with the strategy set out in the *Blueprint*. Its initial brief to MDL was worded as follows:

In terms of the assignment we want you to consider the range of options for rationing medicine including by way of example following:

- Financial rationing -- including by income level or based on economic deprivation factors.
- Geographic rationing -- including making different medicines available by different DHB, PHO or postcode areas.
- Disease state rationing -- making certain medicines available for targeted disease states only.
- Rationing on grounds of ethnicity -- allowing specified population groups only to access certain medicines.

Following further exchanges between MDL and the Guild, the brief was refined to "our expectations are:

1. An overview of rationale for rationing medicines and the options available, considering the case for and against national consistency as part of this overview. This would provide a foundation for stimulating public and professional debate on the issue.

2. Definition of the role community pharmacies play in implementing each of these options.

3. Identification of the implications for community pharmacies in implementing each of these options.

4. Identification of ways in which community pharmacies might play a larger and more autonomous role in rationing access to medicines and the implications for Pharmacy of doing so.

5. Identification of ways the downstream effect on pharmacy of the rationing options could be ameliorated in circumstances where pharmacy implements rationing decisions, but does not make them.

6. Identification of options for modifying the present pharmacy remuneration system to ensure its incentives for pharmacist behaviour are aligned with the each of the rationing options identified."

Layout of the Report

The balance of this report comprises the following sections:

- Background – an overview of the changing role of community pharmacy, including the growing awareness of the impact on both health system costs and health outcomes of issues such as adverse drug reactions and non-adherence.
- What We Did – a brief outline of the work undertaken in the preparation of this report.
- Rationing -- a brief discussion of the current New Zealand context for rationing access to health services followed by a review of international experience with rationing access to pharmaceuticals and the implications for New Zealand. This includes the growing emphasis, in health policy, on the role of cost-benefit analysis.
- Outcomes based rationing -- a discussion of the need to shift from the current rationing model to an outcomes based approach which encompasses both access to pharmaceuticals and to the services required to ensure their effective use. This section concludes with discussion of three options for the Guild to consider as a means of encouraging the shift to a new rationing model which would make better use of the services of community pharmacy.

2. Background

This report takes the perspective that community pharmacy is in the process of transition to a third phase in the role that it performs for the communities it serves. In the early part of last century community pharmacy not only dispensed medicines, for the most part, community pharmacists also compounded the medicines they dispensed. This role gradually changed with the rise of the major pharmaceutical companies producing prepacked medicines. The pharmacist role shifted from compounding and dispensing to dispensing prescribed medicines manufactured and supplied by pharmaceutical companies, and retailing over-the-counter and pharmacist only medicines.

At the same time, the professional training of pharmacists shifted into a university environment with students undertaking a more intensive and professionally demanding course of study than had previously been the case, thus significantly enhancing their therapeutic knowledge as compared with previous generations.

Since at least the 1990s, the pharmacist role has again been undergoing change, with a growing although still often under-recognised role as a provider of professional services, advising patients on the use of medications and undertaking a range of primary health care functions, mostly associated with the use of medicines but also increasingly in areas such as health promotion.

This change is now gathering pace with a number of jurisdictions recognising that the professional skills of pharmacists are currently underutilised but have the potential to make a very significant contribution to improving health outcomes.

In early 2005 the Pharmacy Guild of Australia released *The Shape of Our Future*, the final report of the Change Management and Community Pharmacy Project, a very comprehensive survey of the current and expected demographic and health needs changes expected to impact on the Australian health sector. The report identified a number of opportunities for community pharmacy based on its analysis of need, of public expectations, and of the professional skills of community pharmacists. It identified opportunities in a number of areas. We quote from two -- the increasing need for professional pharmacy services, and entry into fields of health previously managed by others (PGA, 2005 p 94 -- 95):

NEED

The need for professional pharmacy services will increase in at least five types of situations:

- The provision of medicines advice associated with dispensing. Community pharmacy is likely to have an increasing role as an 'information broker' for consumers, helping people to find, understand and use information on health-care issues and medicines.
- The detection of medication-related problems.
- The delivery of medicines-management services, e.g. medication reviews in

patients' homes and nursing homes.

- Support for patients who require advice in the course of self-management. Self-management involves self-care (e.g. appropriate exercise programs and diet, and self-monitoring of weight), the use of prescription medicines (e.g. adjusting dosages of medications for CHF), and the appropriate use of over-the-counter medicines. Community pharmacy is arguably the most accessible source of such advice, with a relatively large number of pharmacies conveniently located in public places such as shopping centres.

- Provision of a broad range of advice on health promotion, prevention, health protection, and the management of health problems.

NEW FIELDS

The new opportunities in prevention and therapeutics are likely to be especially important in the health areas currently identified as national priorities. The opportunities for pharmacy in these areas include the following:

- Heart and vascular disease – for example, provision of information on prevention, routine monitoring of blood pressure and biochemical parameters such as serum lipids, and assisting patients with self-management of chronic heart failure (weighing and adjustment of diuretic dosages).

- Diabetes – for example, screening for diabetes, provision of diabetes education programs in communities that do not have access to diabetes educators, measuring blood pressure, blood glucose and glycosylated haemoglobin, and supporting adherence to treatment regimens.

- Mental health problems – for example, supporting adherence to medication regimens, providing education to patients and their families on medications, solving medication problems, and being alert for signs of deterioration that require referral.

- Asthma - for example, helping patients to find the best combinations of drugs and delivery systems, providing education on asthma management for patients and their families, and monitoring asthma severity with simple lung-function tests.

- Cancer – for example, having a role in screening for colorectal cancer by distributing and explaining faecal occult blood testing kits, providing education and information on early detection of common cancers, solving medication problems for cancer patients receiving palliative care, and enabling people to receive appropriate palliative care in their homes.

- Arthritis and musculo-skeletal disorders – for example, supporting adherence to medication regimens, solving medication problems, and providing education and advice about the prevention and management of osteoporosis.

In 2003 the European Observatory on Health Care Systems published *Regulating Pharmaceuticals in Europe*: *striving for efficiency, equity and quality* (available on the Web at http://www.euro.who.int/observatory/Publications/20040527_2). The book is described as "Taking a broad perspective that encompasses institutional, political

and supranational aspects of pharmaceutical regulation, this book examines approaches used to manage pharmaceutical expenditure across Europe and what impact these strategies have had on the efficiency, quality, equity and cost of pharmaceutical care." It has this to say about the evolving role of the modern pharmacist:

> The traditional agency relationship in which the doctor selects the medicine for the patient is changing in other ways too. Pharmacists have long been involved as an intermediary between the doctor who prescribes the medicine and the patient who takes it, but their role was historically as a manufacturer or compounder of the medicine. As modern pharmaceutical technology has rendered this role redundant, the role has evolved. They have developed roles in acting as a safety net for prescribing errors (by the doctor) and as an information source for patients. The concept of "pharmaceutical care" encompasses the pharmacists' obligations to identify and deal with patients' medicine-related problems. Pharmaceutical care has been officially recognised by the World Health Organisation as an element of the role of the pharmacist. Pharmacists are also beginning to develop more independent professional relationships with patients -- that is, independent of doctors. They have become more active in providing advice and treatment on minor ailments without reference to doctors and have also begun to provide preventive care with in-store blood pressure measurement, cholesterol testing and so on. They are also becoming actively involved in the provision of care management packages for patients with specific long-term illnesses such as asthma, ischaemic heart disease and diabetes. They are also developing a more active advisory/drug information role for doctors and other primary care workers, especially in the context of managing drug budgets where these apply. These developments are being actively encouraged and extended in some health care systems, partly as a way of increasing the accessibility and availability of primary care services, but also as part of cost-containment endeavours (as pharmacists' salaries are less than those of doctors).

In England and Wales the government has taken a number of initiatives in the health sector designed to build on the professional skills of pharmacists as an integral part of the primary health care team. It is currently consulting on a proposal that pharmacists should have the ability to prescribe within defined parameters (the consultation document, *Consultation on Proposals to Introduce Independent Prescribing by Pharmacists* is available at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4112774&chk=YEFQbZ).

Most significantly, in 2005 the UK government moved to a new basis for remunerating community pharmacy designed to reflect the increased emphasis on services rather than simply dispensing prescribed pharmaceuticals. Reflective of this, the recently issued guidance to Primary Care Trusts on contracting with community pharmacy states:

> The contractual framework for community pharmacy makes clear the role of community pharmacy and its contribution to the achievement of the targets for the health sector to improve the health of the population, widen access, increase patient choice and help people with long-term conditions. It also

> brings to fruition the objectives set out in *A Vision for Pharmacy in the New NHS* (July 2003). Drawing on community pharmacy's assets of the skills, expertise and experience of pharmacists and their staff and its presence in the heart of the communities it serves with a tradition of ready access to all, community pharmacy should:
> • be – and be seen to be – an integral part of the NHS family in providing primary care and community services;
> • support patients who wish to care for themselves;
> • respond to the diverse needs of patients and communities;
> • be a source of innovation in the delivery of services;
> • help deliver the aspirations within the National Service Frameworks; and
> • help tackle health inequalities.
>
> Community pharmacies now provide a greater range of services and are rewarded for the range and quality of those services.

