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How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand[☆]

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ABSTRACT

New Zealand's Pharmaceutical Management Agency (PHARMAC) has been highly successful in facilitating affordable access to medicines through a combination of aggressive price negotiations, innovative procurement mechanisms, and careful evaluation of value for money. Recently the US government, through the establishment of a series of bilateral and plurilateral "free" trade agreements, has attempted to constrain the pharmaceutical access programs of other countries in order to promote the interests of the pharmaceutical industry. The Trans Pacific Partnership Agreement (TPPA) represents the latest example; through the TPPA the US is seeking to eliminate therapeutic reference pricing, introduce appeals processes for pharmaceutical companies to challenge formulary listing and pricing decisions, and introduce onerous disclosure and "transparency" provisions that facilitate industry involvement in decision-making around coverage and pricing of medicines (and medical devices). This paper argues that the US agenda, if successfully prosecuted, would be likely to increase costs and reduce access to affordable medicines for New Zealanders. This would in turn be likely to exacerbate known inequities in access to medicines and thus disproportionately affect disadvantaged population groups, including Māori and Pacific peoples.

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1. Introduction

Pharmaceutical coverage and reimbursement programs are important not only for facilitating affordable access to medicines, but also for containing health care costs and ensuring value for money [1,2]. The manner in which they operate – the way decisions are made about which drugs

to subsidise and how much to pay – can have profound consequences for people's health [1].

Recent US free trade agreements have included provisions intended to impose constraints on coverage and reimbursement programs for medicines and medical devices. The US is proposing similar provisions in a new regional trade agreement currently under negotiation, the Trans Pacific Partnership Agreement (TPPA). At the time of writing, there are 12 countries participating in the negotiations: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. The inclusion of provisions in this agreement that affect pharmaceutical and medical device coverage programs will have consequences for access and equity in many of the TPPA countries, both now and into the future.

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This paper looks at New Zealand's Pharmaceutical Management Agency (PHARMAC) – how it operates, its effectiveness in comparison with programs in other countries – and the likely impact of the TPPA on its ability to provide access to affordable medicines and related products. The potential effects of provisions proposed by the US in draft text leaked in 2011 on PHARMAC's operation are explored, the likely outcomes and health equity implications discussed, and lessons for New Zealand and other countries drawn out.

2. PHARMAC

PHARMAC, New Zealand's Pharmaceutical Management Agency, was established in 1993 in response to rising prices for medicines [3]. Initially established to subsidise community medicines, its role was recently expanded to cover hospital medicines, and it will soon take on purchasing of medical devices for hospitals as well [4].

PHARMAC differs from many other pharmaceutical pricing and reimbursement programs in that it combines many functions (management of the formulary, assessment of comparative effectiveness and cost effectiveness, reimbursement decisions, price negotiation, procurement, management of the budget, and payment functions) within one organisation, enabling a greater degree of control over expenditure than some other programs [1]. PHARMAC is also different in that it is required to operate within a capped annual budget, and it has a legal obligation to secure “the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided” [1].

PHARMAC has two advisory committees. The Pharmacology and Therapeutics Advisory Committee (PTAC), is an expert committee that considers the evidence against a set of decision criteria and makes recommendations as to whether new drugs should be added to the Pharmaceutical Schedule, and what priority they should be given [5]. PTAC makes recommendations to PHARMAC; PHARMAC then considers cost-effectiveness and budgetary considerations and negotiates with suppliers. PHARMAC's decisions are also informed by a Consumer Advisory Committee [5].

Decisions about which drugs to subsidise and what priority to give them are informed by a set of nine decision criteria (see Box 1). These decision criteria are essentially factors that are taken into account in decision making, rather than decision rules per se. PHARMAC may apply discretion in how these are weighted and applied [2].

PHARMAC is very effective in using market competition to drive down prices [6]. A range of commercial purchasing strategies is employed to ensure value for money. These are shown in Box 2. Of particular significance are negotiation (primarily used for medicines under patent, for which there are no generic alternatives), tendering for sole subsidised supply (a key strategy for obtaining generics at low prices), therapeutic reference pricing (linking the price of medicines to existing medicines with similar therapeutic effects) and multi-product agreements, where price reductions on older medicines are negotiated by bundling them together with new products considered for subsidy [7].

3. Pharmaceutical expenditure – international comparisons

PHARMAC's processes have ensured that New Zealand performs well on many measures of pharmaceutical expenditure when compared with most other OECD countries. In 2009, New Zealand's per capita expenditure for prescribed medicines was 237 USD PPP compared with 370 for Australia and 815 for the United States [8]. In that year New Zealand also spent only 0.9% of GDP on pharmaceuticals in comparison with the OECD average of 1.5% [8]. Within the OECD only Denmark, Luxembourg and Norway spent a lower proportion of GDP on pharmaceuticals, while the United States spent more than 2% [8].

