PAYING FOR SELF-MEDICATION IN AUSTRALIA

Whether pharmacy medicine rules protect patients or pharmacies is open to debate, argues **David Gadiel**

In Australia, many common non-prescription medicines used to treat minor ailments can be bought only from pharmacies. Some argue that pharmacy restrictions on non-prescription medicines are justified because professional advice is necessary to protect people who are caring for themselves against the risk of using their medicines incorrectly. If consumers were to purchase medicines currently restricted to pharmacies from supermarkets or convenience stores, they would be denied advice on these medicines and on their appropriate use. Inevitably, however, the consumer pays a price for pharmacy restrictions.

Whether it is possible to balance competing consumer interests appropriately—between minimising risks of incorrectly using medications and purchasing them at lower prices—has been the subject of reviews in the past. During the term of the National Competition Plan (1995–2005), arrangements for consumer access to certain over-the-counter (OTC) medicines currently restricted to pharmacies were evaluated in different ways against National Competition principles. One was a cost–benefit analysis, initiated by the Council of Australian Governments (COAG) and conducted by the Pharmacy Guild of Australia ('the Guild')—the peak business organisation representing interests of community pharmacy owners. The Guild found there were net benefits in arrangements that currently restrict about half OTC medicine sales to pharmacies.

This conclusion is debatable. To assess whether consumers are likely to secure 'value for money' on OTC medicines they purchase in community pharmacies, this article considers the background and context of the Guild's cost–benefit analysis and reviews its findings in the light of the assumptions it employed.

How poison scheduling affects access to medicines for self-care

Scheduling of pharmaceuticals in Australia is administered in the interests of public health and safety at the state and territory level, on the *Standard for the Uniform Scheduling of Drugs and Poisons* developed by the National Drugs and Poisons Schedule Committee (NDPSC), which is part of the Therapetic Goods Administration (TGA). States and territories maintain their own poisons lists or codes, which are uniformly based on the national standard but rely on state and territory 'poisons' legislation.[1]

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Scheduled pharmaceuticals broadly divide between prescription and OTC products. Prescription pharmaceuticals mostly belong to poison schedule category S4, 'prescription only' (a few narcotics and the like belong to an S8 category, covering 'controlled drugs'). Some pharmaceuticals scheduled as poisons are also classified as schedule 3, 'pharmacist only' and schedule 2, 'pharmacy only'; others not classified default to the 'open seller' category.

Figure 1: Summary of pharmaceutical poison scheduling in Australia

	Schedule	Outlet
Prescription	S8	Pharmacy
	S4	
OTC (non-prescription)	S3	
	S2	
	Open seller	Pharmacy and other retail

Items classified below S4 are generally available as OTC pharmaceuticals for self-medication without a prescription. S2 and S3 items, however, may be sold only by pharmacies, subject in the case of S3 items to customers being served by a pharmacist. Pharmacies also sell 'open sellers,' but non-pharmacy retail outlets, principally supermarkets, also sell them.

There are 'grey' areas in Australia's scheduling arrangements. Some S3 items may be sold on prescription (principally to facilitate payment of a PBS benefit to those entitled to a concession), and the dichotomy between S2 and 'open seller' often depends on pack size rather than chemical entity. Some larger packs of analgesics (the most commonly sold OTC product group), for instance, are classified as S2 'pharmacy only,' and smaller packs as 'open sellers'—with consumers at liberty to purchase unlimited quantities of smaller packs from general retail outlets. A significant fringe of S2s and 'open sellers' are hence substitutes for each other.

In 2005–06, estimated expenditure on pharmaceuticals below S4 scheduling was about $2.9 billion, consisting of $1.5 billion of sales in pharmacies (covering 'open seller', S2, and S3 products) and $1.4 billion of sales in non-pharmacy outlets (covering just 'open sellers').[2]

Community pharmacy's regulated environment

Aside from poison scheduling, community pharmacy benefits from other exclusive business privileges, including barriers to entry and rigid ownership criteria. Under state legislation, only pharmacists may own pharmacies, and the commonwealth's Pharmacy Restructuring Program imposes strict controls over the number of pharmacies approved to dispense prescriptions under the commonwealth-funded Pharmaceutical Benefit Scheme (PBS)—mostly S4 poisons. Approval to dispense PBS pharmaceuticals is essential to a pharmacy's viability. New entrants to community pharmacy must generally buy an existing approved business, or least at a PBS approval number that can be suitably relocated (also subject to restrictions).