The New Zealand health sector is also starting to focus on how to make better use of the skills of pharmacists. A 1999 publication of the then Health Funding Authority, *Improving our Health*, noted that "the technical skills of pharmacists are underutilised".

Section 7 of the Pharmacy Services Agreement, which is the document used by DHBs for contracting with individual pharmacies, sets out the required Service Components. Although pharmacists are remunerated by DHBs solely on the basis of prescriptions dispensed (apart from a series of very specific services such as the needle exchange and methadone programs), the service components include a range of other requirements, for example:

- Verification of the appropriateness of the prescribed pharmaceutical.
- Checking acquired medication history for consistency of treatment, possible interactions and evidence of non-compliance or misuse.
- Provision of advice and counselling.
- Reporting any significant findings to the prescriber.

The primary health care strategy seeks to change the way in which primary health care services are delivered. Amongst other things, it places a stronger emphasis on performance management at the general practice level, working through PHOs. Amongst the initiatives which the government is putting in place through PHOs is the referred services management strategy intended to provide more effective management and delivery of pharmaceuticals and laboratory services prescribed or ordered by general practitioners (and other prescribers). To quote from version 8 of the PHO Performance Management Operational Framework (which covers both referred services management and clinical performance indicators and is available at http://www.dhbnz.org.nz/SITE_Default/SIG/SITE_PHO_PMP/x-files/12347.pdf), "In

the context of the Referred Services Management Project, 'RSM' refers to prescription of pharmaceuticals and ordering of laboratory tests by primary care practitioners working within primary health organisations."

The document contains some recognition of the potential role of pharmacy through statements in the section setting out the operational framework matrix's governing principles. As an example, in respect of collaboration/stewardship in the section dealing with PHOs as stakeholders it envisages "pharmacist and pathologist involvement in RSM planning and delivery". The involvement of pharmacy skills in oversight is recognised in the following statement from appendix 1 (relating to northern DHBs):

1**Use of PHO Clinical Management/ Policy Committees.** These committees will be assigned responsibility for considering all aspects of the pharmaceutical and laboratory services management plans with particular focus on patient acceptability and quality of care. The committee should include a pharmacist. At least one member of this committee will take particular responsibility for overseeing the progress of the pharmaceutical and laboratory plans.

What is not found in the document is any clear and definitive statement of the role of pharmacists as a full member of the primary health care team.

The need for better engagement with pharmacy is, however, receiving recognition at an operational level through the planning of some DHBs. In September 2005 the Waitemata DHB released its Community Pharmacy Planning Document for public consultation. It had this to say in respect of the current situation of community pharmacy:

> There are some 95 community pharmacies serving approximately 490,000 people in the Waitemata District. These pharmacies operate in a diverse range of settings, dispensing thousands of prescriptions from primary care and specialist doctors, midwives, and nurse practitioners, as well as a myriad of over-the-counter (OTC) medications. A significant component of their work is 'pre-primary care', giving advice to consumers on all manner of healthcare and well-being enquiries. Where possible, data supporting these roles is presented in this Report…. Consultation conducted by pharmacy groups had indicated that community pharmacists wanted to be an integral and respected part of the primary healthcare team (in the same way that hospital pharmacists are a well-regarded part of the secondary care team in New Zealand). They also wanted to be recognised for the extensive work that they already did in pre-primary and primary care, but which has been largely unrecognised by funding agencies. Furthermore they wanted to undertake added value programmes that drew on their expertise and utilised their locations as being in the front line for community access, and be remunerated for such work.

2

Other DHBs are also considering options for different ways of engaging with pharmacy, including closer involvement of pharmacists in value added services.

There appear to be two principal obstacles to progress, although both should be capable of being overcome:

- New Zealand's long history of a relatively narrow view of the role which community pharmacy is capable of playing in primary health care. In recent years this was exemplified, for example, by an experiment in budget holding as a means of controlling expenditure, including expenditure on pharmaceuticals, which focused solely on groups of general practitioners and did not formally involve community pharmacy or provide any scope for sharing savings with community pharmacists.

- The perceived difficulty of designing effective ways of paying community pharmacy for value-added services -- and of funding payment if a suitable means could be identified.

The key to resolving both of these issues is how funders perceive the value of the services which community pharmacy could provide if the operating environment encouraged pharmacists to do so. The traditional debates between funders and community pharmacy have often appeared to be conducted as though paying community pharmacy for additional services would represent a cost with no equivalent benefit to the funder or to the community.

The context for considering the value of additional services is now changing as the result of considerable research, primarily offshore, on two different aspects of the medication experience -- adverse drug reactions and adherence.

ADVERSE DRUG REACTIONS

An adverse drug reaction (ADR) is defined by the World Health Organisation as a "response to a medicine that is noxious and unintended, and that occurs at doses normally used in humans " (sourced from www.who-umc.org/defs.html). There appears to be limited research material available in New Zealand on the extent to which ADRs occur. For this report we have drawn on Australian research in order to provide an illustration of the possible extent and high-risk areas. This requires the assumption experience within the Australian health system is sufficiently similar to New Zealand experience that the presence of a significant health issue in Australia can be seen as an indicator that the same issue will feature within the New Zealand system. In respect of ADRs, this assumption is supported by considerable anecdotal references by primary health care practitioners and DHB staff to ADRs as a matter of some concern.

*Adverse drug reactions in older Australians, (*Burgess et al 2005) reports the findings of a study which examined trends in ADRs in people aged 60 years or over causing admission to or an extended stay in Western Australian hospitals between 1981 and 2002. The authors state the policy implications of the study findings as:

> It has been estimated that at least 80,000 hospital admissions each year in Australia are medication related, at an annual cost of $350 million. Despite significant investment of resources by the Australian Government in targeted

> interventions to empower prescribers, pharmacists and consumers, efforts to reduce the burden of ADRs appear to be faltering against the increasing use of a wider range of medications, especially in older Australians. Arguably, the situation would be worse with no interventions, but our results bring into question their effectiveness and the adequacy of funding.[1]

The issue of the Medical Journal of Australia which featured that article included a guest editorial, *Managing adverse drug reactions: time to get serious,* by Dr Elizabeth Roughead, senior lecturer in the School of Pharmacy and Medical Sciences, University of South Australia.

The editorial raised the question of why, despite initiatives such as the National Strategy for Quality Use of Medicines and the National Prescribing Service, ADR rates are rising. It suggested that "what the data on ADRs in hospitals indicate is our failure to focus on management strategies for ADRs as a specific topic within the national initiatives. Quality use of medicines and safety initiatives have generally focused on development of services, appropriate selection of medicines and error reduction. The focus for ADRs has remained predominantly on reporting and identification, with less emphasis on management." A number of strategies were suggested including better information sources. Of relevance for community pharmacy is the suggestion that "detection of ADRs in routine clinical practice must also be improved, with more training needed in this area for health professionals. An Australian study of older people considered at high risk of medication misadventure found that 19% had had an ADR which had not been detected in routine clinical care, even though most were using multiple medicines, had comorbidities and were aged over 65 years."

ADHERENCE

In 2003 the World Health Organisation published *Adherence to Long-Term Therapies. Evidence for Action* (available on the Web at http://www.who.int/chronic_conditions/adherence/en/). The publication was a review of a large number of studies of adherence undertaken within different national health systems. The press release which accompanied the publication had this to say:

> "Poor adherence is the primary reason for not achieving the full health benefits medicines can provide to patients. It causes medical and psychosocial complications of disease, reduces patients' quality of life, increases the likelihood of development of drug resistance and wastes health care resources," said Dr Derek Yach, Executive Director, Noncommunicable

[1] The study, and the cost estimates, dealt solely with hospital admissions. In this respect the paper notes that "the study was limited to ADRs of sufficient severity to warrant or extend hospitalisation. Thus, the results represent only the extreme end of a continuum of ADRs, most of which occur in the community and are managed on an ambulatory basis. Unfortunately, although the burden of ADRs managed in the community is likely to be significant, reliable estimates of rates of these ADRs were unavailable."

> Diseases and Mental Health, World Health Organization. "Taken together, these direct consequences impair the ability of health care systems around the world to achieve population health goals."
> (On the Web at www.who.int/chronic_conditions/en/1_7_2003_preng.pdf)

The study itself defines adherence to a long-term therapy as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider."

