

## **Tendering for Low Cost Generics in Australia**

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*An Australian federal government committee recently proposed, as a cost-saving measure, the introduction of sealed-bid competitive tendering to exclusively supply the Pharmaceutical Benefits Scheme with specific generic medicines. A similar plan involved an open tender to supply generic products below a government set price, also linked with a reduced patient co-payment as an incentive. These proposals represented an opportunity to encourage the price of generic pharmaceuticals to move closer to the marginal cost of production—a process that could be subsequently applied to innovative (or brand-name) patented medicines in a therapeutic class with many competitors. This article examines these tendering proposals, particularly in relation to the potential for increased involvement of generic pharmaceutical manufacturers in the Australian market.*

### **The Contemporary Australian Generic Pharmaceuticals Industry**

Australia's Pharmaceutical Benefits Scheme (PBS) is designed to ensure timely and affordable access to essential medicines for all Australians, implementing the quality use and equity principles of the Australian National Medicines Policy (Australian Government Department of Health and Ageing 2000). This social justice initiative, however, comes at a cost of more than \$6 billion a year to Australian taxpayers (Australian Government Department of Health and Ageing 2005). Recent proposals for PBS reform have signalled that the Australian Government is increasingly looking to generic medicines to curb the growth of PBS expenditure.

"Generic medicines" is a term used to describe medicines which, whilst duplicating the safety and quality of products whose patents have expired, have increased their social value by being available at a reduced price. A patent provides, essentially, an Intellectual Monopoly Privilege that provides a period of exclusive use for the production and marketing of a brand-name pharmaceutical. This initially results in high prices, but these reduce when patents expire and other companies enter the market with generic versions. The size of the global generics industry is estimated at around US\$45 billion, which represents about one-tenth of the value of total global prescription drug sales (Class 2005). This is likely to increase as a glut of blockbuster drugs in the USA and globally come off patent (Arrow Pharmaceuticals 2005).

Generic products constitute approximately 25% of all Australian prescriptions (12% of the value of the prescription drug market). Generic substitution by pharmacists, however, has been legal since 1994 (unless specifically disallowed on a prescription) and the government has sought in various ways to make consumers and prescribers more aware of the availability of cheaper generics. In contrast, in the USA and the United Kingdom, more than 50% of all prescriptions are filled generically.

The marginal role of generics in Australia is in part the result of strong regulatory lobbying by brand-name companies, the small price difference between brand-name products and generics arising from PBS processes and limited competition between pharmacies (Lofgren 2004; Pharmaceutical Benefits Pricing Authority 2005). Once the PBS listing process has established a benchmark price for a given therapeutic class, there is little incentive for generic suppliers to engage in price competition (Sweeny 2004).

Australian generic competition is additionally weakened by the dominance of two companies—Alphapharm (owned by the German firm Merck KgA) and Arrow (owned by Sigma) which control more than 90% of the Australian generics market. Adding to the problem is the proliferation of linkages (licensing, co-marketing or distribution agreements etc.) between originator and generics firms which further reduce

competition. Nonetheless, the Australian generics sector has been characterised by rapid growth in recent years, because generics firms compete not on PBS price but for acceptance by retail pharmacists by offering convenient supply arrangements. Generic firms also supply products at discount prices allowing pharmacists to pocket the difference between the listed PBS reimbursement and the actual discounted price.

On 1 August 2005, the government imposed a 12.5% mandatory cut in the benchmark price when a generic was first launched within a particular therapeutic class in an attempt to capture some of the cost benefits, currently flowing to pharmacists, for the taxpayer. However, the federal government is further looking to generic medicines to deliver further PBS savings; one radical option for taking advantage of the patent expiry of many products and the availability of cheap generics in the global market to achieve PBS savings is the introduction in Australia of competitive tendering for generic drugs. The impetus for such significant PBS reform stems from the development of such a system in New Zealand and more recently interest in the United Kingdom.

### **Tendering for Generic Medicines in Australia**

The Australian federal government's joint Treasury, Industry and Finance Committee presented new proposals to Cabinet in February aimed at controlling the cost of the PBS though introducing the practice of competitive tendering for generic drugs, to take advantage of the patent expiry of many products and the availability of cheap generics in the global market.

While the Committee's proposals are not yet public, there have been reports of at least three options for a tender system for the supply of off-patent medicines to the PBS. All of them are based on the same premise: the "winning" manufacturer(s) being able to offer the drug to patients at a significantly discounted co-payment of up to 50% (Stafford 2006).

