

Money and Medicines: An Economic Analysis of Reference Pricing and Related Public-sector Cost-containment Systems for Pharmaceuticals with Special Reference to New Zealand, by Alan Woodfield, John Fountain and Pim Borren

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A Review

by

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Money and Medicines (WFB) analyses government provision of prescription pharmaceuticals in New Zealand, focussing on the performance of the Pharmaceutical Management Agency Ltd. (Pharmac). Pharmac is a wholly owned subsidiary of the Transitional Health Authority (THA), and has the responsibility of managing the national Pharmaceutical Schedule on behalf of the THA. Pharmac does not purchase pharmaceuticals, but it does set the terms and conditions under which pharmaceuticals are subsidised to the final consumer.

The operation of Pharmac is so closely intertwined with the unique characteristics of the market for pharmaceuticals and government policy towards the health sector that it is not possible to consider any of these individual elements in isolation. The approach adopted by WFB is to weave the key economic and New Zealand institutional factors into all of their discussion and evaluations. To a certain degree this reflects the “Pharmac” focus of the book, but makes it more difficult for even an informed reader to understand the scope and insights of their analysis and arguments. Some critical features of the pharmaceutical market are not mentioned until late in the book and on occasions are not drawn out as central issues. We believe that it would have improved the clarity of the arguments made in the book if the authors had written a comprehensive introduction summarising the key characteristics of the pharmaceutical market and Pharmac’s role in it. We start by briefly providing such an introduction.

The Supply Side: The provision of pharmaceuticals is characterised by the production of patented and unpatented (generic) drugs, and on-going research into new products. New drugs require approval of “safety” regulatory agencies and if they have patent protection they are priced above variable production costs to an extent that is determined by the level of demand and the existence of close substitutes. Patents when combined with restrictions on parallel importing provide the opportunity for prices of patented drugs to be pitched at a level that seeks to maximise revenue less costs of production and distribution in each country.¹ This surplus over production cost is a reward for innovative new drugs that provides the incentives, and the resources, for the development of new drugs.

¹ The opportunity to garner financial surplus is also affected by the regulatory, purchasing and subsidisation regime of any country.

Although the development costs of existing prescription drugs in the market place are sunk, WFB very reasonably (from an efficiency standpoint) include R&D costs in their pricing models as a cost that is fixed and does not vary with current sales. These costs are the on-going costs of the development of new innovative products and investment in them should be subject to the same general decision principles that affect any sort of investment. The anticipation of future surpluses provides the potential future prize that induces this research. There will still exist surpluses in competitive markets, because there are winners and losers of product and patent races in the development of new pharmaceutical products. Profits to the winners may be very large, especially if the new products are of major benefit to society.

While a pharmaceutical firm may have a monopoly with respect to a product at a point in time, as the patent runs out, and indeed, as the surplus attracts close substitute products, the price and profitability of the drug will decline. Firms' market shares and financial performances follow this path. In other words, patents provide incentives for and are a means of funding research and development, and in a competitive pharmaceutical market investment in research and development will dissipate industry rents arising from patents. We accept WFB's argument that because of the existing, very considerable, number of products and firms and because of the temporary nature of the monopoly position of any one product, the industry taken as a whole is quite competitive: it is particularly so in the production of generics.²

This conclusion has implications for WFB's use of game-theory models to analyse the pricing behaviour of pharmaceutical firms in the context of government sponsored schemes and regulations. For this environment, these models offer the best framework within which to explain pricing behaviour. As WFB point out, outcomes can be different if decisions about price and quantity are taken once (one shot games) or taken repeatedly (repeated games) whence,

² Garber (1993, 15) reports that in 1989 there were approximately 790 companies in the USA that manufactured and marketed pharmaceutical products, of which 100 research-based companies accounted for 90% of US sales.

even without explicit collusion, more co-operative pricing decisions can result. We think that WFB could have made more of the fact that the possibility of these co-operative (less competitive) outcomes are limited by the expectation of innovative new products, and by the incentive of companies with patented products to get any surplus as soon as possible, rather than in the future when additional competition will almost surely reduce it. The arrival of new products will place stress on co-operative strategic arrangements that firms may contemplate.