It reports the extent of non-adherence as "A number of rigorous reviews have found that, in developed countries, adherence among patients suffering chronic diseases averages only 50%".

The WHO concludes that the benefits from improved adherence are not simply improved health. There are also significant economic benefits flowing from reduced health care costs. The argument is expressed as:

> In addition to their positive impact on the health status of patients with chronic illnesses, higher rates of adherence confer economic benefits. Examples of these mechanisms include direct savings generated by reduced use of the sophisticated and expensive health services needed in cases of disease exacerbation, crisis or relapse. Indirect savings may be attributable to enhancement of, or preservation of, quality of life and the social and vocational roles of the patients.
>
> There is strong evidence to suggest that self-management programmes offered to patients with chronic diseases improve health status and reduce utilization and costs. When self-management and adherence programmes are combined with regular treatment and disease-specific education, significant improvements in health-promoting behaviours, cognitive symptom management, communication and disability management have been observed. In addition, such programmes appear to result in a reduction in the numbers of patients being hospitalized, days in hospital and outpatient visits. The data suggest a cost to savings ratio of approximately 1:10 in some cases, and these results persisted over 3 years. Other studies have found similarly positive results when evaluating the same or alternative interventions (p 34).

The study also makes a very important point regarding the nature of adherence. It stresses that adherence should not be seen simply as a failure by the patient to comply. Rather:

> Despite evidence to the contrary, there continues to be a tendency to focus on patient-related factors as the causes of problems with adherence, to the relative neglect of provider and health system-related determinants. These latter factors make up the health care environment in which patients receive care and have a considerable effect on adherence. Interventions that target the relevant factors in the health care environment are urgently required.
>
> Patients may also become frustrated if their preferences in treatment-related decisions are not elicited and taken into account. For example, patients who felt less empowered in relation to treatment decisions had more negative

> attitudes towards prescribed antiretroviral therapy and reported lower rates of adherence.

A recent New Zealand survey, *Cooperation, Compliance and Concordance. Investigating Ways of Improving Adherence to Prescribed Medication*, (Eagle et al 2005) undertook an empirical study of the general population aimed at providing benchmark data regarding patients' beliefs and concerns about medicines in general and those that may have been specifically prescribed for them. The authors report that the study confirms the findings reported in the international literature. As with the WHO report, it emphasises the importance of understanding the influences on patient behaviour, stating that:

> Drawing on models of health behaviour, knowledge of which beliefs are held with what strength across different population subgroups, including sensitivity to cultural differences, is an important step in designing potential interventions aimed at improving medical compliance rates. Potential intervention strategies targeting education, reminder and reassurance issues would therefore appear to warrant consideration.

Using North American data from studies of the cost of medication non-compliance, the authors sought to estimate the cost of non-compliance in New Zealand. They report that " the the cost of medication non-compliance in New Zealand, in direct hospital or related nursing-home expenditure and productivity/mortality costs but excluding ambulatory (ie costs relating to outpatient rather than in patient or hospital clinic periods) can be crudely estimated, from 1990 USA data at approximately $NZ700 million. Using 1995 Canadian data and including ambulatory costs, it can be estimated to be over $NZ1.3 billion."

A related paper*, Breaking Through the Invisible Barrier of Low Functional Literacy: Implications for Health Communication* (Eagle et al 2004) considers the effectiveness of various means of communicating medical information. Methodology included a mail survey, a review of a range of New Zealand material, and a literature search. The extent of the difficulties which arise from low literacy levels can be seen from the following extracts:

> " Wallendorf notes[2] that, while almost all adults in first world countries are assumed to be able to read and write, 21% of adult Americans have only rudimentary skills, leaving them unable to extract even simple information from printed material. A further 25% can perform simple reading functions but "cannot integrate or synthesise several facts" from documents. Further, she suggests that a largely unidentified group could be classed as 'aliterate', in that they are able to read but choose not to, and rely on television rather than print media for news. More importantly, they learn through trial and error rather than by reading instructions. While data from the 1996 International Adult Literacy Survey indicates that there is some variation in these rates across countries, with Scandinavian countries performing

[2] in a 2001 paper, *Literally Literacy,* published in the Journal of Consumer Research

> marginally better and countries such as Poland performing worse, the problem is a global one. The consequences for medication misuse are obvious.
>
> And
>
> Communication, to be effective, extends well beyond the provision of advice or patient education. Patient understanding is impacted by (lack of) fundamental knowledge, patient misunderstanding or misconception about the nature of the medical problem, and information that may be presented in a form that is not readily comprehended. This problem is likely to be exacerbated by the complexity of what material is actually provided to patients. As noted earlier, most patient education material is written at a level that is far beyond the reading ability of most patients; only some 20% of patients will be able to read and understand. This is supported by [research which] in addition to noting that previous studies indicate that only 1/5 of information leaflets will be understood by 75% of the population, also cites examples from these studies in which terms such as "lumbar puncture" and "incubation period" were completely misunderstood.

BACKGROUND: SUMMARY

Community pharmacy in New Zealand is on the point of significant change, reflecting a shift towards much more of a professional services model.

In this, changes in New Zealand reflect and to some extent are following changes in North America, the United Kingdom, Europe and Australia. Although formal policy documentation and contracts relating to community pharmacy still generally reflect a mid to late 20th-century perception of the role of community pharmacy, there are strong signs of funders recognising the need to find a new model.

The drivers for this include accumulating evidence from international research highlighting that the effective use of medication in producing optimal health outcomes requires much more than simply prescribing and dispensing medication appropriate for the patient's condition. Specifically, it requires attention to both the potential for adverse drug reactions and, even more importantly, to ensuring adherence.

Although no New Zealand specific studies have been carried out on the cost of non-adherence, extrapolating from international studies suggests that the costs to the health system alone could be significantly greater than the total current expenditure on pharmaceuticals within the New Zealand health system.

3. What We Did

In order to prepare this report we:

- Undertook extensive Internet searching for information on the changing role of community pharmacy, and of the growing body of research on issues in the effective use of medication including adverse drug reactions and non-adherence.
- Interviewed selected representatives of two PHOs and of two DHBs, with multiple interviews in respect of one PHO and one DHB.
- Had a number of e-mail exchanges with staff of the Guild, which assisted in clarifying a number of issues, especially around the nature of options for rationing access to pharmaceuticals.
- At the stage when we had substantially formulated the approach which is reflected in this report, met with the Guild to review the approach being taken to the report.

4. Rationing

We start by making the point that the term "Rationing" is not being used in any pejorative sense. In this report it simply refers to any set of techniques used to allocate scarce public resources amongst competing demands.

The New Zealand public health system is part of a system of social provision which has traditionally placed a strong emphasis on equity of access and provision -- horizontal equity in the sense that people in like circumstances should be treated in a like manner and vertical equity in the sense that people with greater resources should make a greater contribution.

This is reflected in the current statutory provisions regarding access to subsidised pharmaceuticals. These are found in the New Zealand Public Health and Disability Act 2000. The purpose statement in the Act includes:

> To achieve for New Zealanders:
>
> (i) the improvement, promotion, and protection of their health
> (ii) the promotion of the inclusion and participation in society and independence of people with disabilities
> (iii) the best care or support for those in need of services.
>
> The purpose statement is qualified by the addition of a provision that the objectives are to be pursued to the extent that they are reasonably achievable within the funding provided.
>
> The objectives of DHBs include " to reduce, with a view to eliminating, health outcome disparities between various population groups within New Zealand by developing and implementing, in consultation with the groups concerned, services and programs designed to raise their health outcomes to those of other New Zealanders".
>
> The principal objective stated for Pharmac 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".
>
> The functions stated for Pharmac in the legislation include "to maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies", making national consistency a governing principle for access to pharmaceuticals.

In summary, the New Zealand health system can be seen as characterised by commitment to equality of outcomes within available funding. Necessarily this means rationing whether of pharmaceuticals, elective care or even of emergency care (triage itself is a form of rationing).

As already noted, the *Blueprint* discussed, by way of example, a number of different options for rationing access to pharmaceuticals including clinical rationing, financial rationing, geographic rationing and disease state rationing. The first question for this section of the report to consider is whether these or any other options are inherently different one from another or primarily variations on a common theme.

Although the emphasis in the legislation can appear to be placed on equity of access and inclusion, there is a clear overriding constraint. The public health system will deliver within fiscal constraints. There are no grounds for believing that the present or any likely future government will move away from the current emphasis on keeping health expenditure, as far as possible, within predetermined limits.

What does this mean for rationing access to pharmaceuticals? The European Observatory on Health Care Systems, in a 2002 Policy Brief, *Funding Health Care: Options for Europe* (based on an analysis of the different funding systems in place within the European Union) observes that:

> The ability to control expenditure has been shown to depend on at least three factors: a (hard) budget for health care, monopsony power (a market situation in which there is a single buyer for all sellers) and provider payment methods.

