

Pricing strategies, executive committee power and negotiation leverage in New Zealand's containment of public spending on pharmaceuticals

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Abstract

This paper explores policy mechanisms behind New Zealand's remarkable track record of cost containment in public pharmaceutical spending, contrasting with most other advanced economies. We drew on a review of official policy documents and 28 semi-structured expert interviews. We found that decision making in pricing and reimbursement policy was dominated by a small group of managers at PHARMAC, the country's drug reimbursement and Health Technology Assessment Agency, who negotiated pharmaceutical prices on behalf of the public payer. In formal negotiation over patented pharmaceutical prices these managers applied an array of pricing strategies, most notably, 'bundling' consisting of discounted package deals for multiple pharmaceuticals, and 'play-off tenders', whereby two or more pharmaceutical companies bid for exclusive contracts. The key pricing strategy for generic drugs, in contrast, was 'blind-tenders' taking the form of an annual bidding process for supply contracts. An additional contextual condition on bargaining over pharmaceutical prices was an indirect strategy that involved the cultivation of the PHARMAC's 'negotiation leverage'. We derived two cost containment mechanisms consisting in the relationship between pricing strategy options and various reimbursement actors. Our findings shed light on aspects of the institutional design of drug reimbursement that may promote the effective use of competitive negotiations of pharmaceutical prices, including specific pricing strategies, by specialist public payer institutions. On this basis, we formulate recommendations for countries seeking to develop or reform policy frameworks to better meet the budgetary challenge posed by pharmaceutical expenditure.

Introduction

The cost of public sector expenditure on pharmaceuticals stands at nearly 1 trillion USD globally (OECD 2021), and represents a major policy challenge for all health systems irrespective of size or available financial resources (Panteli et al 2016; Pezzola and Sweet 2016; Morgan et al 2018). Much research has been undertaken on the drivers of increasing spending, including direct mechanisms, such as the growing utilisation and prices of pharmaceuticals, changes in the population, such as ageing, and introduction of new therapeutic approaches (Mousand et al 2014). However, other more indirect mechanisms are also at play, such as evolving medical consensus and popular pressure for increased access to novel pharmaceuticals (Bohm et al 2014) and drug manufacturers lobbying on their own behalf or via seemingly independent third parties, such as medical Key Opinion Leaders or patient organisations (Ozieranski and King 2011; Vilhelmsson and Mulinari 2018).

Against this background, there has been a growing interest in pharmaceutical policies seeking to contain public reimbursement expenditure. In addition to well-described mechanisms such as ‘reference pricing’ (Dietrich 2003) or policies encouraging self-regulation by prescribers (Puig-Junoy 2010), more recent interventions include price-volume or risk-sharing agreements (Kesselheim, Avorn and Sarpatwari 2016; Ferrario and Kanavos 2015; Pauwels et al 2017; Rotar et al 2018; Ferrario et al 2015; Flume et al 2018) and other special reimbursement schemes (Löblová et al 2019). Further, interventions beyond the level of pricing policies include the removal of key counterweights to the negotiation power of the public payer, such as the institutional norm of insurer negotiation of prices on behalf of the public payer (Henschke, Sundmacher and Busse 2013; McEwen et al 2017).

An emerging complementary body of research considers direct and indirect pricing strategies employed by drug companies (Shah 2019). One direct strategy involves setting list prices that far exceed conventional coverage thresholds—sometimes by orders of magnitude as a way of maximising the company’s bargaining position in confidential negotiations with public payers (Morgan, Bathula and Moon 2020). In addition, marketing and advertising campaigns are key examples of indirect strategies that attempt to strengthen drug companies’ political leverage in negotiations with public payers (Shwartz and Woloshin 2019; Patterson and Carroll 2019; Ozieranski and King 2017). However, given the opaqueness of the drug reimbursement process (Csanádi et al 2019), especially the commercial sensitivity of price negotiations (Ozierański et al 2019; Morgan, Bathula and Moon 2020), few studies have investigated the approaches that public institutions, namely government departments, expert agencies or public payer bodies, use to negotiate pharmaceutical prices. One exception has been a study of formal and informal strategies applied by the English public payer body, NHS England, in obtaining a lower price for a revolutionary – yet very costly – hepatitis C medication (Gornall et al 2016). Outside Europe, the introduction of competitive negotiations by public bodies is also credited as one factor in the recent dramatic fall in reimbursement expenditure in China (Tang and Song 2020) after rapid spending growth in the early 2010s (Hu and Mossialos 2016).

With this article we seek to contribute to developing a systematic understanding of the range of pricing strategies public institutions can employ, how they are applied, in what circumstances, and with what degree of success. In doing so, we conducted an instrumental case study of New Zealand, a country where regulators have applied a set of strategies, which have resulted in consistent success in driving down public reimbursement spending. Our focus is on the

Pharmaceutical Management Agency (PHARMAC), New Zealand's health technology assessment (HTA) agency, which has overseen a stable decrease in pharmaceutical expenditure from 15% annual average increases in the 1980s to 1% increases in the last 40 years (Cumming 2010).

The drug reimbursement process for patented medicines is broadly similar to Single Technology Appraisals carried out by the National Institute of Health and Care Excellence (NICE) in England. The only major difference between NICE as well as other similar HTA bodies in Europe is that PHARMAC is tasked not only with the scientific evaluation of drugs but also negotiating prices with drug companies, the process which is typically led by public payer institutions (Charlton 2020). Applications for generic pharmaceuticals typically require less HTA evidence than patented pharmaceuticals but as a formal process has only a minimally different procedure (PHARMAC 2017; terms of reference manual ('TOF') s 9.1-9.3).