Exclusive rights to sell prescription and non-prescription S2 and S3 pharmaceuticals are claimed to yield a variety of public health benefits.

Ownership restrictions in conjunction with exclusive rights to sell prescription and non-prescription S2 and S3 pharmaceuticals are claimed to yield a variety of public health benefits associated with appropriate selection and effective use of medicines and reduced medicinal misadventure.[3] Such arrangements are also prima facie evidence the commonwealth and consumers may be paying more for medicines than in a less regulated and more competitive environment.

The commonwealth seeks to limit pharmacy margins on PBS pharmaceuticals, on which it may pay a benefit, by setting a 'PBS Dispensed Price.' In the case of prescription pharmaceuticals not attracting a commonwealth benefit and S2 and S3 medicines, however, the exclusive control pharmacies exercise over their sale gives them an ability to set retail prices that yield gross margins considerably greater than where a PBS benefit is paid.

In the case of the market for S2 and S3 medicines, pharmacies operate in a quasi-monopoly environment. There is a fringe of mail order and

warehouse-type pharmacies that compete on S2 and S3 prices amongst themselves and with mainstream pharmacies. Notwithstanding the introduction of s45(A)(1) of the *Trade Practices Act* (pursuant to the *Competition Policy Reform Act*), prohibiting behaviour that could be deemed to lessen price competition, the majority of pharmacies set S2 and S3 prices in a closed environment, frequently (because of location restrictions) in local monopoly situations.[4] The Guild vigorously opposed this amendment.[5] Aware that price-cutters supply a small fraction of the total market, mainstream pharmacies appear reluctant to retaliate,[6] either because it is unnecessary since they enjoy a local monopoly, or else in fear that a price war could precipitate more damage than their forbearance.[7]

Australia's two-tier regulation of non-prescription medicines offers less general retail access than in the United States.

Few countries possess pharmaceutical scheduling arrangements for non-prescription medicines as complex and restrictive as in Australia. The United Kingdom and France, for instance, simply use a pharmacy medicine classification for their scheduled pharmaceuticals.[8] The Netherlands and the United States restrict only the sale of prescription medicines. Based on the experience of ten countries and the EU, the United States General Accounting Office found no evidence to support the alleged benefits of pharmacist counselling or of retaining a pharmacy-controlled class of OTC pharmaceuticals.[9]

Comparative trends in pharmaceutical scheduling

There has been a long-term trend, encouraged by an interest in promoting greater consumer self-care and accountability, to switch pharmaceuticals in the United States, as in many countries, from prescription to non-prescription (equivalent to 'OTC' in the United States and 'open seller' in Australia).[10] In Australia, there has been an analogous switch from S4 'prescription only' to S3 'pharmacist only' medicines.[11]

It is argued that Australia's S3 classification has facilitated a larger switch from prescription medicines than would otherwise have been possible, and that this is a measure of greater consumer accessibility to medications in Australia than in the United States. Nevertheless, Australia's two-tier regulation of non-prescription medicines offers less general retail access than in the United States.

A study on a limited number of comparable medicines found considerably more of them were OTC in United States than were 'open seller' in Australia.[12] Examples meeting this criterion would include antihistamines for hayfever, such as cetirizine and loratadine; antifungals used to treat athlete's foot and other tineas, such as clotrimazole; H2-receptor antagonists, such as famotidine, for heartburn and acidity; corticosteroid nasal sprays, such as fluticasone, for allergic rhinitis and so on. All of these, sold under various well-known brand names, are classified S2, 'pharmacy only,' in Australia, but are classified as OTC and available in supermarkets in the United States.

Potential expenditure that would be associated with an additional layer of general retail access to commonly used OTC medicines (currently restricted to pharmacies in Australia), moreover, would likely be considerably greater than expenditure associated with any incremental ex-pharmacy, off-prescription access now available because of the S3 'pharmacist only' schedule.