The Demand Side: The demand for pharmaceuticals stems from their therapeutic effects: but there are a number of key factors that make actual demand the outcome of a very complex process. The first of these is an inability to quantitatively measure health status. Health status is inferred from external and internal signals that are open to interpretation. Not only does this affect the establishment of any individual's health status, it also affects the ability of trials to demonstrate the efficacy or otherwise of particular pharmaceuticals. Trials with human subjects frequently yield outcomes with very high variation across individuals, even if, on average, they have a positive therapeutic effect. This characteristic makes it very difficult to measure the extent of any additional therapeutic benefit of one pharmaceutical over another. It also carries with it the fact that when new drugs emerge their characteristics are not known thoroughly. Although they will have been widely tested and passed tests of safety, the limitations of measured trial outcomes contributes to lingering uncertainty about their therapeutic characteristics and side effects, and learning takes place when they are first widely used by patients. This together with prospective price declines affects the anticipated time profile of the cost/effectiveness of newly introduced drugs, and hence their indicated use over time. WFB do not mention this timing factor. They do make much of individual variation in therapeutic effect and side effects to argue the case for consumer, or prescriber, choice among all, including new, pharmaceutical products.

A second demand characteristic is that final consumers do not know the range or properties of pharmaceuticals, nor do they understand the links between their signals of health status and indicated pharmaceutical products. The diagnosis of

the signals and the indicated pharmaceutical response is the purview of doctors acting as the agents of the consumer. This asymmetric information (the doctors know more than their patients) introduces an agency relationship between the doctors and consumers. The incentives and monitoring of the contract between patient, doctor and (in most countries) government regulations and drug subsidisation schemes critically determine the actual pharmaceutical consumption of individuals. They are reviewed in some detail by WFB.

Information is also a critical determinant of prescribing practices. Doctors are flooded with information about the performance of existing drugs and the evolution of new ones: sources include medical journals, professional publications, pharmaceutical manufacturers and other bodies. Such is the volume of material that it would require a vast amount of time for any doctor to assimilate it. In this situation publications and other mechanisms that provide credible screening of this literature for medical practitioners have an important role.

For given health signals, the demand for pharmaceuticals is affected by the standard components of demand: income and price. For particular health signals and income, price will affect demand: however, the extent of price sensitivity will be significantly influenced by the information and prescribing opportunities and practices of doctors. In a second stage, the doctor's recommendation is taken to the pharmacist who also may have some scope in selecting the pharmaceutical ultimately consumed: in particular, the pharmacist may substitute one generic drug for another.³ Thus, in this second stage, the incentives and opportunities facing the pharmacist also influence price sensitivity. Ellison, Cockburn, Griliches and Hausman (1997) (ECGH) explicitly allow for this two-stage process in their estimation of the demand for cephalosporins in the US between 1985 and 1991. They conclude that under the system in the USA where doctor decision making is not as proscribed by government schemes as it is in some other countries, there is significant price sensitivity in drug consumption: in particular that the choice of generic is definitely price sensitive, and to a lesser degree there is price substitution

between some therapeutic substitutes. ECGH argue that their data do not reflect recent developments in the USA which have increased the ready availability of price information to prescribers in recent years, and hence that there is now increased price sensitivity.

A final key aspect of demand that is important is that the pharmaceutical costs of different conditions vary very widely and there is uncertainty for individuals about which sorts of pharmaceuticals they may require and what sorts of pharmaceuticals will be available in the future. These represent risks that are more predictable in the population as a whole than for an individual and hence are amenable to insurance contracts. However, persons with certain existing conditions may not be insurable:⁴ thus even if drugs were purchased through insurance contracts there is likely to be a role for government in the case of uninsurable risk.

Government: In New Zealand health is the sector for which government has retained almost completely the combined roles of provider and funder. Government has deemed a very limited role for prices: yet in other sectors prices are critical in matching consumer demand to supply in a way that is in the interest of consumers and producers. The difference for health may to some extent lie in the informational problems that have been mentioned above, and perhaps in an intent to redistribute income by means of the health system. The bulk of the population relies on the public health system where, with limited exceptions, visits to the doctor draw the only charge to consumers. Without prices that fully reflect costs of services and drugs consumed by individuals the health system has to be managed by various rationing schemes throughout the sector.