The formal reimbursement process begins with PHARMAC receiving a company's HTA dossier either as part of an application to update the pharmaceutical schedule or amend an existing listing on the schedule. Once received, an overall dossier including HTA information is sent to PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) comprising a central committee and a network of specialist subcommittees, which are typically made up of between 5-10 members. These members are drawn from the area of the medical specialty that is clinically relevant to the pharmaceutical in question (PHARMAC 2017). To assess applications PTAC uses a 'decision making framework', including the 'statutory objective' and a 9-point list of decision criteria, including clinical effectiveness and cost effectiveness. PTAC's written advice to

PHARMAC consists in a prioritisation decision based on a scale ranging from 'high' to 'low' priority. The prioritisation is said to also establish whether a funding proposal from pharmaceutical companies represents a good 'deal' (PHARMAC 2017).

After the PTAC process is completed further cost utility analysis and a budget utility analysis is undertaken by PHARMAC's in-house health economists, who estimate, among other things, the impact of a proposed change to the pharmaceutical schedule over a period of 5 years (PHARMAC 2017). The previous recommendations for priority level made by PTAC are combined with this analysis and collated by a 'therapeutic group manager' into a final submission to the PHARMAC executive committee. At this stage a reimbursement decision may be made or a number of alternative immediate actions are possible, including negotiations with companies, a request for further information from suppliers, a further PTAC or PTAC sub-committee appraisal, or a further pharmacoeconomic assessment (PHARMAC 2017).

The final decisions about the reimbursement of a medicine is made by PHARMAC's 'executive management team'(PHARMAC 2017) a committee normally comprising six members: a chief executive with overall oversight and five further members which head up individual teams of employees with specific specialisms such as health economics and legal (PHARMAC 2017). The executive committee has general discretion over all stages of the reimbursement process (TOF s 3). PHARMAC operates with what is called the 'statutory objective'. This sets out PHARMAC's commitment to maximising health outcomes within their capped annual budget (PHARMAC 2021).

PHARMAC's success in containing pharmaceutical expenditure is well acknowledged in the scholarly community (Metcalf et al 2003; Cumming et al 2010). Research carried out thus far has noted PHARMAC's use of 'reference pricing' as well as risk sharing, multiproduct deals with drug companies, and use of expenditure caps, rebates and competitive tenders for generics (Grocott 2009; Main and Ozieranski 2021). Nevertheless, less attention has been paid to PHARMAC's specific pricing strategies for patented drugs or how price negotiations between the agency and drug companies are conducted in practice and their link to effects on levels of expenditure (Main and Ozieranski 2021). Separately, although the uniqueness of PHARMAC's approach to price negotiations has been attributed to its 'commercial astuteness' (Cumming 2010), it is fair to argue that the empirical content of this description needs to be clarified.

This article's objective was to use a qualitative case study design in order to examine the policy mechanisms behind New Zealand's exceptional track record of cost containment in pharmaceutical spending. We focus on PHARMAC's pharmaceutical pricing strategies and the institutional sources of its negotiation leverage vis-à-vis the pharmaceutical industry.

Methods

Study design

Fieldwork consisted of 28 in-depth, semi-structured elite interviews which were conducted in Auckland, Wellington, and in the Northland region of New Zealand. Drawing on the methodology developed in interviewing HTA agency representatives in Central Europe (Ozieranski and King 2011, 2012, Csanadi et al 2019, Loblova et al 2019), the fieldwork concentrated initially on constructing a purposive sample of interviewees in the broad categories seen in Table 1. Online searches were used to produce lists of potential interviewee names, which were then followed up in interview requests made by email. We approached a total of 47 potential interviewees representing all key categories from our purposive sample. In doing so, we sought to achieve a similar sample size as other studies of HTA agencies (Ozieranski and King 2012) and reimbursement processes (Loblova et al 2019). In all, 5 interviews were conducted through a combination of Skype and telephone, while the remainder were conducted face to face and tape-recorded with permission. Care was also taken to reassure interviewees of their anonymity. Most of the interviews lasted at least one hour, and were characterised by an extensive level of detail.

In preparing the interview topics, prior research on PHARMAC was consulted (e.g. Cumming 2010). This allowed for the construction of five broad issue areas with which to guide interviews. These were: ‘PHARMAC and pharmaceutical expenditure’; ‘the operation of the PTAC committees’; ‘Generic drugs in New Zealand’; ‘Patented drugs in New Zealand’ and ‘PHARMAC-industry relations’.

Qualitative analysis

The interview data was analysed using the NVivo software package based on the principles of grounded theory (Charmaz 2014). Initially, we used line-by-line coding of interview transcripts before linking emerging themes in the data, for example, PTAC's influence on decision making and pricing strategies to our two guiding research questions:

1. Which institutional mechanisms can explain PHARMAC's track record of contained spending?
2. Can the content of PHARMAC's 'commercial astuteness' be specified?

We then identified further inductive themes that were connected to the theme of pricing containment and collapsed these themes into 'code families' (Charmaz 2014). A code family was built under the general category of 'pricing strategies' and in turn organised into two subcategories: pricing strategies for patented drugs ('bundles' and patented 'tenders') and pricing strategies for generic drugs ('generic' tenders'). Subsequently, a further code family was established by 'condensing' lower and higher level codes. This stage of analysis pertained to 'sources of negotiation leverage' in New Zealand's drug reimbursement and formed two sub-categories: those of 'separation from politics' and 'agency manager influence on the HTA process'. By then analysing condensed codes at a higher level of theoretical abstraction - relating analyses to our research questions as we did so - we developed an explanation of the specificities of negotiation leverage and its impact in containing costs. At a later stage of coding we integrated an approach to 'mechanisms' as 'bits of theory about entities at a different level to the main entities'(Stinchcombe 1991:367). This process culminated in the derivation of two candidate institutional mechanisms for cost containment effects. Overall, the data analysis aimed to develop

a ‘thick’ account of cost containment to enable an explanation of how cost containment effects were generated from institutional sources (Geertz 1973).