The first two proposals involve a period of market exclusivity for the winning tenderer. The first requires that PBS reimbursement accorded other drugs in the same therapeutic class be reduced to match the price offered by the winning tenderer, who alone could offer the drug at a reduced co-payment. The second proposal grants the winning tenderer six months of reduced co-payments while drugs in the therapeutic group would not be forced to match the winning price. At the end of this period, any manufacturer offering the reduced price would also be able to offer patients the discounted co-payment (Stafford 2006). The third, more of an open-tendering proposal, involves the federal government initially specifying a desired reduced price level itself for a generic medicine. A reduced co-payment then provides an incentive for any generic manufacturers agreeing to provide medicines below that stated amount. Estimated PBS savings resulting from the various proposals are between \$300 and \$800 million a year.

Brand-name pharmaceutical subsidiaries in Australia keen to promote pharmaceutical "innovation" as a core lobbying principle have opposed the tendering scheme, countering with their own proposals (Medicines Australia 2006; Tassone 2006). One involves the PBS paying less for a generic every time the sales increase by a certain percentage. Others require generic manufacturers to compete for the right to a period of market exclusivity (McKay 2006).

## The New Zealand Tendering Experience

In 1996, the Pharmaceutical Management Agency Ltd of New Zealand (PHARMAC) introduced competitive tendering for pharmaceuticals (Davis 2004). PHARMAC is a non-profit company owned by the Health Funding Authority of New Zealand. Its board uses cost-effectiveness analysis and reference pricing to maintain the national pharmaceutical schedule.

The tendering mechanism required that PHARMAC initially identify suitable off-patent pharmaceutical ingredients, with the help of a medical evaluation board. Tenders were then sought for specific related generic medicines. Only community pharmacy prescription medicines were included (not hospital-delivered or over-the-counter products). After further consultations, PHARMAC issued an invitation to tender, including terms of the contract. PHARMAC explicitly allowed bids from manufacturers of products presently lacking marketing approval on quality and safety grounds. If such an unlicensed supplier made the lowest bid, the authority indicated it would delay award of the contract and “fast track” the product’s licensing (OXERA 2001). One reason for this may have been the prohibitively high cost of seeking such regulatory approval, for example; each application for generic market entry to the Australian Therapeutic Goods Administration (TGA) costs A\$75,000 (TGA 2005).

Suppliers had two to three months to submit closed bids. The winner was obligated to supply the fluctuating total market demand for three years and to indemnify the government against unexpected disruption of production or supply. In that case, the government could legally approach other suppliers with the winning tenderer paying the difference (OXERA 2001). Evaluation of the bids was staggered, with those offering greatest cost savings processed first. An important public health principle was that continuity of supply should always take precedence in tendering evaluations over lowest price (OXERA 2001).

After the winning tender was announced, a transition period of two months allowed suppliers and pharmacists to use up old stock while the successful tenderer increased production. At the end of the two months, the tender price was established and after four months, other suppliers were delisted from the PHARMAC schedule.

As a result of tendering, the New Zealand generics market rapidly shifted to a “low-price, high-volume” model with increased generic competition expanding to a 25% share of the total pharmaceutical market. Tendering soon became a powerful bargaining tool for the New Zealand government against the pharmaceutical industry. Some generic suppliers initially offered to reduce prices between 20% and 60%, if PHARMAC would defer its tender on specific chemicals. These price reductions saved PHARMAC NZ\$18 million in 1996 alone. Tendering for the remainder of the general active pharmaceutical ingredients saved an additional NZ\$7 million. In 1998/99, PHARMAC managed a reduction in pharmaceutical expenditure by NZ\$55 million owing to major price reductions (60-70%) for eight different medicines (OXERA 2001). Post-tender, the winning company had a new, larger, market share and was able to buy chemicals in bulk and exploit economies of scale in production, while no longer needing to pay bonuses to pharmacists. New entrants were primarily New Zealand companies and emerging suppliers from India. In a small market such as New Zealand (less than 0.1% of global pharmaceutical sales), tendering is an important strategy for ensuring small-volume medicines continue to be available for New Zealand patients (McNee 2006).

## Potential Advantages of Pharmaceutical Tendering

Centralised purchasing through tendering for specific generic products has many potential advantages for the PBS (OXERA 2001).