In the case of pharmaceuticals, Pharmac operates by restricting the variety of drugs that will be provided free to patients on prescription and by seeking to negotiate and induce low prices from pharmaceutical suppliers.

³ In New Zealand such substitution requires authorisation by a medical practitioner.

⁴ There are several elements of uninsurability. Given that the existence of a condition is certain, there is no uncertain contingency to be insured against. There may, however, be uncertainty about future costs of treatment and this might represent an insurable risk. Given the existing condition high expected costs, and perhaps low income earning capabilities, people with existing conditions may seek relief from the social welfare system.

Although there is a good deal of overlap among topics in the book, WFB first appraise Pharmac's ability to achieve its goals, and then consider empirical evidence and thence alternative schemes: we shall follow this sequence.

Pharmac's goal can be summarised as maximising the contribution to health status from a given public pharmaceutical expenditure budget. It seeks to do this through its management of the Pharmaceutical Schedule (PS) that lists the drugs subsidised by the government. The PS is managed by classifying drugs into therapeutic groups within which all drugs are used to treat the same condition. They further subdivide groups into therapeutic sub-groups that contain those drugs that are assessed as producing the same therapeutic effect on the indicated condition. The use of "Reference Pricing" means that all drugs in a subgroup are subsidised at the cost of the lowest-price drug in that sub-group: those which have a higher price carry a part charge. Different prices between sub-groups reflect Pharmac's willingness and ability to pay for pharmaceuticals that do not produce the same effect. WFB report that Pharmac can also take actions such as de-listing or refusing to list a drug on the PS, and instituting restricted prescribing. It can also negotiate prices and packaged arrangements whereby the PS positions of different pharmaceuticals are negotiated jointly. New pharmaceutical products that do not fit easily into an existing group are listed singly in their own group. Pharmac is advised about its decisions by the Pharmacological and Therapeutics Advisory Committee (PTAC). It is composed of medical practitioners that typically include general practitioners, specialists and clinical pharmacologists. Special subcommittees with co-opted membership are convened for decisions about particular therapeutic groups.

There is not space here to review the multitude of issues that WFB canvass and we confine ourselves to just a few. Their analysis of the negotiated reference price is very thorough and worthwhile. Using the natural monopoly model they start by asking when can welfare be enhanced by price control, and whether it is feasible or desirable that price should be set as low as marginal cost? It is a natural starting point because the intended outcome of the scheme is a subsidy making the drug free to consumers at a price lowered by reference pricing. They invoke the argument that the drug

companies have more information about their costs and product than does Pharmac (the regulator in standard models) and that the process of setting the reference price can, or is likely to, mean that higher, not lower, prices are paid for the drug that is fully subsidised. Drawing on an existing game theory model, they analyse the strategic behaviour that can take place between firms that are vigorously competing. They argue that barriers to entry are such that their higher-price result is robust to the presence of other firms, although other outcomes are possible. Their barriers to entry include firms seeking listing on the PS having to price below the reference price (p.75) unless they can do joint deals with Pharmac that include pricing at the reference price and some facet of listing another pharmaceutical product on the PS. A related barrier to entry that WFB list results from an asymmetry in the game between the incumbent and potential entrant. If a drug is not listed its price will carry no subsidy and be substantially above the zero price of the reference-price incumbent. If the potential entrant does enter by offering a lower reference price, the incumbent's price will be higher than that of the entrant only by the amount of the part charge.

There is an incentive for manufacturers to seek to list new drugs in a separate therapeutic sub-group, because here there is no reference price and the listed price will be the outcome of negotiation. In addition, the product will be fully subsidised. In this circumstance, if this drug can also be used to treat conditions addressed by drugs in other therapeutic groups, then prescribers have an incentive to provide patients with this drug as an alternative to drugs from other sub-groups that are perhaps much cheaper but which carry part charges. In this situation, the scheme will be providing an incentive for the more expensive pharmaceutical to be used.