We used Nvivo software to triangulate our interview data with two sets of documentary sources (annual reports and the operating procedure manuals which were available on PHARMAC’s website) (PHARMAC 2017). These documents helped clarify any rationales for gaps between the procedures in the formal reimbursement application process listed in PHARMAC’s operating procedure and the accounts given by our interviewees. The data triangulation helped us achieve a high degree of confidence in the data not repeating misrepresentations. In presenting our findings, we follow standards for reporting qualitative research (Tong, Sainsbury and Craig 2007).

Research team

BM and PO designed the study and defined the research questions. BM conducted the fieldwork, qualitative analysis and interpretation of the findings. PO and MC and contributed to the interpretation and contextualisation of the findings.

Results

The non-response rate was 40% and was largely made up of representatives of multinational pharmaceutical companies, which, we suspect, could be attributed to commercial confidentiality concerns (Table 1).

Table 1 (about here)

We divide our results into two sections. We start by setting out three pricing strategies applied by PHARMAC in relation to patented and generic drugs. We then follow this by characterising the sources of PHARMAC's 'negotiation leverage' before turning to potential relationship between executive agency management strategy and cost containment effects specified at the level of policy mechanisms.

In presenting the themes, we use selected quotations from our interviews which are the best examples in the data to support the conclusions made, while at the same time ensuring that they come from diverse organisational perspectives. The quotations are followed by interviewee identifiers in square brackets which correspond to the anonymised interviewee numbers listed in Table 1.

PHARMAC's pricing strategies

Tender strategy for patented pharmaceuticals - 'preparatory instruments' and 'play off' tenders

We found that PHARMAC used two preparatory instruments to initiate its tender process: '*request for information*' (RFIs) and the '*request for proposals*' (RFPs). Distributed online via the PHARMAC website, RFIs were designed to generate information for PHARMAC's executive committee. A PHARMAC employee indicated that PHARMAC used RFIs to gather information to assess future supply and to stimulate deal making on future commercial arrangements. When used in this way, an RFI was used as a way of 'smoking out' willing negotiators.

‘RFIs are ways of looking to see what’s coming down the line, you know, we might be able to do some sort of commercial arrangement as a result of this (..) They are a way to get a feel for what’s out there, what’s coming.’[15]

A key example of this approach is an RFI related to hepatitis C drug supply, geared towards generating information on drugs in development and ‘particularly those agents in phase 2 and phase 3 clinical trials (...) and unregistered agents in development’ (PHARMAC 2015). As well as initiating future supply arrangements, RFIs could also prefigure the subsequent deployment of RFPs. Specifically, our data indicated that RFIs and RFPs were used in a two-stage process. As an PHARMAC employee remarked,

‘[W]e see what comes in from an RFI and then we go back to each of the suppliers. So we can run a two-stage process, first we seek information, and then (...) we may run a more competitive process as a result of what comes out of this first step.’[15]

RFPs invite specific proposals for funding arrangements. PHARMAC used RFPs in a staged process of negotiations with multiple companies. RFPs may also represent a ‘re-run’ of an invitations to tender where PHARMAC opt to initiate a further tender process where no

satisfactory deals are made in formal negotiations. As with RFIs, RFPs resulted in commercial arrangements. As a PHARMAC employee expounded,

‘RFPs give [sic] us that ability to free-up money but they can take a while. I would describe them as a sort of cycle (...) so because we are known for running a tight process (...) there are approaches to us with offers after the RFP’s and we consider these. We can then start negotiations or we can continue the process until we get what we want (in the shape of offers).’[15]

Overall, RFPs appeared to narrow down the number of interested suppliers, particularly in the case of companies that may have several patented products of varying efficacy for a given condition. RFPs were also targeted at condition areas where patented drugs were nearing the end of their data exclusivity period.

The preparatory phase of the tender process, involving the use of RFIs and RFPs, indicated that PHARMAC was using in-depth knowledge of the marketplace to gain advantage in the subsequent stages, ultimately resulting in price negotiations that resulted in a ‘contracting stage’. As an industry insider put it when detailing how one strategic use of a tender targeted a small group of companies,

‘[In one case] because PHARMAC already knew there were only two researchers in New Zealand interested (...) they ran a tender and the

company that whipped together the best commercial price got the deal (...)'[14].

This account was confirmed by an academic who suggested the tender process involved continuing negotiations with multiple companies,

‘PHARMAC extracted large price savings through discreet negotiations. PHARMAC play companies off against each other in order to get competitive reductions’ [27].

From a broader perspective, our interviewees noted that the tender system had encouraged the entry of pharmaceutical companies to New Zealand. While some of our interviewees noted that they feared that pharmaceutical companies might ‘up sticks’ and leave New Zealand, others more readily noted that companies were incentivised by the possibility of longer term and exclusive contracts for pharmaceutical supply - in the shape of three to five year sole-supply contracts. These contracts, therefore, appeared to raise the stakes of negotiations in PHARMAC’s favour with pharmaceutical companies prepared to reduce their prices to access the New Zealand market. One hospital consultant confirmed this when saying,

‘[T]here are actually more drug companies in the country now than there were when PHARMAC started which is because they do these single provider contracts for three to five years. So if you are Drug

Company and you get one of those it is worth a bit because you have got no competition.’[25]

This perception was supported by an academic who pointed to the exclusive sole supply element in these contracts as a crucial difference between New Zealand’s tender system and that used in Australia.

‘[T]he difference is that in New Zealand tenders have a sole supply outcome, in other words one product has the business for three to five years. Whereas in Australia, you can stay on the market so long as you meet the market price or you are on the market, so you have multiple suppliers of the same.’[23]

Correspondingly, a PHARMAC employee also suggested that the certainty offered by sole supply contracts was attractive to industry.