New Zealand's approach to rationing access to pharmaceuticals is certainly consistent with that statement. Its significance is not just an endorsement of a particular approach. It reflects the experience of a large number of relatively diverse health systems.

What this strongly suggests is that any alternative to the current rationing system -- which is inherently a clinical rationing system with an element of disease state rationing -- would need to operate in much the same way. Specifically, a monopsonistic purchaser would remain essential in order to exercise control over the cost of pharmaceuticals. A list of subsidised pharmaceuticals, and the conditions governing access to them, will also remain essential. The alternative would be uncapped access and thus loss of control over volumes and hence expenditure.

For reasons of public health and safety there will remain controls over the gatekeeper function -- prescribing. Only persons who satisfy whatever requirements are in place from time to time will be authorised to grant access in individual cases.

The underlying concern of the Guild is that currently the professional skills of pharmacists are underutilised. Although there is an element of pharmacy self-

interest involved, the overriding issue is the considerable and mounting evidence from a wide range of international, and some local, research that one of the most significant and expensive issues now facing the health system is effective use of medication, something that does require pharmacists' skills.

What needs to to be considered is whether the underutilisation of pharmacists' skills is necessarily a consequence of the current or any other rationing system or whether the reasons lie elsewhere. A consideration of current practice suggests that the critical factor currently is what could be termed the "jam jar" approach to funding pharmaceutical services. Although Pharmac acts as a single monopsonistic purchaser for subsidised pharmaceuticals, the actual funding comes from the individual budgets of 21 DHBs.

Their pharmaceutical budgets cover pharmaceuticals dispensed through community pharmacies, the dispensing fee paid to individual pharmacists, and the costs of hospital pharmaceuticals (pharmaceuticals prescribed and dispensed within a hospital setting)[3]. The budgets are managed separately from the budgets for other DHB funded services. There is currently little scope for trade off between (say) expenditure on pharmaceuticals or medication management on the one hand and expenditure on emergency admissions as the consequence of medication misadventure (ADRs or non-adherence) on the other.

This judgment appears consistent with the nature of the negotiations between the Guild and at least the majority of DHBs. Debate over the range of services which community pharmacists might supply over and above the core dispensing function generally takes place on the assumption (at least on the part of the DHB) that there is little or no funding available for any significant extension of service unless it can somehow be found within current levels. At the extreme this can give rise to the suggestion that the pharmacist's dispensing fee should be reduced in order to free up funding to purchase additional services.

Despite the "jam jar" approach, there does not appear to be any evidence that individual DHB pharmaceutical budgets are being overspent -- in recent years, for example, Pharmac's expenditure on the purchase of pharmaceuticals has consistently come within its overall budget. As already noted, its budget is in essence an amalgam of the budgets of individual DHBs. Public concerns over pharmaceutical funding can themselves in a way be seen as evidence that the tight fiscal controls which set the framework for the current rationing regime are effective. Generally these concerns focus on matters such as the time taken to add new pharmaceuticals to the Pharmaceutical Schedule, the conditions of access, the effect of reference pricing and discretionary funding for high cost treatment.

[3] As well, DHBs also fund some specific additional services such as the needle exchange and methadone programs.

It is simply inherent in a system which seeks to ration access, in a context where the evidence is clear that unfettered demand would very significantly increase volumes, that there will be user concerns about the impact of the means used to ration access. This is especially the case when those responsible for rationing (in the context of this report, primarily the government which determines the rationing policy) are focused on optimising societal outcomes from a limited resource and individuals seeking treatment are focused on improving their personal outcomes often without regard to the wider public interest.

Rationing with a primary focus on cost containment depends not just on defining conditions of access, but also on incentives or controls designed to discourage what, in the context of the resources available, may be seen as excess demand. Two examples which have received coverage in the international literature are copayments and caps on the number of prescriptions an individual may receive over a given period.

A recent paper in "Health Affairs" by Alan Maynard and Karen Bloor, "Dilemmas in Regulation of the Market for Pharmaceuticals (Maynard A. & Bloor K. 2003 -- available on the Web at http://content.healthaffairs.org/cgi/reprint/22/3/31.pdf)" notes that:

> Evidence about cost sharing for pharmaceuticals is consistent across countries and studies in demonstrating that utilization is reduced when patients have to pay. User charges reduce efficient use of pharmaceutical products as well as "unnecessary" care, particularly among low-income groups. There may be a role for user charges in newer "lifestyle" products, but these can be difficult to define and isolate. In general, cost sharing has been summarized as "misguided or cynical efforts to tax the ill and/or drive up the total cost of health care while shifting some of the burden out of government budgets." In addressing inappropriate prescribing, it may be more suitable to target regulation at doctors, not at patients." (p 34).

Patricia Danzon & Stephen Soumerai, in *Pharmaceuticals: Access, Cost, Pricing, and Directions for the Future,* a policy brief presented in 2003, [4] put forward an argument against the use of copayments for the less well off and based on a review of international experience:

> Our first principle is that poor and low-income people, maybe up to 200 percent of poverty, have an urgent need for an immediate unlimited benefit, because these are the people—we have data now from many environments and countries—for whom limited access to prescription drugs actually affects

[4] The brief was presented as the 13th annual Herbert Lourie Memorial Lecture on Health Policy, sponsored by the Maxwell School of Citizenship and Public Affairs of Syracuse University and the Central New York Community Foundation, and is available on the Web at http://ideas.repec.org/p/max/cprpbr/23.html

> their health and ultimately their ability to live independently. Limited drug coverage, especially for low-income people, reduces uses of essential medications that doctors clearly do not want to see reduced, nor does the clinical literature. It increases adverse costly outcomes such as institutionalization, hospitalization, and even mortality.

They go on to argue that " there is no perfect solution. We agree that using copayments is inappropriate for the low income and needy. However, it is a very appropriate way of giving choice to higher income people while constraining the overuse that results from moral hazard. Copayments should be targeted at upper income people who can afford them, while lower income people should be protected."

On the application of caps on the number of prescriptions, they draw on research undertaken by Stephen Soumerai and colleagues comparing changes in prescription drug usage of both essential and non-essential drugs among Medicaid beneficiaries in New Hampshire under two different regimes in the 1980s (a three prescription per month cap during one year, replaced by a one dollar copayment the following year) and New Jersey, which had no cap.

A first study found a reduction of nearly 30% in filled prescriptions following the imposition of the cap. When the cap was lifted and replaced by a one dollar copayment, prescription fills returned to nearly the same level as before the cap. Over the period of the study, no change was noticed in the comparison state.

In 1991 they undertook a similar study. To quote from the policy brief:

> Again, prescription drug usage declined substantially, by 35 percent, among the New Hampshire sample when the cap was imposed. This decline was associated with a significantly increased risk of admission to nursing homes, although not to hospitals. When the cap was discontinued, the use of medications returned to nearly pre-cap levels, and the added risk of admission to a nursing home ceased. However, nothing could turn back the clock: the authors note that, "in general, the patients who were admitted to nursing homes did not return to the community". This was the first time that a study actually demonstrated a link between coverage policies and an outcome like permanent institutionalization.

Three years later they looked at the effects of the New Hampshire Medicaid cap on the use of psychotropic drugs and acute mental health care services by permanently disabled, noninstitutionalized Medicaid recipients diagnosed with schizophrenia, ages 19 through 60 years of age. Imposition of the cap resulted in:

> Immediate reductions (range 15 to 49 percent) in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs....It also resulted in coincident increases of one to two visits per patient per month to [community mental health centers] (range of increase 43 to 57 percent)...and sharp increases in the use of emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month), but no

> change in the frequency of hospital admissions. After the cap was discontinued, the use of medications and most mental health services returned to base-line levels." During the cap there was an increased use of emergency mental health services that are only provided in New Hampshire, a special service to prevent institutionalization for people who are having a psychotic episode. This indicates that a coverage cap can actually cause psychotic episodes among schizophrenic patients, because these services were only provided for people who had severe schizophrenic illness occurring at that time. Furthermore, in this study the cap clearly had a negative effect on overall Medicaid program costs: "the estimated average increase in mental health care costs per patients during the cap ($1,530) exceeded the savings in drug costs to Medicaid by a factor of 17.

Earlier we noted the suggestion by Maynard and Bloor that regulation should target doctors rather than patients with the intention of influencing prescribing practice. This approach was tried in Germany in the mid to late 1990s by imposing a pharmaceuticals spending cap on physicians associations, with the associations to be responsible, without limit, for expenditure above the cap, later amended so that the maximum clawback was reached at 105% of the cap (for details see the WHO country profile of Germany available on the Web at http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020425_2).

A WHO discussion paper, *Health care cost-containment policies in high-income countries: how successful are monetary incentives?,* suggests that the impact of the spending cap lead to savings of about 10% of the total drugs budget. Part of this reduction was attributable to physicians who had on average prescribed drugs of a higher quality.