Thus WFB's careful analysis of strategic behaviour by competing companies under reference pricing leads them to question the ability of the scheme to contain costs. The empirical evidence, however, is not analysed in quite such depth. They argue (WFB p.194-6) that barriers to entry, the authority's inferior knowledge of costs and product characteristics when combined with firms' rational responses to negotiated reference prices, explains the significantly higher pharmaceutical prices of the Ontario scheme in comparison with those in other provinces. While this example is instructive, WFB do not provide conclusive evidence for New Zealand, instead suggesting (p.138) work that would be useful. They provide some indicators. It may be that the reported low

number of generics prescribed in New Zealand (8% of all medicines in New Zealand as compared to 50% in the UK and more than one third in the US) are indicative of the barriers to entry identified by WFB. That this a distinct possibility is also suggested by data that indicate that generic products sold in New Zealand are much closer in price to branded products than is the case in the USA or the UK (pp.148-152). Whether this smaller gap results from brand prices that have been lowered to generic prices, or from generic prices that have been raised to brand prices is not clear. The indication (WFB p.152) that there are very few, perhaps one, generic in each subgroup for which generics are available, as opposed to the situation where generics are concentrated in few groups, may be indicative of little competition between generics when at least one has entered. International comparisons of prices are fraught with difficulty: even using exchange rates to convert to the same currency is controversial.⁵ The discussion of WFB does not consider the complicating factors, and thus is indicative of a research programme rather than definitive conclusions.

The lack of empirical work does not detract from the fact that WBF make a strong case on conceptual and theoretical grounds that an in-depth analysis of the performance of reference pricing in cost containment alone would be very worthwhile.

WFB also criticise the health-status efficacy of reference pricing. They emphasise that it interferes with the physicians' choice of drugs to prescribe and that Pharmac (seemingly) does not have quantitative indicators of the trade-off that it is making between side effects and cost (for a given therapeutic outcome) when it is limiting (either directly or indirectly) the number of pharmaceutical products in any therapeutic group. These are important points to make, but bearing in mind the difficulties of measuring health status, we cannot expect to observe these data except in particular cases. These are subjective trade-offs that are presumably sanctioned by Pharmac's advisory body, the PTAC. Consider those therapeutic sub-groups that retain subsidised choice with part charges that represent the extra cost of these drugs over the reference drug: here the (subjective) extra-benefit/extra-cost trade-offs for doctors prescribing drugs that are priced above the zero-priced drug are the same as if there

⁵ The OECD typically use purchasing power parity conversions and these can give quite different outcomes from those of exchange rates.

was no pharmaceutical benefits scheme, except for a uniform subsidy.⁶ Of course, this situation is unsatisfactory if a uniform treatment of all patients as measured by the same (zero) price of pharmaceuticals to each individual is the desired outcome, but this is not Pharmac's scheme.

The points that WFB emphasise are that different individuals will react differently to different drugs; and that doctors have more client information and are in the best position to choose the right medication for any client; and that this choice can be significantly affected by the reference pricing scheme.⁷ They consider that the problems result from altered relative prices (via part or full charges) and restricted availability of, particularly new, pharmaceutical products associated with the operation of the scheme. The consequences of restrictions on the array of pharmaceuticals will depend upon the therapeutic substitutability of the compounds in any sub-group. While particular important cases are analysed, WFB do not provide hard information about prescribers' own views of the substitutability in any existing sub-groups.⁸

WFB (see, for example, p.201) argue that, because they are normally highly priced, the entry of new innovative drugs is inappropriately delayed under Pharmac's policies and they suggest that this problem is endemic to any reference-pricing or restrictive subsidy list scheme. We note that the learning and price paths associated with new drugs may not suggest immediate cost efficacy at the time of introduction: however, this will vary by product. We consider that this poses a major issue for cost-containment schemes in which benefits are not directly traded-off against actual

⁶ We recognise that operation of the reference price scheme can widen the dispersion of prices and that where this occurs the prescribing calculus will differ from that which would obtain under a uniform subsidy.