‘[I]f they (industry) get something on a schedule that’s it. They’ll make money. It’s a guaranteed market and they get into a contract. So we might award somebody a contract and we guarantee that that product will not be delisted or the access will not change. So if they negotiate well, they can do quite well after that (...) Here they come to us, they

get the tender. They don't have to do any marketing, don't have to do any promotion.'[15]

Beyond the use of the RFI and RFP instruments, RFIs and RFPs, price negotiations with drug companies were shaped by a broader policy context. This context further strengthened PHARMAC's position in price negotiations. One source of pressure on the negotiating companies was the operation of a five year data exclusivity period, meaning that patented products faced a zero-sum game of tenders for exclusive contracts in a truncated data exclusivity period. Equally, there was 'generic pressure' on companies in the same data exclusivity window. This consisted in contextual pressure - exerted by the presence of generic companies in New Zealand - on the negotiation positions for product funding. These contextual factors underpinned what one interview called PHARMAC's 'commercial savvy' in the context of price negotiations.

We now turn to consider a further strategy for patented products.

'Bundling' strategy - new drug access, volume based deals and 'pipelines'

Our interviewees indicated that drug 'bundling' formed a further pricing strategy for patented pharmaceuticals. Drug bundling represented negotiated agreements combining multiple single agreements for pharmaceuticals from different clinical areas in one deal. A former PTAC member and industry expert described the process whereby agreements were combined in bundle deals.

‘PHARMAC says to a company like X, “well, based on your current pricing, your cost utility for this new drug is not going to make it, plus you’re not getting any priority for funding. But (..)if you can offer us a package of drugs we buy, so if you didn’t specifically reduce the price of that drug, but you reduce the price of the others, so that we get the cost shifted to offset of that price, then we will consider making it a higher priority for funding.” And the big companies like x and y make good use of it (...). So PHARMAC has been able to, say yes, based on the overall package, if the price that we’re getting for the drug, is to us discounted and the cost utility looks better, we’ll give it a higher priority.’[6]

A PHARMAC employee indicated a further agreement structure, namely bundle deals specifically facilitated by combining newer drugs and large volume-based deals for groups of older drugs.

‘[PHARMAC] agree bundles all the time. So there’s been a couple of big bundles we have done in the last couple of years (...) maybe they (the industry) do not want to reduce the price on a new drug. But they can significantly reduce the price on some of their old drugs, so that we can do a sort of package deal.’[16]

These large bundles were mutually beneficial, and represented attractive deals to industry with bundles crucial in increasing coverage at the same time as controlling budgetary expenditure. Like

tenders, bundle agreements could secure sole supply contracts for 3-5 years and this appears crucial to industry-PHARMAC relationship and the wider environment of competitive price negotiations created in New Zealand. As a hospital consultant and PTAC member suggested,

‘PHARMAC’s use of bundles increases the number of reimbursed drugs at the same time as lowering overall prices, And people will criticise them to begin with and say all the big companies will disappear offshore because they won’t be interested (...) But actually most of the big companies stayed and do these bundle deals with them.’[25]

Our interviewees also indicated that PHARMAC’s bundle strategy extended to inclusion of agreements both for future drugs under development and drugs that can ‘piggyback’ on the rest of the bundle deal when these drugs would not be individually funded. Industry officials apparently offered PHARMAC these drugs during direct negotiations on the overall bundle deal. As an industry consultant put it,

‘[N]ew drugs have been allowed into the country, when they wouldn’t have been based on pure hard nosed technology assessment. So that’s how they operate, yes there are drugs (in multi-product deals) which would not otherwise get into the country on the basis of HTA assessment.’[8]

This approach to the ‘pipelining’ of future pharmaceutical deals was therefore similar to PHARMAC’s RFI strategy of ‘smoking out’ interest while ostensibly using the RFI to generate information. A number of interviewees noted that large bundles were becoming typical in drug reimbursement in New Zealand and that PHARMAC used negotiations over bundles to secure future supply and long term budgetary control. A PHARMAC employee suggested that bundles involved this sort of consideration.

‘We negotiate their prices, but they are more than that (...). I mean it’s a two way thing and we do deals based on that, you know, on what they have coming in the future.’[15]

Overall, the bundling strategy reflected PHARMAC’s closest working relationships with industry with tenders, in contrast, taking place at arm’s length and having a rationale of competition . The particular form of a bundle agreement was highly flexible, combining elements such as volume based offsetting and new or future drug access offsetting of costs depending on the offers made and the pharmaceutical involved. A further related mechanism, which we could not fully confirm, was that bundles were being made with ‘repeat customers’ i.e. that relationships with particular companies were cultivated by the use of bundles. This was because bundles represented mutually beneficial ways to promote respective certainty for PHARMAC and industry: securing market share in the case of industry, reducing public payer costs and extending coverage in respect of PHARMAC.

Finally, it is worth noting that PHARMAC's executive committee' retained strategic choice and flexibility over pricing strategies. This meant in practice that PHARMAC retained an ability to agree specific 'bundles' in negotiations and/or select - on the basis of the pharmaceutical area's specific issues - from their other strategic resources namely the preparatory options of RFI or RFP and a format for a tender process and price negotiations to take (eg 'playoffs'). In this context, a key enabling factor for cost containment was that the drug reimbursement policy process was controlled by a close knit, small group of agency managers and health economists who were able to use professional and commercial expertise, specialist market knowledge to select the appropriate contexts in which to deploy, for example, an competitive approach via tenders or whether to rely on cultivated relationships with industry as is the case in the contexts of supply decisions where bundles are a more appropriate strategy.

Tender strategy for generics - 'blind tenders' and sole supply contracts

The central strategy employed by PHARMAC to drive down generic drug prices was an annual sole supply tender process. The key characteristic of this pricing strategy was its 'blindness', with PHARMAC inviting annual bids for supply contracts for generics without negotiation and leaving the price points to be decided by individual suppliers to make in their bids. A PHARMAC employee outlined the process for generic drugs.