It would:

- allow the PBS system to use cost-effectiveness evaluation linked with their power as largely the sole buyer of medicines in Australia to leverage lower prices;
- make prices paid to manufacturers (and other suppliers) more transparent;
- give manufacturers (and other suppliers) enhanced certainty over demand than current fluctuating arrangements with wholesalers;
- create a negotiating lever to facilitate entry of new generic manufacturers into a more competitive market;
- reduce the likelihood of “actual” and “artificial” (“speculative”) supply shortages and facilitate longer and more efficient production runs;
- reduce price fluctuations; and
- open the door to tendering for innovative products where numerous competitors exist in a therapeutic class.

A key benefit of the tendering mechanism is that it will provide a good means for the government and its cost-effectiveness evaluators to gain an understanding of the marginal cost of production for specific PBS-listed medicines. This would be especially true if PBS tenders were in the form of first-price sealed-bid auctions, in which bidders provide a secret bid. A staggered approach to issuing PBS tenders would allow the PBS system to track the development of prices and number of potential suppliers. The threat of turning to such a system could itself be a powerful driver for lower generic prices.

Critically, under a generics tendering system, brand-name medicines that demonstrated therapeutic benefits would still be priced by the PBS process according to the principles of cost-effectiveness, and thus, appropriately valued. Tendering would not, therefore, conflict with Australia’s obligations to recognise the value of innovative pharmaceuticals under the Australia-United States Free Trade Agreement. Tendering would also encourage innovation in the affordability aspect of products by generic manufacturers.

## Potential Disadvantages of Tendering

Repetition of tendering rounds may increase the likelihood of market concentration if the same suppliers win contracts, so that competitors let their expensive (\$A75,000) product licence expire. Tendering may also drive the price down rapidly once a drug comes off patent, but facilitate the market exit of unsuccessful generic suppliers and further price increases. Tenders, however, can be set up so as to minimise incentives to collude, especially if the Australian Competition and Consumer Commission takes an active role in monitoring the process and the industry in general.

The brand-name pharmaceutical lobby in New Zealand has alleged, however, that tendering has caused problems with security of supply, quality and safety of medicines (McKay 2005, 2006). While securing supply has been a problem in isolated cases in New Zealand, this problem is less likely to arise under the Australian proposals, because other supply sources will still be available at a subsidised price. If not carefully managed, frequent changing of tender suppliers may result in changing of patient’s treatment regimes and minimisation of patients’ choice, although the Health Minister, Tony Abbott has pledged that consumer choice will not be affected by any PBS reforms (Chamberlin 2005).

Some of these patient concerns may be alleviated by including criteria other than price in the request for tender such as quality of the product, quality of the delivery system (e.g. appropriate coating of tablets for ease of swallowing) and security of supply. The tendering system could be structured to ensure patients and their doctors retain adequate choice of subsidised treatments.

Tendering may cause difficulties in planning production for generic manufacturers, because they will not know which tenders will win. Such concerns would be minimised if the tender process adopted in Australia involved an open tender for generics below a government set price, especially if it was linked to tax incentives for companies to create head-to-head clinical trials of their generic products against brand-name and other generic competitors, and a systematic program of physician education.

For tendering contracts to function properly, enforceable penalty clauses for failure to deliver or other contract default are crucial. The simplest such clause would specify that a defaulting contractor should reimburse the PBS for the extra cost of obtaining supplies from elsewhere. The contract between the supplier and the PBS should allow, however, for some flexibility in the agreed volume if demand turns out lower than forecast, or a supplier fails to deliver.

## **Conclusion**

The discrepancy between low international market prices for generics and high PBS prices, that constitutes the crux of recent health policy debates including the radical proposal to introduce a tendering system. A careful assessment would need to be undertaken of any trade-offs offered to brand-name companies, to compensate for lower returns in the off-patent (or generic) market. There is also a need for analysis of the implications for pharmacies of the potential removal of present discount arrangements. Tax incentives for head-to-head clinical trials of Australian generics against existing and brand products would be a valuable linked investment. The federal Treasurer, Peter Costello has remained tight-lipped about the Cabinet's response to the tendering proposals put forward in February (Costello 2006). While the proposed reforms did not feature in the May Budget, tendering still remains a viable policy option for maintaining the sustainability of universal access to essential medicines in Australia. A failure of such a proposal, due to closed-door lobbying by representatives of the brand-name (or patented) pharmaceutical industry, may represent a significant policy impact of the contentious and deliberately ambiguous provisions concerning reward of "innovation" in Annex 2C of the Australia-United States Free Trade Agreement.

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