4. PHARMAC's effectiveness

Growth in pharmaceutical expenditure has also slowed since the establishment of PHARMAC [2,3,9]. According to PHARMAC's 2012 annual report [10], more than \$5 billion has been saved since 2000 as a result of PHARMAC's strategies for containing costs (based on 1999 pharmaceutical prices). During the period 1993–2007, the number of medicines on the pharmaceutical schedule and the number of prescriptions increased significantly [2]. However PHARMAC's success at cost containment also means that more of the health budget is available to be invested in other health services [3,10].

Co-payments for medicines in New Zealand are also low by international standards. Since January 2013, co-payments for fully subsidised medicines have been set at a flat rate of \$5 NZD (equivalent to approximately \$4 AUD), with additional charges for some medicines that are not fully subsidised [11]. Once an individual/family has obtained 20 subsidised items in a 12 month period, the copayment is waived [11]. In comparison, co-payments in Australia are up to \$36.10 AUD for most beneficiaries and \$5.90 AUD for concession card holders [12].

There are nevertheless inevitable trade offs between affordability and the availability of newer and more expensive drugs. A 2012 study comparing access to medicines in single-payer systems in the US, the UK, Australia and New Zealand [1] found that the NZ program subsidised fewer, older and 'less innovative' drugs. Another study comparing the impact of cost containment policies on the range of medicines available and subsidised in Finland and New Zealand also found that NZ tended to subsidise older medicines – but the level of subsidy was higher in NZ, making medicines more affordable for patients [9].

5. US free trade agreements and pharmaceutical pricing and reimbursement programs

Because of its effectiveness in negotiating prices for medicines, PHARMAC has long been in the sights of the pharmaceutical industry. The 2012 special 301 watch report of the United States Trade Representative cites US industry concerns over “unfair reimbursement policies” in several countries, and particularly the operation of PHARMAC:

Box 1: PHARMAC's decision criteria

- The health needs of all eligible people within New Zealand;
- The particular health needs of Māori and Pacific peoples;
- The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- The clinical benefits and risks of pharmaceuticals;
- The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
- The budgetary impact (in terms of the pharmaceutical budget and the government's overall health budget) of any changes to the Pharmaceutical schedule;
- The direct cost to health service users;
- The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such 'other criteria' into account.

Source: PHARMAC (2012) Making Funding Decisions. Available from:
http://www.pharmac.govt.nz/2011/09/16/04FUNDING_DECISIONS.pdf

Box 2: PHARMAC's commercial purchasing strategies

- Negotiation
- Tendering
- Alternative commercial proposals (ACPs)
- Requests for proposals (RFPs)
- Reference pricing
- Rebates
- Expenditure caps
- Multi-product agreements

Source: PHARMAC (2013) Purchasing Medicines. Available from:
http://www.pharmac.health.nz/ckeditor_assets/attachments/378/infosheet-05-purchasing-medicines-2013.pdf

"The industry continues to express concerns regarding, among other things, the lack of transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as the negative aspects of the overall climate for innovative medicines in New Zealand [13, p. 21]".

In recent years, the US Government has sought more favourable market access for its pharmaceutical industry through bilateral and plurilateral trade agreements. The first attempt to modify another country's drug coverage program was made in the Australia–US Free Trade Agreement, which came into force in January 2005. However, although some process changes were made to the Australian Pharmaceutical Benefits Scheme (PBS), the core listing and pricing mechanisms of the program remained unchanged, and the US was unsuccessful in its pursuit of the industry's key offensive interests [14,15]. A second and far more successful attempt was made in 2007 as part of the negotiation of a bilateral free trade agreement with South Korea (KORUS), and led to much more substantial changes to the operation of various South Korean programs [14,15].

More recently, the US pharmaceutical industry has sought to use negotiations for the Trans Pacific Partnership (TPPA) to constrain the operation of pharmaceutical coverage and reimbursement programs in several other countries. While among the negotiating countries to date only Australia and New Zealand have established national pharmaceutical coverage programs, the eventual

provisions of the TPPA may well circumscribe the manner in which any future programs are developed in the other TPPA parties, and will extend to any countries that sign up to the TPPA in future [14,16].

Leaked negotiating documents [17] show that in the TPPA negotiations, the US has proposed similar provisions to those in KORUS. However, the US ambitions extend beyond even KORUS – both in reach (extending to developing countries) and in scope.