'[I]t's a very open process, a tender process, it's really our annual invitation to tender (...) they (industry) put a price in and that's it. There is no negotiation.'[15]

The generic strategy shared with tenders for patented products a sole supply contractual outcome over three years. Industry insiders agreed that this arrangement incentivised companies to offer deals. As one chief executive put it, ‘Generic business is good if you get sole supply contracts, you tender a volume and get a price over 3 years, so you get certainty.’[3] Many interviews shared the view that the generic tender system had been crucial in driving down pharmaceutical costs and reducing their revenue. This outcome appeared to have been facilitated by the interaction of three main factors, namely, the exclusivity or ‘winner takes all’ nature of the contracts,, the competitive effects of the use blind bidding and PHARMAC’s reputation throughout the generic industry for cost and price containment. A number of interviewees noted how these factors, combined with the format of an annual tender promoted low bids from generic companies. An executive at a generic firm expressed a typical view on this matter, ‘It’s price, price, price for PHARMAC they (PHARMAC) have produced a lowest common denominator system (for generic supply), everybody knows they have to bid low.’[1] Indeed as one chief executive noted, the generic tender system in the eyes of industry had had a major effect on drug expenditure in New Zealand.

‘Am I supporter of tenders for generics? Well, they have dramatically reduced the costs across everything, really the whole range (...) from a taxpayer perspective it is (generic tenders) a very effective system.’[3]

A further consistent theme across our interviewees were the ways in which PHARMAC stipulated its preferred supply arrangements in the generic contracts subsequently offered to industry, including penalty clauses in respect of failure to supply. A number of our interviews spoke of the

pressure that PHARMAC places on industry through these clauses and the importance of maintaining the contractual deal. A chief executive of a pharmaceutical multinational said,

‘PHARMAC puts pressure on industry though (...) penalty clauses in the contracts (...) for example a factory burnt down in India affecting our supply (industry) and we had to pay to supply a drug and lost money (...) I mean, we have to supply at tender price, we can’t increase price to take into account of our losses (...) because the danger is we lose the three year contract and other contracts.’[2]

Additionally, the wider characteristics of generic business in New Zealand included the presence of a very large New Zealand based generic company. In two interviewees with executives of this company, both noted ‘a close working relationship’ [3] with PHARMAC board members. An industry consultant backed this up and spoke of how ‘PHARMAC work extremely closely with them [company name].’[19] Further interview data confirmed that the same company had, in contrast to others, been highly successful in New Zealand’s generic drug market. An academic expert explained,

‘In New Zealand there has never been an indigenous "innovator" pharma industry, but one indigenous generic pharma outfit in New Zealand has benefited hugely because of the way PHARMAC relies on therapeutic equivalence and generics to stir competition.’[28]

Having considered the direct pricing strategies, we now turn to consider key sources of PHARMAC's negotiation leverage.

Sources of 'negotiation leverage'

We identified two main themes describing the sources of organisational leverage PHARMAC enjoyed in the negotiation of prices – separation from politics and the influence of agency managers. We then consider how pricing strategies are related to agency management and cost containment effects.

Agency separation from politics

PHARMAC's track record of cost containment in drug reimbursement had earned popularity among politicians. A cabinet level politician noted that 'PHARMAC's model is very popular with New Zealand's taxpayers because it is free from political interference and that is why PHARMAC is popular with politicians too, because it insulates them (politicians) [19]. In turn, this had established PHARMAC's reputation in the wider policy environment for their having power and influence. PHARMAC's popularity extended to medical scientists and the medical profession. As a prominent medical scientist noted,

‘[W]hat has happened is we have put one body in charge (...) and it is getting on with a clear mandate on its spending and that has even convinced doctors here (...) PHARMAC is quite popular amongst

doctors bizarrely (...) there is compliance, acceptance that this is being handled at arm's length from politicians (...) the key thing is that it involves technocratic criteria and PHARMAC stick to it, that is where the popularity comes from.'[27]

The concern to reduce expenditure was driven by the way in which PHARMAC was organised when it was introduced in the early 1990's. As an academic and clinician put it, 'The goal was explicit: to give the company, PHARMAC maximum leeway to negotiate prices (..) It started out in the 1990's as a cohesive small bunch of people and it still is.'[28] PHARMAC had been a sea change from the previous system. This was adverted to by this industry consultant,

'Before this change drug buying had been managed within the ministry of health so, before PHARMAC there was a special entity within the ministry of health in charge (..) But they wanted more commercial brains and personnel to deal with pharma (..) I think, because before companies would just come along and say 'this is the price' and we would pay it.'[14]

Agency manager influence on the HTA process

Many interviewees pointed to how PHARMAC's executive committee - the agency managers which are comprised of a chief executive and under them, 5 or 6 senior personnel - used the HTA appraisal process in a tactical way. One consultant expressed a typical view,

‘The sub-committee has been used as a method to delay consideration regarding a medication, so it goes PTAC and then PHARMAC will say we need more information and PTAC will send it across to the subcommittee, and then the subcommittee have to go back to PTAC, and then they’ll have to go to the PHARMAC executive committee .’[15]

A chief executive of a pharmaceutical company agreed with this account, pointing to how PHARMAC targeted particular drugs which were close to their patent expiry. ‘Yes (they use delay) and because of the patent issues they frustrate the company. The company gets so frustrated that they enter into a commercial arrangement.’[7] Further, PTAC’s cost-effectiveness judgments were used by PHARMAC in price negotiations. One former PHARMAC employee and industry consultant pointed to how PHARMAC’s executive committee harnessed PTAC for this end,

‘PTAC will say this product is not cost effective on price effectively setting up a negotiation position for PHARMAC. I knew a clinician who left PTAC in frustration because it's not about increasing access for patients but getting everything within budget (.) It is not a free and independent committee as it has always been framed by ‘PHARMAC‘ (i.e the executive).’[14]