The discussion paper reports that the substitution effect referred to above was in evidence with the comment "it is important to bear in mind, however, that a sectoral budget policy may impact on other sub-sectors of the health system. For instance there was evidence that office-based physicians increased referrals to specialists and hospitals, subsequent to the drug budget policy. This 'substitution' cost has reduced the amount of 'net' global savings in the health sector that was finally realised.".

These examples illustrate a very common phenomenon with regulatory intervention, especially when the intervention is focused on a particular input rather than on a more holistic approach balancing the cost and utility of different means of managing a patient's condition in order to choose the optimal mix. Too often, restricting access to one input such as pharmaceuticals simply leads to a blowout in expenditure on others sometimes because of unanticipated adverse impacts, sometimes because of a conscious decision by health care providers to use alternative and potentially more expensive inputs as a substitute for pharmaceuticals in order to keep within budgetary or other limits on prescribing.

It is worth taking time to consider the implications of the WHO comment on the impact of a sectoral budget policy on other sub-sectors of the health system. The rationing systems which have been considered by the literature drawn on for this report share a common focus on expenditure constraint for a single input -- pharmaceuticals. None take the broader perspective of treating pharmaceuticals, including pharmaceutical care, as part of a set of tools for managing health outcomes. Specifically, comparatively little attention appears so far to have been paid to the trade-offs between expenditure on pharmaceuticals, or pharmaceutical care, on the one hand and expenditure on in-patient or ambulatory treatment on the other.

The WHO comment is a timely reminder that tight expenditure controls over one input, or even simply a focus on one input to the exclusion of others, can be self-defeating. In a world of limited resources, tight expenditure controls make sense but only to the extent that they are designed and implemented to ensure that they result in net benefits.

From Clinical Effectiveness to Economic Evaluation

Maynard and Bloor's paper cited above begins by noting that over the past three decades there has been considerable investment in the systematic review of clinical trials of drugs and other treatments, to determine the effectiveness of competing medical interventions and that evidence from this work informs, to varying degrees, the regulation of pharmaceuticals at the national level and in individual consultations. They go on to argue that evidence of effectiveness alone as the basis for clinical choices is incomplete. Instead:

> Where health care resources are scarce, decisions based on effectiveness alone do not maximize health benefits for a population and can result in inefficiency and inequity. Economic evaluation may improve health care by including opportunity costs in decisions. Economic frameworks are increasingly having an effect on public reimbursement of pharmaceuticals, particularly in Australasia and Europe.

In 1993, Australia set up new rules governing acceptance of individual pharmaceuticals for subsidy. Drug makers were required to report economic data to the Pharmacy Benefits Advisory Committee. In New Zealand Pharmac's criteria for amendments to the Pharmaceutical Schedule include " the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services". In England the National Institute for Clinical Excellence (NICE) was established in 1999 to assure that the best treatments

are available to all patients[5]. Amongst the criteria which NICE applies is the cost per quality-adjusted life-year.

These initiatives can be seen as a progressive refinement of rationing access to pharmaceuticals (more correctly, to subsidised pharmaceuticals -- it always remains open to individuals to purchase pharmaceuticals which are not available to them through public funding subject only to the pharmaceutical not being a prohibited substance). In theory, the outcome should be that, **within the funding available**, governments will subsidise access to that mix of pharmaceuticals which will result in the best set of health outcomes for their populations.

This leads to the conclusion that there is little role for community pharmacy to play in the choice of the rationing model so long as the primary criterion is fiscal constraint. Whether it is based on clinical, financial, geographic, ethnic, disease state or other criteria (or any combination), the choice of what criteria to use to ration access within a given fiscal constraint is essentially a policy/political issue. Once made, actual administration will be dominated by clinical considerations constrained by available funding.

This conclusion is reinforced by reflecting on the implications of an approach to rationing based on criteria other than health need. Adopting (say) a geographic or ethnic based approach would amount either to allocating funding for pharmaceuticals on a basis unrelated to the health care benefits to be expected from their use or using location or ethnicity as a proxy for health need. The former approach would be inconsistent with the objectives of any public health care system considered in the preparation of this report. The latter amounts to using an inefficient proxy. If location or ethnicity is associated with a greater need for access to pharmaceuticals, then that is a need which should be captured by a rationing system based on health need, as the present system is.

There remains one significant gap in the current approach being followed in New Zealand, Australia and England. Cost benefit analysis necessarily assumes that the pharmaceutical the subject of the analysis will be administered (taken) strictly in accordance with professional guidelines. It is certainly capable of capturing the benefits of using pharmaceuticals as a preventive -- statins provide an obvious example. However, it does not address the costs associated either with ADRs or with non-adherence. The result can be seen as a series of rationing systems which cope well, in isolation, with allocating scarce financial resources for funding pharmaceuticals but do not address the broader question of ensuring optimal health outcomes from the prescription **and** administration of pharmaceuticals.

The accumulated evidence, primarily from international research, of the cost of ADRs and non-adherence in both health and other terms suggests that it is now an

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[5] A major reason for establishing NICE was the perceived inequity of the previous system for funding access to pharmaceuticals. Public health services in England are funded through a series of regional Health Authorities. Their funding arrangements resulted in significant differences in the resources available to individual health authorities so that one might be prepared to fund access to a particular pharmaceutical but another might refuse to do so because of the cost. It was common to describe access to pharmaceuticals as being a "postcode lottery".

imperative to find means of addressing these matters. There is welcome evidence that the need to do so is now attracting attention within the New Zealand health sector. In December 2005 the DHBNZ Safe and Quality Use of Medicines Group released *Safe and Quality Use of Medicines National Strategy 2005.* The executive summary observes that:

> Safety is one part of the quality use of medicines. To achieve the quality use of medicines people must be provided with safe, effective and appropriate treatment and have the knowledge and skills to use of medicines both to their best effect and safely.

The publication recognises the importance of covering activities in both primary and secondary care although its emphasis, perhaps naturally because of the composition of the group responsible for its preparation, is primarily on technical requirements and on the proper specification and observance of the conditions for prescribing medicines and instructions to accompany them. The publication does not address the extensive literature on matters such as the social dimensions of adherence and literacy.

The fact that DHBNZ has undertaken this work suggests that it is timely for practitioners working in primary care to take the initiative in developing a strategy for improving adherence (or concordance as it is increasingly termed) which addresses directly the major problems encountered in a community as opposed to a hospital environment.

This should include putting in place a program of research to provide better information than is currently available through extrapolation from overseas experience to determine the nature, extent and cost of ADRs and non-adherence in a New Zealand context. Options for this will be addressed in the next section. This section concludes by summarising briefly experience with different approaches to rationing.

SUMMARY

Rationing systems for access to subsidised pharmaceuticals, internationally, are shifting from an emphasis on clinical effectiveness to an emphasis on cost-effectiveness. This reflects a growing concern with how best to achieve value for money.

Whether the health system concerned is primarily tax funded, as with New Zealand and England, based on social insurance as in Germany, or a mixed private health insurance and taxpayer top up as in the United States, there has been an increasing concern with how to contain expenditure.

As the policy brief, *Funding health care: options for Europe*, states "the ability to control expenditure has been shown to depend on at least three factors: a (hard) budget for health care, monopsony power (a market situation in which there is a single buyer for all sellers) and provider payment methods.".

Often, rationing systems have complemented an emphasis on clinical effectiveness (and increasingly cost-effectiveness) with the use of incentives, sometimes focused on restraining demand, sometimes on altering prescribing behaviour. The weight of evidence suggests that there are a number of problems with this approach including both issues of equity in access and unintended side-effects. These include the use of high cost institutional care as a direct consequence of restricting access to preventive medication, and health professionals referring patients to other and more expensive sectors of the health system as a means of constraining expenditure on pharmaceuticals.

All of the material reviewed in the preparation of this report reinforces the conclusion that, if the objective of a public health care system is to optimise the health status of a given population, then there is really no alternative to a rationing system which combines an emphasis on fiscal constraint with access criteria based on the health gain expected to result from the appropriate prescription and use of pharmaceuticals.

The only example of a rationing system which could be seen as being at least in part based on criteria other than clinical considerations is the pre-1999 situation in the United Kingdom in which decisions on what pharmaceuticals to fund rested with individual regional health authorities. Because the size of health authority budgets depended on the strength of their regional economies, the ability of individual authorities to fund pharmaceuticals varied significantly. In effect, access to pharmaceuticals was at least partly dependent on where you lived. The practice became known as "postcode" rationing. It would, however, be wrong to see this as a deliberate application of geography as a criterion for access. Instead, it simply reflected an unintended consequence of the NHS funding arrangements.