6. 2011 US Transparency Chapter Annex draft text – analysis of likely effects on PHARMAC

While draft text proposed by the US in 2011 for an 'Annex on Transparency and Procedural Fairness for Healthcare Technologies' (hereafter referred to as the 2011 draft TPPA annex) [17] was reportedly rejected by all other TPPA parties, revised text tabled at the September 2012 round of negotiations (which is not publicly available) has been described as not significantly different from earlier versions [18]. Here we examine six issues of particular concern in the 2011 draft TPPA annex that have implications for PHARMAC (as well as the other TPPA countries). These are not the only issues of concern, but those most likely to present particular difficulty to PHARMAC. They are:

- Text that may preclude the use of therapeutic reference pricing;
- Introduction of an appeals process that would allow challenges to PHARMAC's decisions;
- Requirements to specify and disclose formulary decision criteria (which may create inflexibilities);
- Transparency and disclosure requirements that may undermine price negotiations;
- Mechanisms for ongoing engagement that would facilitate further industry influence; and
- Text mandating the legalisation of direct-to-consumer advertising of prescription medicines via the internet.

6.1. Therapeutic reference pricing

A core concern for all TPPA countries that use (or seek to use) therapeutic reference pricing or other forms of administered pricing, is the inclusion of text that specifies that reimbursement amounts must be determined on the basis of “competitive market-derived prices in the Party's territory” or “an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognise the value of the patented or generic pharmaceutical products or medical devices at issue” [2011 TPPA Annex Art. X.3(d)]. It is not clear how such benchmarks would, or indeed could be derived and what would be deemed ‘appropriate’.

Critical wording within AUSFTA enabled Australia to retain its evidence-based processes for formulary decision-making. References to “objectively demonstrated therapeutic significance” – which protected Australia's capacity to continue to apply assessments of comparative effectiveness and cost effectiveness in formulary decision-making and apply therapeutic reference pricing – are notably absent from KORUS and from the text referring to the basis for determining the reimbursement amount in the 2011 draft TPPA annex [14,15].

6.2. Appeals process

The 2011 draft TPPA annex includes a provision [Art. X.3(i)] specifying that the TPPA countries will introduce an independent appeal or review process that covers both listing and pricing decisions. This goes significantly further than AUSFTA Annex 2-C which required an independent review process which only applied to recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC) not to list a drug on the Pharmaceutical Benefits Scheme [14,15]. Australia's independent review process was also limited in several important ways – for example, no new evidence may be presented (if new evidence is available then the applicant must resubmit rather than go to review, and reviews can only consider specific issues in dispute). The findings of a review are then reconsidered by the PBAC and if inconsistent with its original findings, PBAC may consider whether they are sufficiently persuasive to require a reconsideration of its original recommendation [14,15]. The findings of a review thus cannot make an alternative recommendation or overturn the original recommendation of the Committee.

In contrast to the limited review process established by the AUSFTA, the appeal process specified in KORUS allows for appeal regarding any decision regarding listing or pricing [14,15]. Prior to the ratification of KORUS, South Korea introduced an appeal mechanism that can result in the re-evaluation of applications to its expert Drug Benefit Coverage Assessment Committee [19]. A side letter to KORUS also specifies that the appeal mechanism must involve establishment of a review body, which carries the risk that a designated panel of non experts could overturn the decisions of experts [14,15].

Currently PHARMAC does not have a formal appeal or review mechanism, but pharmaceutical companies seeking different outcomes are able to resubmit applications [20] and can challenge PHARMAC's decisions in court. Introduction of a formal appeal or review mechanism, pertaining to both listing and pricing decisions and able to overturn PTAC's recommendations (as indicated in the 2011 draft TPPA annex), would facilitate pharmaceutical company challenges to formulary decision making. Depending on the nature of the appeal mechanism and the way in which it is implemented, it could also undermine the scientific rigour of PHARMAC's process by supplanting the decisions of experts with those of a less expert body. Establishment of an appeal body could lead to decisions that undermine PHARMAC's attempts to achieve distributional fairness in expenditure. The establishment of an appeal body not subject to the same budgetary constraints as PHARMAC would be a particular concern for New Zealand. Even the existence of an appeals mechanism could have a ‘chilling’ effect on PHARMAC's decision-making processes.

6.3. Specification and disclosure of decision criteria

The 2011 draft TPPA annex includes a disclosure requirement applying to procedural rules and decision criteria used to determine pricing or reimbursement [Art. X.3(b)]. Again this goes further than the AUSFTA, which includes a requirement that appears similar but in fact only applies to decisions about listing, not pricing [14,15]. This could mean that PHARMAC's flexibility in applying its decision criteria could well be lost, locally significant decision criteria could be supplanted by rigid decision rules, and any variation from them could then become grounds for appeal.