Similarly, a consultant asserted, ‘Some independent clinicians put forward a view on X and received a response saying you have got four funded so why do you need another one, so regardless

of clinical input the budget is driving things'[8]. A view also emerged that PTAC was influenced by cost considerations in giving recommendations that fitted in with the PHARMAC strategy. The influence of PHARMAC over PTAC was echoed by another consultant, who suggested, 'They are [PTAC] making recommendations based wholly on price'.'[1]

Finally, a PTAC member pointed to other ways cost utility assessments can influence PHARMAC's HTA process,

'There was a drug that was not made for eyes, it was made for cancer. So it's made in bulk and it's given in large doses to people who have advanced retinal cancer or advanced colon cancer or something like that. Turns out (..) it's very good for eyes, so we can take the drug (..) and project it into eyes for peanuts. Well the company did not support that of course, so they developed a specific drug. And they did trials with that, and showed that it was pretty safe and effective on eyes, but it was ten times the price. So we just went ahead with using x and did not approve of y. And they have made many, many decisions like that.'[6]

Relationships between pricing strategies, sources of negotiation leverage and cost containment

We have argued that PHARMAC's negotiation leverage is underpinned by three major institutional sources: their separation from politics, PHARMAC's executive management

committees's influence over the HTA process and strategic management by this executive committee which consisted in preparatory pricing strategies and pricing strategies developed for patented and generic products. However, pricing strategies and institutional sources of negotiation leverage should not be seen in isolation. We found that cost containment mechanisms generating cost containment outcomes consisted of relationships between PHARMAC's pricing strategies and reimbursement actor interactions. Our data indicate two key institutional mechanisms.

Firstly, there was a *'formalised informal openness to dealmaking'*. PHARMAC's agency managers were formally open to informal dealmaking approaches at any stage of the reimbursement process. PHARMAC's deal making discretion was also explicitly envisaged in PHARMAC's own procedural manual (PHARMAC 2021). As one industry consultant put it, 'PHARMAC appears willing to do deals at any time (in the process)'[14]. Approaches by industry that consist of offer making and price discounting are welcomed. A PHARMAC executive noted how industry actors approach PHARMAC,

'The relationships are quite variable. Some companies will be coming to us with sort of really (..) innovative proposals all the time. And you know, they are the companies that will get things over the line.'[15]

This contrasted with informal openness and formal closedness in the European context (Ozieranski and King 2017) Additionally, PHAMRAC's openness to dealmaking extended

beyond PHARMAC's amenability to dealmaking approaches (eg: offers of bundles, deals during the negotiation phase after registration and application for funding), to drugs that were yet to be registered in New Zealand. As such, PHARMAC's executive committee has used its influence across the wider drug reimbursement policy environment in situations (or to promote such situations) where industry had agreed to reduce its prices in prior communications. As one former consultant suggested, PHARMAC's executive members may agree price or a deal because they have sufficient direct influence over MEDSAFE New Zealand's drug registration agency to facilitate its registration,

'I've done it myself [on behalf of a company] (...) we say this is the price we'd likely go to in the New Zealand market, and it's going to save you 4 Million Dollars (...) PHARMAC would say [to MEDSAFE]), can you please expedite this product.'[14]

This mechanism can be further characterised as a way the PHARMAC's executive committee produces competitive pressure in the drug reimbursement arena. PHARMAC's formal openness to deal making at all stages of the reimbursement process fosters deal making pressure on industry actors vis a vis other competing industry actors, reinforcing the containment effect of the individual pricing strategies. In other words, the prices obtained by PHARMAC from formal tenders are potentially related to the agency's formal openness to informal dealmaking: because deal making opportunities are on offer to industry actors 'at any stage', downward pressure is applied to the prices bid in formal tenders as well as to prices offered in deal making approaches. Thus, the contextual conditions - i.e the potential for a deal with the executive committee that

obviates a competitive tender - impact the prices that are offered informally, via deal making approaches, and formally by way of a tender. In the former case a deal is made more attractive than formally tendering at a price and in the latter situation the tendering party's price has to compete with other 'deal making' actors.

Therefore, 'negotiation leverage' - specified at the level of its mechanisms - consists in the persistent dealmaking pressure created by PHARMAC's formal openness to anti competitive approaches - and competing industry's actors' knowledge of this specific openness. PHARMAC'S negotiation leverage - and the intensity of 'competition' in New Zealand's reimbursement - appears, then, to be in part a function of a formal openness to informal, anti-competitive dealmaking approaches. These offer industry a way to avoid formal, competitive tenders and is aided by PHARMAC's cross-cutting influence over MEDSAFE.

A second key institutional mechanism was '*sub-institutional influence by executive managers*'. This can be related to how industry's relationship with PHARMAC is patterned by the status and role of the 'executive committee' in the wider context of PHARMAC-industry relations. In contrast to formalised informality in dealmaking this is a sub-agency mechanism denotes managerial influence over HTA and managerial expertise - for example market knowledge, and pricing strategies and preparatory instruments, (e.g. RFIs and RFPs) developed by the agency managers. PHARMAC's strategic operations have become part of industry's 'institutional' knowledge (as opposed to their and PHARMAC's 'market knowledge') and in turn strengthen conducive conditions for cost containment. For example, PHARMAC's sub-institutional influence over their HTA system provides an explanation for why sub-institutional influence is

important in reinforcing cost containment: PHARMAC's executive committees overriding influence over PTAC (and potentially MEDSAFE) in addition to industry's reaction to this institutional reality encourages dealmaking approaches to the 'dominating' executive committee. Moreover, these processes provide a potential rationale for industry not seeking to influence drug reimbursement pressure points in New Zealand (Main and Ozieranski 2021) by for example, deploying more expensive drug marketing and lobbying of the medical milieu including PTAC members (cf Ozieranski and King 2017). In effect, then, PHAMRAC's executive management committee's sub-institutional power constrains the use and efficacy of indirect industry strategies (such as lobbying) by shaping and funnelling the industry's strategic approach to gaining favourable reimbursement decisions into executive-level approaches, in other words, deal making approaches. This may intensify a cost-containing, 'anti-competitive' logic - alongside aspects of promoted competition - in New Zealand's reimbursement policy (see Main and Ozieranski 2021 for the judicial-legislative context to this logic).