⁷ We note that the possibility canvassed by WFB (p.215) of a scheme with low uniform subsidies and rigorous auditing must presume that there exist peer-group-accepted (PGA) prescribing practices. Given such practices, the scheme proposed is one driven by monitoring. The existence of these practices means that the Pharmac scheme can be viewed as encouraging PGA prescribing strategies by means of incentives, as opposed to monitoring. There is not space here to canvass the pros and cons of adopting PGA practices as the goal of a scheme.

⁸ They do report (p.154) a statement from a survey by *Consumer* of 120 GPs that "about half thought all drugs in a therapeutic sub-group had the same outcome for patients at least 50% of the time". While WFB suggest that this statement can be taken to indicate reluctance to substitute generics, the fact that only 8% of medicines in New Zealand are generics leads us to doubt that it says much about generics versus brand drugs. Incidentally, many prescribers in the USA and UK obviously consider that the price gap between generics and brand drugs in those countries very often outweighs any therapeutic differences.

pharmaceutical costs in decisionmaking. WFB have raised a genuine point of concern for the design of the market and for the evaluation of current practices.

The prescribing decisions of doctors and the practices of pharmacists have a major effect on the pharmacological products consumed and the nation's total expenditure on them. These decisions are analysed in some depth by WFB. As we have already noted, in addition to skills of diagnosis, the doctor has an agency relationship with the client that results from the information the doctor, rather than the client, holds about health services in general and pharmaceutical services in particular. Doctors' prescribing will be influenced by the incentives that they face and by the information (about their clients and pharmaceuticals) that they face. WFB point out that incentives for cost-effective prescribing are non-existent where pharmaceutical products carry zero prices for the consumer and the doctor.⁹ In this circumstance a doctor has no incentive to consider cost when prescribing, but should simply consider anticipated therapeutic outcomes.¹⁰

Cost/effective prescribing requires information about pharmaceutical products. Given the cascade of information that doctors have to manage, a time-efficient way to obtain this information may be to use the information contained in the PS as a guide.¹¹ The appearance of a pharmaceutical in that schedule and its (part) charge status has been approved (subjectively) by a peer group and, if credible, this can convey useful information in a summary way to prescribers.¹² In this situation, decisions based on the PS means that whether or not cost-efficiency is achieved will depend critically upon the efficacy of reference pricing.

⁹ As WFB emphasise, non-prescription price rationing such as that of limiting pharmacy distribution of drugs as Pharmac has done in some instances, can impose very high effective prices at the point of consumption.

¹⁰ Presumably, the zero cost to consumers of prescription pharmaceuticals under previous schemes is a major contributory factor to the observation that in 1985 and 1990 New Zealand had by far the highest expenditure on prescription and over the counter pharmaceutical products as a share of total health expenditure of 7 OECD countries (OECD *Health Data* (1977)). For New Zealand, this share has generally continued to decline.

¹¹ In fact New Zealand doctors have been provided with information about costs and therapeutic effects by an organisation that is under contract to Pharmac. In addition there has been prescription monitoring in the past and currently there are schemes to evaluate and advise on prescribing conducted under the THA (WFB p.216).

¹² The credibility of the PS and other information disseminated by Pharmac will be affected by information drawn from other sources and by practitioners' experiences. WFB argue that there is no reason why such cost/efficacy information should not be provided by private suppliers in the absence of Pharmac.