6.4. “Transparency” provisions

PHARMAC's success in negotiating low prices for medicines depends on its effective use of competition, which depends in turn on price information being kept confidential [6].

The 2011 draft TPPA annex includes a number of provisions that seek to increase “transparency”. At face value, this seems reasonable. But PHARMAC is particularly vulnerable to these types of provisions because its price negotiations need to take place in conditions of confidentiality. Text such as this might require PHARMAC to identify/disclose price information, or reasons for selecting a specific supplier (thereby providing grounds for appeal).

The pharmaceutical industry claims that PHARMAC is not sufficiently transparent and that the TPPA proposals

will be improvements [21]. However in many respects PHARMAC is already transparent. For example, while assessments of evidence conducted by PTAC are not publicly available, minutes of PTAC meetings are posted on PHARMAC's website and minutes of subcommittee meetings are also published following review by PTAC [22].

6.5. Cooperative mechanisms for ongoing engagement

A placeholder in the 2011 draft TPPA annex [Art. X.6.2] refers to possible mechanisms for international cooperation. The US is likely to seek similar arrangements to those established for KORUS. Under KORUS, a Medicines and Medical Devices Committee has been established with a far more extensive and influential remit than the Medicines Working Group set up under the AUSFTA, which is essentially a discussion forum [14,15]. The committee established under KORUS is co-chaired by health and trade officials, has a specific mandate for monitoring and implementing the pharmaceuticals and medical devices provisions of KORUS, is required to meet at least once a year and reports to the Joint Committee [14,15]. Such a committee could have the ability to influence domestic policy in New Zealand in ways that promote the interests of the pharmaceutical and medical device industries at the expense of affordable access for the public.

6.6. Institutionalisation of direct-to-consumer advertising

The 2011 draft TPPA annex includes a clause mandating the legalisation of direct-to-consumer advertising (DTCA) via the internet [Art. X.4]. While New Zealand already permits direct-to-consumer advertising of pharmaceuticals, there is a mounting body of evidence that suggests that DTCA carries more harms than benefits [see, for example, 23–26]. Accepting this provision in the TPPA could effectively 'lock in' DTCA for the future and prevent NZ from making different policy choices in response to new evidence or changing circumstances.

While by no means benign, DTCA does not present as significant a problem in New Zealand as in the US, this in large part because of the tight controls PHARMAC wields over which drugs are subsidised in NZ [23]. However, were some degree of control to be lost through other TPPA provisions that required changes to PHARMAC's processes, DTCA might well represent a more significant risk to prescribing patterns and expenditure than is currently the case.

7. Other TPPA provisions likely to adversely impact PHARMAC

Beyond the proposed Annex on Transparency and Procedural Fairness for Healthcare Technologies, two other areas of the TPPA text could affect PHARMAC's ability to contain pharmaceutical expenditure and ensure access to affordable medicines in New Zealand. Proposals made by the US to extend intellectual property rights (IPRs) for pharmaceuticals [27,28], if accepted, would expand patent protection and delay the introduction of generic medicines

through a range of provisions that extend well beyond existing patent law in New Zealand [14,16,29] including:

- extending patentability to cover new forms, uses and methods of using a known product (even without evidence of additional benefit);
- requiring countries to allow patents for diagnostic, therapeutic and surgical methods;
- adjustments to the term of patents to compensate for delays in issuing patents or in providing marketing approval;
- elimination of the process for opposing patent claims before they are granted (a safeguard that can be used to prevent unwarranted patents from being granted);
- provision for at least 5 years of data exclusivity for new pharmaceutical products, plus an additional 3 years for new uses of existing drugs, and possibly up to 12 years for biologics; and
- linking marketing approval for generic drugs to patent status – requiring regulatory authorities to scan for existing patents, provide notification to patent holders, and delay granting marketing approval until any disputes are settled.

Extensions to originators' monopoly periods and consequent delays in the market entry of generics could be expected to seriously compromise PHARMAC's ability to source low cost generic drugs. Extensions to IPRs could therefore prove to be one of the greatest threats posed by the TPPA to New Zealanders' access to affordable medicines.

A proposed investor-state dispute settlement (ISDS) provision, which leaked text suggests is supported by New Zealand [30], could provide an additional avenue for pharmaceutical companies to challenge, in international tribunals, domestic pharmaceutical policy processes and decisions that are perceived to affect the value of their investments.

8. Likely impact on the cost of medicines, health equity and indigenous rights

If PHARMAC were to become less effective at containing pharmaceutical costs post-TPPA, there are three possible outcomes, all of which have implications for the health of the New Zealand public, as well as health equity and indigenous rights.