Another potential interplay between pricing strategies and dealmaking pressure are that bundles and tenders mutually reinforce their respective intensities of competitiveness: for industry offering a bundled deal is one way to avoid a tender, to achieve commercial certainty and competitive advantage and to promote a relationship with PHARMAC. Correspondingly, this means that the potential commercial uncertainty of tenders for industry - the loss of a tender and an exclusive contract with PHARMAC to a rival - promotes their use by PHARMAC. As such, the continued use of tenders for patented products is in part strategic: their potential use and interplay with other strategies promotes deal making (and deal making conditions) in addition, in formal tender processes, to playing companies off against one another and extracting

competitive prices. Our view is that a core strategic goal for PHARMAC is cost containment of reimbursement spending which simultaneously maximises the agency's public or welfare function and which - the medium term and longer term - is best served by promoting dealmaking conditions. More specifically, PHARMAC seek to make the deal making conditions that promote bundle deals, the par excellence examples of deals that combine savings with greater drug coverage, and which share a clear institutional affinity with 'formal informal openness' to deal making and centralised executive manager control over agency decision making.

Discussion

Summary of key findings

We used a qualitative research methodology to account for PHARMAC's exceptional track record of cost containment in pharmaceutical expenditure. We identified two core individual pricing strategies for patented products, those of bundling and play off tenders. With the bundling strategy PHARMAC could facilitate an overall deal - and expenditure containment - by reimbursing 'newer' drugs as a part of agreed package deals of pharmaceuticals. By contrast, the tender strategy for patented drugs involved a competitive process which could be initiated with preparatory strategies in the shape of RFPs and RFIs. In the case of generic drugs, we identified PHARMAC's core strategy to be an annual tender process characterised by 'blind' bidding for exclusive supply contracts.

Our findings also illustrated how the negotiation of pharmaceutical prices - whether as part of bundles or for negotiations that were integrated with tender processes for patented products -

were a significant feature of the agency cost-containment strategy. We demonstrated that PHARMAC has cultivated ‘negotiation leverage’, which is drawn from institutional features of the drug reimbursement policy. First, control over strategy and decision making rests with a small group of agency managers that utilise a number of direct pricing strategy options for different areas of pharmaceutical need. Second, the institutional role agency managers and health economists play extends to sub-institutional influence over HTA appraisals. This is manifested as close managerial supervision over the judgement of cost effectiveness and the use of the PTAC committee system to delay funding decisions and encourage dealmaking. Finally, the separation of PHARMAC from politics was a structural feature of the drug reimbursement system that facilitated cost containment by reducing the political imperatives attached to reimbursement decisions and closing the avenue of political leverage for industry and the effect that this can have on expenditure (Ozieranski and King 2017). Therefore, while PHARMAC have used direct pricing strategies (e.g. volume based bundles) seen in other reimbursement contexts they have also demonstrated how an extensive usage of indirect pricing strategies can reduce expenditure. This contrasts with the current scholarly emphasis on indirect strategies as they have been utilised by industry and which in many cases are associated with increased expenditure (Schwartz and Woloshin 2019; Patterson and Carroll 2019).

Finally, in outlining potential relationships between the executive committee management, pricing strategies and cost containment effects we derived two related potential policy mechanisms. These were *sub-institutional influence by executive managers* and *formalised informal openness to dealmaking*. We showed that one rationale for cost containment effects drawn from these mechanisms is that industry have had avenues for employing their own indirect

strategies effective - eg. public pressure, lobbying of PTAC - circumscribed leading them, in greater numbers, to seek deals directly with PHARMAC.

Additionally, we demonstrated that PHARMAC combines competitive and anticompetitive and direct and indirect pricing strategies. PHARMAC combines anti competitive pricing strategies (e.g. informal dealmaking and ‘pipelining’) with ultra-competitive pricing strategies (‘play off’ tenders for patented products and ‘blind bidding’ for generics). These strategies are harnessed by executive managers for particular purposes dependent on the area of pharmaceutical need and market and supply conditions. These managers also benefited from intra-institutionally cultivated sources of negotiation leverage (e.g. influence over HTA). As we have seen, PHARMAC seeks to promote mutually beneficial relationships with industry actors in some cases - and especially in generic supply from domestic based industry - at the same time as they maintain the overall conditions of competitive and anticompetitive pressure on prices through a bricolage of pricing strategies (Main and Ozieranski 2021).

In sum, PHARMAC used the reimbursement procedure flexibly to further advantageous deal making. This echoes similar findings on contact between payer bodies and industry where market access has been smoothed informally by institutions (Ozieranski and King 2016, Ozieranski and King 2017). However, in contrast to increasing expenditure PHARMAC’s articulation of this institutional characteristic is to have sought to normalise approachability to deal making outside normal procedural parameters as part of a cost containment strategy. One explanation for this was that it could potentially create greater impetus for deal making in the wider drug reimbursement environment in New Zealand with industry seeking deals outside the formal drug

reimbursement process and before market entry. These deals also represented sound bargaining in some respects for industry in obviating the need for drawn out applications and price negotiation and avoiding marketing costs.

Comparison with European context

Our study provides important context for existing research on the practical operation of HTA agencies in Europe. Although their official mandate typically only involves the scientific evaluation of drugs (Kawalec, Sagan and Pilc 2016) there has been increasing evidence of the impact of this phase of the reimbursement process on subsequent price negotiations as well as formal and informal pressures from policymakers on HTA agencies.