When compared to Australia's, scheduling arrangements in the United States have been found to offer benefits that include 'better consumer access, with medicines available at a wider range of outlets … (and) lower medicine costs, due to competition and availability of medicines in stores with lower overhead structures.'[13]

Figure 2: Examples of non-prescription pharmaceuticals scheduled as S2 and S3 poisons

S2 'Pharmacy only'	S3 'Pharmacist only'
Analgesics in packs > 25 tablets or capsules; common analgesics componded with low strength codeine, etc.	Analgesics compounded with with higher concentrations of codeine, etc.
NSAIDS (non-steroidal anti-inflammatory drugs) in lower strength formulations and smaller pack sizes	NSAIDS in stronger formulations and larger pack sizes
Cough medicines, including those with codeine	Cough medicines with pseudoephedrine and higher concentrations of codeine; paediatric syrups
Nasal decongestants	Pseudoephedrine (in small quantities, for example <721 mg per pack of tablets)
Antihistamines	Antihistamines that may cause drowsiness
Dermatological creams and ointments	More potent dermatologicals
Eye drops	More potent eye drops
Antispasmodics, anticholinergics	Cleansing laxatives
H2-receptor antagonists for heartburn, etc.	Some proton pump inhibitors
Fluoride drops	Topical fluorides for dental use
Nicotine patches / chewing gum	Nicotine inhaler cartridges
Anti-diarrhoeals	Anti-diarrhoeals containing opioids
Others, including insect repellents, worm remedies, and strong anti-dandruff shampoos	Others, including anti-obesity preparations, angina remedies, and vasodilators

Source: NSW Department of Health[14]

Figure 2 provides an indication of types of non-prescription pharmaceuticals that the NDPSC has scheduled as either S3 or S2 poisons in Australia. Generally, medicines classified as S3 are more potent versions of those classified as S2. Examples would include antihistamines that may cause drowsiness or analgesics or cough mixtures that are compounded with larger concentrations of codeine. Medicines may be similar, but sold as S3s in larger pack sizes or with labelling recommending larger doses. Many less potent medicines now classified as S2 might be considered candidates for 'open sale' in the event of a rationalisation of poison scheduling in Australia. As discussed below, the NDPSC contemplated this in 2005.

Besides alleged public health considerations, Australia's OTC poison scheduling arrangements are a reflection of effective lobbying and zealous professional advocacy by the community pharmacy industry. This has included efficient networking both within the bureaucracy and amongst politicians and with other peak bodies in health. Public policy on community pharmacy is also sensitive to industry research controlled by the Guild and funded under a series of five-year Community Pharmacy Agreements between the commonwealth and the Guild.[15]

Options for poison scheduling

In recognition of anomalies apparent in Australia's poison scheduling, the Australian Health Ministers Conference (AHMC) was requested by COAG in July 1999, under the National Competition agenda, to review that scheduling against National Competition principles. This included an interest in simplifying Australia's OTC scheduling under the umbrella of an Australia New Zealand Therapeutic Products Authority. The AHMC commissioned a comprehensive review of drugs and poisons, the Galbally Report, which among other things recommended evidence should be assembled and evaluated to test whether health outcomes had improved because of

- S2 and S3 OTC pharmacy scheduling arrangements, and
- the effectiveness of professional standards for counselling pharmacy customers on the appropriate selection and purchase of scheduled OTC products.[16]

Professional standards for pharmacy counselling had originally been introduced in handling S2 and S3 pharmaceuticals in response

to an Industry Commission review in 1996.[17] Failing evidence of net benefits associated with retention of the S2/S3 OTC regime, Galbally favoured simplification and amalgamation of Australia's OTC poisons into a single schedule with effective 'risk-based professional standards.'[18]

Supermarkets had foreshadowed the likelihood of considerable consumer savings if they were to sell deregulated scheduled products.

Although OTC sales represent about 14% of pharmacy gross revenue, they contribute nearly 20% of gross profit.[19] Any general deregulation of S2 and S3 products that increased competition could prove disproportionately injurious to community pharmacy businesses. Because of Galbally's recommendations, many OTC products were at risk of being deregulated. Different scenarios were possible. For instance, with an S3 'pharmacist only' type schedule, S2 'pharmacy only' products could migrate to 'open seller' status and could so become immediate prey to price competition from supermarkets and general retail outlets. Supermarkets had foreshadowed the likelihood of considerable consumer savings if they were to sell deregulated scheduled products.[20]

Alternatively, with an S2-type amalgamated schedule, the more potent S3 products could shift to the S4 schedule where, if not sold as under copayment or private prescriptions,[21] they could become subject to a controlled PBS Dispensed Price.