One possible outcome is a rise in co-payments (higher out of pocket costs for prescriptions) to offset increased acquisition costs. Increased co-payments are likely to disproportionately disadvantage those New Zealanders who are least able to pay the extra costs, in particular people from low-income households and beneficiaries. Māori, indigenous New Zealanders, are over-represented among these groups. Jatrana et al. [31] studied ethnic differences in access to prescription medicines in New Zealand. They found that during a 12 month period, Māori and Pacific peoples were approximately three times more likely than New Zealanders of European background to have postponed purchasing a prescription medicine at least once because they could not afford the cost of the medicine.

These findings are consistent with international literature that shows that groups most likely to report cost barriers include ‘elderly, women, non-white and low-income populations’ [31].

Cost barriers result in decreased medication use for serious illnesses, low adherence to treatment and higher risk of hospitalisation, leading ultimately to adverse health care outcomes and higher economic costs to society [31]. As well as experiencing cost barriers to use of prescription medications, Māori and Pacific peoples have higher health needs and experience other barriers to healthcare services [31].

Secondly, if the rising costs of pharmaceuticals are not met by increased co-payments, they could be met by either increasing government health funding (Vote Health) or by increasing the proportion of Vote Health allocated to pharmaceuticals. This latter proposal would probably mean decreasing the funding to other essential publicly funded health services. Such funding cuts may particularly affect services targeted to high needs population groups rather than ‘mainstream’ health services.

Finally, the third possibility is increased rationing, by restricting either the range of medicines that are subsidised or by the more extensive use of restricted access criteria. Currently there is evidence of significant under-utilisation of pharmaceuticals by Māori aged less than 15 years [32]. It is possible that efforts to restrict access could lead to further inequities.

New Zealand, like many nations internationally, is committed to the elimination of health inequity [33]. Adopting policies that will, in all likelihood, increase inequities in health would seem to be acting against the spirit of the New Zealand Public Health and Disability Act. Furthermore, adopting policy in the knowledge that Māori health will be further marginalised would breach the intention of the government to act in good faith in respect of the Treaty of Waitangi and would be an infringement of indigenous rights.

Increasing co-payments and introducing tighter rationing would both be politically costly options. It seems the most likely governmental response, should the New Zealand government agree to alter PHARMAC’s operation consistent with US ambitions, would be to devote a greater share of health expenditure to pharmaceuticals and medical devices in order to offset increased costs. However, as we have argued above, this option may also increase inequities, as disadvantaged groups tend to be affected more by cuts to other health and community services.

The New Zealand government has maintained throughout the TPPA negotiations that the “fundamentals” of PHARMAC are not negotiable in the TPPA [34]. However, it is unclear which features of PHARMAC are considered fundamental to its operation and whether the government may in fact be considering conceding to procedural changes that may substantially affect PHARMAC’s operations. In December 2012, New Zealand’s trade minister reportedly indicated his preparedness to be “somewhat flexible” in response to US concerns about PHARMAC [35].

Many provisions in the 2011 draft TPPA annex tabled by the US could undermine the operation of PHARMAC.

While this text is said to have been superseded, a subsequent revised draft reportedly retains many key issues of concern. The best case scenario would be for all TPPA countries to refuse to accept any provisions that would circumscribe programs for subsidising medicines and medical devices. However, if the TPPA countries agree to negotiate such provisions, it will be vitally important for policy makers to understand the nuances of the texts and their implications for institutions and programs such as PHARMAC, so that risks to public health and equity are given appropriate weight in the negotiations. Meaningful engagement with health sector stakeholders (including health organisations and pharmaceutical policy experts) is important for ensuring that such risks are fully understood and that the advancement of sound health policy is prioritised over the lure of potential gains to other sectors of the economy.

9. Conclusions

PHARMAC is a highly effective model for containing costs while ensuring affordable access – important to preserve not just for New Zealanders, but also as a potential model for other countries to adopt. PHARMAC’s processes are particularly vulnerable in the TPPA negotiations. Any intrusion into domestic decision-making about medicines – even seemingly reasonable requirements for greater “transparency” – could have adverse consequences for PHARMAC’s ability to manage expenditure and ensure value for money, and potentially serious effects on health expenditure, health equity and indigenous rights.

Disclosure statement

At the time this paper was drafted Ruth Lopert was a Visiting Professor in the Department of Health Policy at George Washington University in Washington DC (rlopert@gwu.edu). The views presented here are strictly those of the authors and do not represent those of the Australian government or any other institution with which the authors are affiliated.

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