In Poland while the HTA agency only provided ‘recommendations’ to inform the final decision taken by the Minister of Health, these documents had important political implications as policymakers sought to avoid decisions that would contravene the expert judgement, especially in relation to covering new drugs by public reimbursement with potentially major budget impact. It followed that, unlike in PHARMAC, policymakers sought to influence the HTA agency informally to preempt recommendations which were likely to be politically problematic (Ozieranski and King 2017).

A recent case study of relationships between NICE and NHS England provides further evidence of policymakers’ influence on the formally separate appraisal process (Gornall et al 2016). In contrast to the non-binding recommendations issued by the Polish HTA Agency, drugs positively appraised by NICE must be funded by the National Health Service. Given the high levels of

uncertainty surrounding the potential budgetary impact of novel hepatitis C medicines, NHS England sought to influence the outcomes of the appraisal process, for example by questioning the supporting evidence provided by the manufacturer and, at a later stage, introduced quotas on patient numbers despite the universal coverage included in the guidance issued by NICE.

Nevertheless, a case study from Hungary (Csanadi et al 2019) showed that a public HTA agency's work is not necessarily linked tightly to the price negotiation process. In fact, not sharing the information about the discounted price achieved by the national payer, might be a key factor limiting the influence of the HTA agency. The Hungarian case illustrates a situation where the contribution of HTA is limited to the earlier phases of the pricing and reimbursement process (i.e. critically appraising the manufacturers' evidence submissions), without exploiting its full potential for driving down prices.

More broadly, pricing and reimbursement decisions might also be augmented by publicly available expert recommendations. For instance in case of the evaluation of advanced therapeutic medicinal products it is widely recommended that existing decision making procedures should be followed instead of creating ad hoc frameworks for such cases. These could provide bases for additional considerations like early dialogues with manufacturers or new types of financing schemes (Ronco et al 2021).

Policy recommendations

We conclude our study by formulating key lessons for policymakers seeking to reform or adapt policy frameworks with a view to reducing the budgetary impact of pharmaceutical expenditure. Our findings indicate that PHARMAC's extensive use of direct pricing strategies contrasts with regulatory regimes that predominantly seek structural effects on prices by influencing prescriber decision making in 'reference pricing' systems (Paris and Docteur 2008). PHARMAC's extensive use of price negotiation also contrasts with insurer based negotiation (McEwen et al 2017) and systems which prohibit price negotiation. Additionally, PHARMAC's indirect strategies involve the development of negotiation leverage. These features inform four specific policy recommendations:

1. The adoption of specialist public payer HTA agencies which are formally separate from government ministries. The characteristics of PHARMAC include a core group of decision makers and negotiators made up of agency managers and health economists operating within a fixed budget. Agency self-promotion and recognition within an applicable country also appears a valuable way to increase public trust in the decision making process and - relatedly - potentially reduce the politicisation of pharmaceutical spending and unjustified budgetary spending.
2. The extension of opportunities for price negotiation - which is facilitated by agency discretion - to negotiate agreements with industry over and above formal reimbursement application procedures.

3. An extensive use of direct pricing strategies. Our findings indicate that for patented products, staged bidding processes (integrated with negotiation) for exclusive supply arrangements over three to five year periods have a cost containment effect.
4. For generic products, the institutionalisation of annual ‘blind bidding’ for generic drug supply contracts also appears to lower expenditure.

Limitations

We must note some limitations of our study. First, we included a fairly small interviewee sample size due to the constrained resources available to this study. As we were aware of this limitation before the study, we applied a purposive sampling approach aiming to illuminate our research questions with as many organisational perspectives as possible. Second, we had no opportunity to directly corroborate our findings about PHARMAC’s negotiation power and leverage using documentary sources as this would have required access to commercially sensitive price negotiations. We offset this as far as possible by triangulating interviewees who had direct experience of working for PHARMAC and negotiating on behalf of pharmaceutical companies’ via consultancies. Third, given that PHARMAC was the focus of the study our data may overstate the causal sufficiency of purely institutional factors as against unexplored contextual factors such as the local or Asian-pacific legal environment. Finally, two discrete components of ‘price erosion’ that is, whether erosion is due to discounts obtained on newer drugs or alternatively, consists in obtaining older drugs at lower prices were not disaggregated.

Recommendations and further research

Further research could integrate a more extensive analysis of how New Zealand's intellectual and commercial property laws - and the legislative context of the Asian Pacific context - and how far these contextual features have facilitated the effectiveness of cost containment in comparison with other global regions legislative backdrops. Other research could also develop understanding of the contextual features that specifically underpin negotiation power and leverage in different institutional contexts. More generally, there is scope for comparisons of HTA systems - and their impacts - which concentrate on pricing strategies and pharmaceutical cost profiles.

Table 1
Interview list

<i>No. of interviews held</i>	<i>Interviewee Sector, position</i>	<i>Interview number</i>
1	Industry, chief executive	1
1	Industry, senior lawyer	2
1	Industry, chief executive	3
1	Journalist, editor	4
1	Journalist, staff writer	5
1	Agency, PTAC member	6
1	Industry, consultant	7
1	Industry, consultant	8
1	Academic, professor	9
1	Academic, professor	10
1	Industry, chief executive	11
2	Medicine, GP	12,13
1	Industry, senior consultant	14
1	Agency , board level	15
2	Industry, senior consultant to industry and former, Agency employee	16,17
1	Industry, executive	18
1	Politics, cabinet level	19
1	Patient association, senior employee	20
1	Patient association, employee	21
1	Academic, post doc	22
1	Academic, tenured	23
1	Industry, board member	24
2	Medicine, Consultant	25,26
2	Academic, tenured	27,28
Total		28

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