The shift to cost-effectiveness as a principal criterion for funding is a partial shift to an outcomes focus. It is, however, still a partial focus to the extent that the concern of the rationing system ends at the point the pharmaceutical is dispensed. A fully outcome based rationing system for pharmaceuticals would include those services deemed necessary to ensure adherence -- that the pharmaceutical is not only dispensed, but taken in accordance with the directions of the health professional or professionals involved. Ideally, it would include evaluation -- assessing the extent to which the expected outcome from using the pharmaceutical as directed was the actual outcome and if not why not.

The next section of this report considers what steps might be involved if the rationing of pharmaceuticals was fully outcomes based and, within that, what could be the role of community pharmacy.

5. Outcomes Based Rationing

Section 2 of this report provides an overview of recent research on the incidence and cost of adverse drug reactions and non-adherence. Although there are no direct estimates of the cost to the New Zealand health care system, extrapolation from North American data by Eagle et al suggests that the cost could be as high as $1.3 billion for non-adherence alone.

Although estimates of that type need to be treated with caution, they do make a strong case that the arrangements for access to subsidised pharmaceuticals should focus on outcomes from the use of pharmaceuticals and not simply on the output -- the dispensed prescription and the process for getting to that point.

An outcomes based approach to the rationing of access to subsidised pharmaceuticals is consistent with the Primary Health Care Strategy Section 4 of which includes statements such as:

- Effective coordination of care will become even more important as we extend the focus of primary health beyond treatment and support services towards a more comprehensive disease prevention and management approach.
- There is good evidence that adopting a broader approach to primary health care can contribute to reducing health inequalities in improving outcomes.
- The broad vision of primary health care in this Strategy means that no single practitioner or type of practitioner can meet people's needs completely.
- The world of primary health care is changing and old isolated ways of working must be replaced by new collaborative models.

When read in conjunction with estimates of the cost to the health system of ADRs and non-adherence, these statements from the Primary Health Care Strategy reinforce the view that any system for rationing access to pharmaceuticals cannot stop at the point of delivery of the prescription but needs to encompass the use of the medication and its impacts.

This gets directly into the question of the role of community pharmacy in medication management. In this respect, the literature is highly variable. Some material strongly supports the role of community pharmacists in ensuring the effective use of medication. Other material still appears to be prepared on the assumption that the sole task of a pharmacist is to put a label on a bottle or packet and pass it across the counter.

In the latter category comes the 2005 Commonwealth Fund International Health Policy Survey, a cross national telephone survey of sicker adults aged 18 and older in Australia, Canada, Germany, New Zealand, the U.K., and the U.S.. Adults included in the survey met at least one of the following criteria:
– Self reported health status is fair or poor.
– Serious illness in the past 2 years.
– Hospitalized or had major surgery in the past 2 years.

The survey explored experience with the health system including hospitals, doctors, and the use of medication but made no reference to pharmacists.

This type of approach can now be seen as reflecting traditional views of the role of pharmacists, rather than the more current view consistent, for example, with the WHO definition of "pharmaceutical care" which sees pharmacists involved in a range of services beyond dispensing pharmaceuticals.

The more traditional approach does still seem to play a role in the development of primary health care policy in New Zealand despite the emphasis in the Primary Health Care Strategy on collaboration. Support for this view can be seen in the current state of development of a key element of the Primary Health Care Strategy, the referred services management strategy (RSM). (RSM refers to prescribing pharmaceuticals and ordering laboratory tests by primary care practitioners working within PHOs).

The development of that strategy can be placed in the context of the statement in the Primary Health Care Strategy in respect of PHOs that "All providers and practitioners must be involved in the organisation’s decision-making, rather than one group being dominant."

It is strongly influenced by the fact that affordability remains an important factor. Version 8 of the PHO Performance Management Operational Framework states " The volume of pharmaceuticals has continued to rise and now there is a need for DHBs (who manage the finite budgets for health services, including referred services) to ensure that their prescribers' expenditure is affordable and delivering value."

Eight key activities are proposed to facilitate education, feedback and eventual change when needed. These include within each PHO:

- A broad-based approach, with each PHO establishing and maintaining a performance plan with implementation and review guided through a PHO clinical governance function.
- Access to detailed information and analysis on utilisation patterns and performance against indicators.
- Personalised feedback to PHO providers on their utilisation and outcome patterns compared with peers and best practice.

- Facilitator visits and/or peer review groups to discuss diagnostic and treatment patterns, disease management strategies, and best practice.
- Programs to implement national guidelines.
- Bulletins to members on best practice.
- Incentives to encourage practitioner participation in performance, and
- Electronic decision support to facilitate delivery of best practice care to the individual patient.

The focus of these activities is very much on the process of general practitioners diagnosing a patient's condition and prescribing medication, and on ensuring equitable access to pharmaceutical funding. There is no reference to the role of pharmacists and no apparent focus on what happens when and after the patient takes the prescription to a community pharmacist.

This is despite the fact that the primary health care strategy itself refers to all providers and practitioners being involved in the PHO's decision-making process.

That the emphasis of the referred services management strategy is on the process up to the point of prescribing is reinforced by the performance indicators set out in version 1.2 of PHO Performance Management Target Setting for Primary Health Organisations and District Health Boards issued in October 2005.

This focus needs to be seen in context. The process of developing PHOs, and determining how best to ensure equitable allocation of resources, has been an extremely complex one. Adding to that process a requirement to change the longstanding relationship between general practice and community pharmacy, and moving to a new model for rationing access to subsidised pharmaceuticals which incorporated the services required to minimise ADRs and non-adherence would almost certainly have resulted in severe system overload (implementation of the referred services management strategy is already some two years behind the original target date).

Work is, however, going on within the New Zealand health system assessing the potential for pharmacist involvement in medication management and the benefits which could result from that. What follows is an extract from the Waitemata DHB's Community Pharmacy Discussion Document reporting a study which considered the potential benefits of greater pharmacist involvement in medication management for older persons:

Analysis of prescription use among older people

1. A qualitative study undertaken by the School of Pharmacy at the University of Auckland, looked at use of prescription medicine among 31 people aged >65 years in the Waitemata DHB area. The authors concluded that, of the various medicine issues identified, all could be addressed through improved patient-pharmacist communication and education.
2. A study of 54 older people (average age 80 years) with multiple diagnoses and medications (average of 14.8) who were regarded as 'not coping' in central Auckland found that half had dose discrepancies in their prescribed medications, and that only one patient was taking their medications as prescribed and dispensed. Intervention by a pharmacist led to improvements in patient quality of life measures and reductions in the number of medications taken – this equated to a 9% reduction in daily costs of prescribed medicines, equivalent to a potential annual savings of $7,500 for this particular sample of patients. GPs involved in this study recognised the value of pharmacists working as part of the health care team in the primary care sector. The authors concluded that:
1. Suitably trained pharmacists can successfully conduct clinical medication reviews and participate successfully in a patient's health care team;
2. Optimisation of individual medication regimens can result in reduced number of medications taken, with direct cost savings from this;
3. Medicines management services have the real potential to achieve therapeutic benefits (as well as associated cost savings) e.g. fewer hospital admissions for adverse drug reactions such as acute renal failure, gastric ulceration; improved control of complex medical problems such as heart failure, COPD, ischaemic heart disease.
4. These are cost-neutral benefits.

The question for community pharmacy is how to encourage a shift from the dominant current approach to rationing, including the emphasis within the referred services management strategy, to more of an outcomes based approach where the focus is on access not just to pharmaceuticals as such but to a combination of pharmaceuticals and the services required to ensure that they are used effectively.

The obstacles community pharmacy needs to overcome are a combination of a relatively low awareness of the avoidable costs associated with the present approach, and a lack of appreciation of the potential role of community pharmacy (it should be noted that it is difficult to assess whether the lack of appreciation is genuine in the sense that funders really do not understand the potential, or whether it is in the nature of a defensive mechanism because of funder concern that they do not have the resources needed to pay for the additional services -- which itself could be a function of a lack of understanding of the avoidable costs and thus the potential for funding additional services from savings elsewhere).

On the second point, there is extensive research and other material available which now supports the role of community pharmacy in medication management and recognises the nature of the shift taking place towards more of a professional

services orientation rather than simply one of dispensing as a technical function. We now consider some examples.

England

This report has already outlined, at page 9 above, the new approach to contracting with community pharmacy set out in the recent guidelines from the National Health Service to Primary Health Care Trusts, which is quite explicitly driving a change to more of a professional services role.

This approach is consistent with surveys of pharmacist attitudes (aspirations). The *Pharmaceutical Journal* for 7 December 2002 (available on the web at http://www.pharmj.com/ContentsPages/Contents20021207.html) reported on two recent surveys of community pharmacists. Priority areas for future development that were most commonly identified in research for the first report[6] included medicines management, health screening/diagnostic testing, and health promotion.