Sharp incentives for self-interested medical practitioners to employ cost-effective prescribing can only come from two sources. One is their immediate personal direct (financial) interest in the prescribing activity. The other is longer term and more indirectly through patient satisfaction, and thus repeat visits and reputation. Both these factors are affected by the general structure of health service provision in New Zealand. WFB identify and discuss these issues in depth. Where patients face co-payments for their prescriptions, there are incentives for prescribers to take cognisance of prices in their pursuit of client satisfaction.¹³ Where prescribers are themselves responsible for pharmaceutical expenditures and retain cost savings for themselves, WFB suggest that there may be inappropriately strong incentives for the prescriber to recommend low-cost pharmaceuticals. The actual incentives will depend upon institutional arrangements. Where the prescribing decisions are made under pre-paid health maintenance plans -as in Health Maintenance Organisations (HMO), for example - the doctor has a long term incentive to prescribe cost-effective drugs, even though that person is a residual claimant under the contractual arrangement.¹⁴ The demand for the HMO will stem from the perceived quality of its services. The fact that decisions about all aspects of care are taken under its auspices means that the longer term health of the client will be an exceedingly important factor in prescribing. It also means that cost-effective trade-offs between pharmaceutical and other treatments jointly considered for individual patients are possible in the face of the real costs of resources. These trade-offs are absent from centralised schemes, in particular from the New Zealand pharmaceutical scheme (WFB). The emergence of these sorts of institutional arrangements is beyond the pharmaceutical scheme itself: rather it is inhibited by centralised provision, funding and concomitant rationing of health services in general.

Summary

¹³ If pharmaceuticals are provided for in insurance contracts held by clients this incentive may be weakened depending upon the deductibles and co-payments of the contract. Under private insurance, contracts are likely to be designed to sort individuals according to their preferences for different deductibles and co-payments. It can also provide for prescribing monitoring and information provision by managed care drug companies (see WFB and ECGH).

¹⁴ ECGH report a study that finds that doctors that prescribe for HMO or other Pre-Paid Plans prescribe generics more frequently to all their patients (i.e. those within and without the plan) than other doctors and they infer from this that the plan-prescribing doctors are more price-aware, and prescribe more cost efficiently than other doctors.

WFB argue that the reference pricing system embodied in Pharmac "neither contains costs nor prevents losses in health status, broadly defined". They view the failure to contain costs as a result of the use and allocation of subsidies, particularly the existence of some fully subsidised prescription drugs which doctors can prescribe at no cost to the patient. Losses in health status are claimed to arise from the distortions in prescribing patterns and consumer preferences that arise where drugs in each subgroup are subsidised only at the level of the price of the cheapest product in that class and others are not listed (subsidised) at all. They make strong claims about the different therapeutic effects on individual patients of even drugs from the same subgroup, and the reductions in the quality of health outcomes that arise from limitations on choice being embodied in the subsidisation policy. Finally, if choices must be made, they view Pharmac, a monopoly supplier of services to the THA's, as an inefficient vehicle for these to be made.

As an alternative to Pharmac's reference pricing system, WFB suggest a reallocation of subsidies to provide a more comprehensive range of alternative prescription drugs, all of which have part charges. They suggest that this would reduce costs and improve efficiency by giving physicians and patients an incentive to consider the costs of alternative treatments. WFB would deal with the social welfare component of current policy by having the government purchase health insurance policies for target groups: for example, those who cannot afford to purchase their own, or who are high users of prescription pharmaceuticals. They also suggest making the Commerce Act the sole restriction on anti-competitive practices in the pharmaceuticals industry, removing the claimed role of Pharmac in reducing rents accruing to pharmaceutical producers. In these circumstances, they claim, there would be no need for a single monopoly supplier of services to the THA, and the activities of Pharmac could be opened up to competing service providers.

In putting forward these arguments, WFB have made a major contribution to the debate about the provision of public subsidies to health care in New Zealand. In particular, they have properly highlighted the significant improvements in welfare that can be brought about by a system in which incentives are provided by actual prices. Their policy recommendations could not, however, be adopted without further consideration. All private sector health insurance policies contain exclusions or

benefit limits, and WFB have not attempted to compare in any detail the types of policies that the health insurance industry would provide with those represented by the reference pricing policy of Pharmac.

Whether the scheme recommended would actually reduce costs would depend crucially on how the government chose to define and subsidise the targeted groups. Politicians will always get some votes from expanding a subsidisation scheme to cover those not previously included, as the cost blowout in Ontario shows. Institutional arrangements would benefit from consideration of political economy issues as well as the place of prescription medicines in the totality of the health system. Finally, as WFB recognise, changes in policy would benefit from more detailed analysis of the costs of purchasing and delivering subsidised drugs in New Zealand and other countries than WFB have provided in their manuscript.

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