Of particular relevance for community pharmacy in New Zealand is the following finding on differences between independent and multiple pharmacies:

> Significant differences were found in the provision of additional services by independent and multiple pharmacies. Independents were significantly more likely to provide nicotine replacement therapy, health promotion schemes, advice to residential and nursing homes, advice to general practitioners and other healthcare professionals, health screening and diagnostic testing and prescription collection and delivery services. No significant differences were found in the likelihood to provide medicines management or repeat and instalment dispensing services.

The second study found that 95% of community pharmacists believe their future lies in clinical practice and direct patient care. The researchers (led by Professor David Taylor, professor of pharmaceutical and public health policy at the School of Pharmacy, London University) reported that:

> From being a Cinderella among the primary health care professions, community pharmacy could within five to 10 years come to play a more central role in determining medically and self-initiated pharmaceutical treatment choices and promoting desired health outcomes.

At contributing factor in the shift is stated to be "the desire for role change of younger, better educated and more health orientated pharmacists is coinciding with complementary demand from government and the NHS.".

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[6] This report surveyed all community pharmacists in charge of pharmacies with National Health Service contracts in the area of the North East London Strategic Health Authority.

Australia

The Australian Government Department of Veterans' Affairs has issued a series of briefings for veterans to assist them and their general practitioners in the management of their medication. *Flag Veterans for Medicines Review,* a briefing specifically for general practitioners (available on the Web at http://www.dva.gov.au/health/veteransmates/pdf/M1-Brief.pdf), reports the following research findings:

- In an Australian trial of Home Medicines Review services, 90% of veterans felt it was important or very important that their doctor and pharmacist worked together in helping them manage their medicines. While GPs regularly review medicines, a collaborative approach involving a pharmacist provides a different perspective and focus.
- Only 27% of Australian veterans rated their understanding of their medical conditions and medicines as very good prior to a home medicines review. This rose to 87% after the home medicines review visit.

The executive summary of *The Shape of Our Future,* the final report of the Pharmacy Guild of Australia's Change Management and Community Pharmacy Project, observes that:

Pharmacies represent an existing community-based network with a powerful potential to contribute to many areas, including:
- Healthy lifestyle and disease prevention.
- The provision of community-based health services.
- Advice to carers and patients in self-management of chronic illnesses.
- Assisting in the quality use of medicines.

Europe

The chapter on regulating pharmaceutical distribution and retail pharmacy in Europe in *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* notes that, in some EU contexts, a combination of new government policies, changing professional aspirations and rising public expectations (regarding not only health care, but also the maintenance of good health) could be sufficient to drive a major transition in the role of community pharmacy towards a more clinical orientation in the next five to 10 years. However there are many factors inhibiting progress. One is reflective of the context for community pharmacy in New Zealand and is described as:

Lack of consistent public pressure for better pharmacy services, and of a coherent political vision of how pharmaceutical and other forms of health care should in the future be improved. There appears to be a growing consensus that all forms of medicine use and healthy living demand significant self-care skills, and that pharmacists are well placed to move on from traditional models of professional care towards establishing equal, supportive rather than infantilizing relationships with service users. In countries like Canada, where there are established examples of innovations such as community pharmacy access to service user health/medication records and online remuneration systems, pharmacy service providers have arguably already moved some way towards this end. Nevertheless, paternalistic attitudes still dominate many European decision-making bodies. An apparent concern for public safety and protection could on occasions conceal a desire to preserve the *status quo*, and to inhibit developments that might in fact benefit community pharmacy service users.

A WAY AHEAD?

This report has argued strongly that policy for rationing access to subsidised pharmaceuticals needs to move on from the present approach with its focus on cost-benefit analysis carried out on the assumption that medication will be taken in accordance with advice from health professionals. Instead, it needs to reflect the reality of high levels of non-adherence and associated costs both to the public health system and to the community at large. To do this will require a new emphasis on professional services whose purpose is to support patients in the effective and appropriate use of medication.

Two dilemmas face community pharmacy in advocating for this change. The first is the relative dearth of New Zealand-based research on the extent of non-adherence and the associated costs, as well as of research on the extent and cost of adverse drug reactions. The second, which to a significant extent is a consequence of the first, is a lack of appreciation of the role which community pharmacy should play in an outcomes based approach to rationing access to pharmaceuticals.

Both are highlighted by the following extract from the Waitemata DHB's community pharmacy discussion document:

> What is missing from New Zealand literature on community pharmacy is recent, rigorous data demonstrating:
> (a) the extent of interventions undertaken by community pharmacists – exactly how often do they pick up clinically significant prescribing errors, drug-drug interactions, and potential adverse drug reactions?
> (b) the significance of such interventions – do these interventions impact on morbidity and mortality? It is by no means established that community pharmacy interventions make a positive impact on health outcomes.
> (c) benefits of qualitative outcomes such as 'improved relationships' and 'team building'.
> (d) Whether the public is receptive to an increased role of community pharmacists in primary healthcare.
>
> In this regard, community pharmacy in New Zealand has not been its own best advocate. While community pharmacy organisations have cited the lack of recognition given the value of services provided by community pharmacies, these same services in New Zealand have not been well documented and analysed, nor published in authoritative forums such as peer-reviewed journals.

In some respects, this assessment is less than fair to community pharmacy. First, as the discussion document acknowledges elsewhere, funders do not pay community pharmacists to deliver the extensive range of services which they are or wish to be capable of providing. Accordingly, it is hardly surprising that there is a relative dearth of information on the potential of those services -- in the absence of funding, provision is relatively minimal. Where there have been initiatives to encourage the purchase of additional services, these appear to have been inadequately funded so that the incentive for pharmacists to participate has not been strong. As an example, in respect of Pharmaceutical Review Services the *Blueprint* notes:

> Small service volumes purchased by all DHBs from some providers. Patient access to the services is uneven and the cost to the pharmacy of providing the service is not matched by the revenue.

Next, although it is clearly in the interests of community pharmacy to do what it can to support research on the potential role of community pharmacy, community pharmacy is not the only element of the health sector with an interest in doing so. To the extent that the health system incurs additional costs as a consequence of non-adherence or avoidable ADRs, it is DHBs as funders who are the primary risk bearers. As such, they clearly have a vested interest in assisting commission research to determine both the extent of the problem and appropriate means of managing it.

Against this background, there is a clear strategic choice for community pharmacy. It can continue to advocate for a systemic recognition of more of a professional services role, or it can seek out one or more alternative means of making the case for a greater role for community pharmacy. Systemic recognition would require government itself, through the Ministry of Health, and through DHBs, to adopt a new rationing model and a different approach to contracting with community pharmacy generally.

The experience to date within the primary health care strategy, and the apparent lack of awareness of the potential gains from a new role for community pharmacy,

both suggest that a strategy of seeking systemic recognition will face very real difficulty, at least unless the context for the debate is first changed in favour of community pharmacy.

THREE OPTIONS

We identify three complementary options which community pharmacy could adopt in order to raise the profile of the case for an outcomes based approach to rationing access to pharmaceuticals and the services required to make the use of pharmaceuticals more effective. They are:

- Research.
- Pilot projects.
- Changing the context -- a national medicines strategy.

Research

Although the Guild can be entitled to feel somewhat disappointed at comments such as those by the Waitemata DHB cited above, this should not distract attention from the fact that there is a need for robust New Zealand-based research on the prevalence and cost of problems such as non-adherence and adverse drug reactions. So long as the New Zealand debate proceeds on the basis of estimates extrapolated from overseas research, it will remain very difficult to gain the necessary traction. Even in situations where population demographics and socio-economic factors appear similar, there is considerable room for discounting overseas research on the grounds that New Zealand conditions are different. In discussing the prospects for change in community pharmacy in Europe, the authors of Chapter 11 of *Regulating pharmaceuticals in Europe: striving for efficiency equity and quality* observe that:

> the current forms of pharmacy service found across the EU (for example, the Scandinavian approach, the Dutch and British models, southern European pharmacy) are deeply embedded in local cultural structures, and broader health care provisions. This in itself generates resistance to change, and can conceal differences in approach is to service provision that are greater than is commonly understood.

The Guild should expect the same response in New Zealand. Ideally, research on issues such as the impact of ADRs and non-adherence should be commissioned jointly by the major stakeholders with an interest in managing the adverse impacts.

Pilot projects

As already noted, seeking system wide change requires a systemic response which would mean persuading the government, through the Ministry of Health, and DHBs

as a group, of the desirability of change. It would also require persuading those entities that introducing an additional and substantive element of change into the management of primary health care was desirable at a time when the health sector is clearly suffering from "change fatigue".

Another factor to consider is that, in the context of the primary health care strategy, expanding the role of community pharmacy so that it had much more of a professional services emphasis would necessarily require working closely with PHOs. It is clear that the country's 82 PHOs are at different stages of evolution, for reasons of scale have different capabilities (enrolled patient numbers range from fewer than 10,000 to in the order of 150,000 and more), and serve populations with different socio-economic and cultural mixes. As experience with the implementation of the referred services management strategy already indicates, seeking to bring about systemic change at the PHO level is a very challenging and time-consuming process.

One virtue of a pilot project approach is that it can be seen as a form of action research. What this means is that, prior to completion and evaluation of the project, the commitment being sought is not to a new way of working -- which might require a very substantial shift in attitude -- but rather to exploring the potential of a new way of working.

As part of the work undertaken for the preparation of this report, we had discussions with people associated with two District Health Boards and with two substantial PHOs. What became clear from those discussions is that there are elements within both sets of entities which are prepared to consider innovative approaches to the management of primary health care with a focus on improving health outcomes. Options such as combining together for continuing professional education were seen as worthwhile possibilities. The question of whether any of these entities would also be interested in working with the Guild to develop one or more pilot projects was canvassed and received a generally positive response. Caveats included:

- Whether an appropriate and sufficient source of funding would be available.

- The potential impact on community pharmacy of introducing a significant professional services component, even on a pilot basis.

Overcoming the funding issue may not be straightforward. PHOs do have available discretionary funding but this is quite jealously guarded. Any pilot would almost certainly require not just a PHO commitment to explore a different means of working between general practice, pharmacy and other primary health care professionals, but also a DHB commitment to contribute funding as a means of testing the potential.

For any pilot to have a reasonable prospect of success, it would be essential for funding to be sufficient to attract pharmacists to become involved -- in other words to avoid the impact of underfunding in previous attempts to extend pharmacy services such as the Pharmaceutical Review Services initiative. It would also be

essential to select a PHO catchment whose pharmacists themselves were open to innovation.

This may be less straightforward than might be inferred from recent initiatives such as the *Blueprint.* That document can be read as suggesting that pharmacy as a whole is ready and anxious to move forward.

In June 2004 the Pharmacy Practice Research Trust[7] released the briefing paper *Innovation in Community Pharmacy: Accelerating the Spread of Change* (available on the Web at http://www.rpsgb.org.uk/pdfs/innovcommphbrief.pdf). It provides a very useful overview of the issues which need to be addressed in order to achieve success in innovation within community pharmacy. One important point which emerges from the research reported in the briefing paper is that only a minority of pharmacists (in the research approximately 16%) will be either 'innovators' or 'early adopters'.

The most important consideration for effective innovation is sustainability. On this theme, the briefing paper has this to say:

> Above all, for innovative services to be widely available and cost effective they must be sustainable. Resource is wasted where pilot projects are inappropriately placed with less innovative pharmacists, where they are not followed through, and where successful experiments are abandoned when funding ceases. The research suggests that innovators and early adopters do not seek financial reward for new service provision, but that appropriate remuneration is required for mainstreaming an innovation through the majority and late adopter populations.

This emphasises the importance of careful selection of any pilot project. It is virtually inevitable that a pilot exploring collaborative working between general practice and community pharmacy through the medium of a PHO would need to involve not just pharmacists who qualified as 'innovators' or 'early adopters' but also what the briefing paper refers to as the majority and late adopter populations.

The second caveat, the potential impact on community pharmacy, also needs careful consideration. This was raised by a community pharmacist within the area of one of the PHOs contacted for this project. He recognised the merits of community pharmacy extending in to services of the type described as pharmaceutical care services and advanced or complex services in the *Blueprint's* proposed redefinition of the community pharmacy service structure. However, he did not see this as an area which his own pharmacy would want to enter.

This left him concerned that such a service extension would disadvantage his business. As he saw it, patients of his who required or wished to access those

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7 An independent research charity established in July 1999 with core funding provided by the Royal Pharmaceutical Society of Great Britain.

services will almost certainly seek their essential service requirements, such as prescriptions, from the pharmacist providing those additional services.

That is an inherently negative response but one which quite possibly reflects the views which could be expected from a significant section of community pharmacy -- reluctant to innovate but concerned that innovation by others would cut into their core business.

There is another factor to consider as well; the propensity identified in international literature for independents to be more disposed to innovation in service delivery than multiples (see the material quoted at page 31 above). In the New Zealand context this may mean that some of the chains now emerging will be less willing to become involved (this matter was traversed in more detail in the recent MDL report for the Guild, *Pharmacy Ownership*).

What is not yet known in a New Zealand context, and could only be established through a pilot approach, is how viable it would be for individual pharmacies to make the investment in time and facilities required to be able to offer a full range of additional services -- this is a function of a number of matters including the likely level of activity.

In practice, it is possible that, at least in piloting the potential of a shift to more of a professional services model, it may be necessary to seek an option under which the pharmacist or pharmacists delivering the services was available to all of the pharmacies within the district of a PHO but in a way which did not suggest a threat to their individual businesses. One possibility is for the pharmacist to be employed by the PHO but accountable to a sub-group of the PHO's governance body which incorporated representatives of community pharmacy within a brief to ensure that this approach did not become a first step towards PHOs competing with community pharmacy.

Ultimately, what could result from the shift to more of a professional services orientation is a measure of specialisation within community pharmacy, with some pharmacists preferring to focus on retail pharmacy -- much along the lines of the present approach -- and others opting to become providers of professional services not associated with the retailing and delivery of products. This would offer pharmacists a choice in how they wished to practice their profession and could also be an appropriate response to a potentially significant workforce issue; avoiding the risk that, if all retail pharmacists chose to adopt a professional services role as well, few might have a sufficient workload to develop fully the experience and specialisation needed.

Changing the context -- a national medicines strategy

Currently, public debate about the role of pharmaceuticals in health care is focused on access, most obviously on the inclusion of new therapeutics in the Pharmaceutical

Schedule, and payment for high cost treatment. This is an emphasis which is very much on the claimed right of individuals to receive treatment which will benefit them personally, often regardless of cost, rather than on the role of pharmaceuticals in population health.

Specifically, it is a debate about " how can I get the pharmaceuticals I require (demand)?" rather than "how can I best ensure that the pharmaceuticals I receive will generate the health outcomes I seek?". So long as the debate remains focused in this way, the prospects of community pharmacy gaining public support for an increased role, especially one which seeks to ensure better adherence (concordance) are going to be limited. In this respect note the comment cited above (page 32) regarding the future of community pharmacy in Europe that one factor inhibiting progress is the "lack of consistent public pressure for better pharmacy services, and of a coherent political vision of how pharmaceutical and other forms of health care should in future be improved".

If community pharmacy is to improve its prospects of achieving the changes it seeks, then it seems essential to shift the nature of the debate from access to outcomes -- what are we seeking to achieve through the use of pharmaceuticals, where are we currently (including the costs both fiscal and otherwise from problems such as non-adherence) and what do we need to do to get the outcomes we require.

Australia provides a possible example through its adoption, in 2000, of a National Medicines Policy and the associated National Strategy for Quality Use of Medicines (both available on the Web at http://www.google.co.nz/search?hl=en&q=%22national+medicines+policy%22+%2B+Australia&btnG=Search).
The strategy seeks to establish a partnership for better health outcomes involving stakeholders from government through to health care consumers. There is an emphasis on not just on access but on use. The strategy notes that "to achieve quality use of medicines, people must be provided with the most appropriate treatment, and have the knowledge and skills to use medicines to their best effect." It goes on to state that:

> To achieve optimum use of medicines:
> • consumers and health practitioners should have timely access to accurate information and education about medicines and their use;
> • public health and health education programs, and other programs relating to quality use of medicines (eg development and implementation of guidelines, implementation of schemes for the disposal of unwanted medicines) should be coordinated between the Commonwealth Government and State/Territory Governments as well as others in this partnership;
> • industry and health practitioners should contribute through appropriate information, education and promotion activities; and
> • issues relating to use of medicines should be reported accurately and responsibly by the media.

In the light of the research and other material referred to in this report, it could be argued that the Australian strategy is somewhat sketchy in its coverage of problems associated with non-adherence and ADRs but it is certainly a far stronger commitment to focusing on outcomes from the use of pharmaceuticals than New Zealand has, for example, in the primary health care strategy.

The recent DHBNZ publication demonstrates that there is now a climate favourable to the development of a national medicines strategy. This report argues that such a strategy must have a strong community focus as it is in the community that the most serious problems of non-adherence and ADRs arise.

MDL would recommend that the Guild give serious consideration to taking the lead in developing a national medicines policy for New Zealand with a very specific focus on minimising the fiscal and other costs associated with non-adherence and ADRs.

The objective should be to set the context for an effective public debate leading to a shift from the present rationing model, to a rationing model with a focus on access both to pharmaceuticals and to the services required for their effective use.

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