Troubled at the NDPSC's parallel, case-by-case approach to deregulating OTC medicines, which it perceived a harbinger of a general, 'across-the-board philosophy,' the Guild had long resisted OTC deregulation. In June 2003, for instance, when the NDPSC decided to remove the NSAID ibuprofen (in packs of less than twenty-six doses of 200 mg or less)[22] from the S2 'pharmacy only' schedule and relegate it to 'open seller' status, the Guild proclaimed it had 'grave concerns for public safety.'[23] In May 2004, the NDPSC did the same for nicotine replacement therapies, which the Guild alleged was based upon 'flawed criteria.'[24] While such assertions have never been substantiated with evidence from high-quality studies, the products concerned are now widely sold in supermarkets at considerable savings to consumers.[25]

Evaluation of S2 and S3 poison scheduling

In the meantime, pursuant to Galbally's recommendations, the commonwealth funded the Guild (under its five-year agreement with the commonwealth), to evaluate the costs and benefits of amalgamating S2 and S3 non-prescription schedules in conjunction with effective risk-based pharmacy counselling.

The ensuing study, supervised by the Guild, used an epidemiological model to estimate the costs of any illnesses avoided because of professional counselling at points of sale for S2 and S3 medicines in pharmacies.[26] It extrapolated the experience of a sample of so-called professional interventions (episodes of patient counselling) to all interventions in a year associated with the sale of OTC S2 and S3 pharmaceuticals. Illnesses and adverse drug interactions so avoided were clinically assessed and appropriately coded.

Gross benefits were measured in healthy life years saved, with assumptions about the statistical value of a life and expected survival. *Only the producer costs of the interventions were considered* (professional time, training, labelling, pharmacy layout, and so on).[27] The central estimate of annual net benefits at 2000–01 prices attributed to the current dual S2/S3 scheduling arrangements was $2.7 billion.[28] This finding was publicised by the Guild as evidence of 'how pharmacy teams manage the potential risk of harm to the consumer.'[29]

Roughly comparable savings were claimed in scenarios with an amalgamated schedule—except it was unrealistically assumed, if the S2 schedule were abolished, that all S2 products would migrate to the more restrictive S3 classification rather than to 'open seller' status. Similarly, if the S3 schedule were abolished it was assumed all products would shift to S2 status, instead of many becoming S4 prescription pharmaceuticals.

The TGA's National Co-ordinating Committee on Therapeutic Goods ('the National Co-ordinating

Committee') were dubious about the Guild's findings (for reasons other than shortcomings of the economic model), but decided there were grounds for maintaining existing S2 and S3 scheduling until at least 2010.[30]

'Willingness to pay' for pharmacy professional services

Had scheduling on S2 and S3 OTC medicines been abolished, supermarkets could have sold them from their 'health and beauty' shelves (although some S3s could become S4s). The experience of parallel markets under the *status quo* for 'open sellers,' which currently are sold in both pharmacies and supermarkets, is instructive.

As remarked above, 'open sellers' and S2 'pharmacy only' products may be differentiated only by pack size. Pharmacy transactions involving small packs of 'open seller' analgesics, for example, may be accompanied by professional advice and recommendations typically given with larger (S2 'pharmacy only') packs of their similarly formulated counterparts. Pharmacies claim that as this service is not offered by other outlets, they should be entitled to recoup its cost.[31] Since not all consumers may value this advice, not all of them may be willing to pay for it. Industry advocates regard professional interventions as part of a new category of 'cognitive' services for which pharmacies should be entitled to charge. Supermarket prices for 'open sellers' are thus substantially lower than in pharmacies.[32]

In the parallel, unregulated environment, consumers are evidently more conscious of price than any possible risk of buying an 'open seller' analgesic without a professional intervention. Indeed, 79% of 'open seller' sales occur in general retail outlets, mainly supermarkets (worth about $1.4 billion in 2005–06).[33]

The experience with 'open seller' products illustrates the existence of two classes of health consumers: the risk conscious and the price conscious. The former are evidently willing to pay for higher levels of service they perceive to be available from community pharmacies; the latter buy largely on price and their demand is price elastic. Because the demand of the risk-averse clientele attracted to pharmacies is relatively price inelastic,[34] pharmacies maintain their prices and some seek to compete on service by offering professional advice. The risk-averse minority who are prepared to pay for these services in the unregulated 'open seller' market hence throws an important light on the revealed preferences of health consumers.

It is plausible that patterns of business behaviour and consumer risk behaviour inherent in the different markets for 'open seller' medicines could replicate themselves if schedules for S2 and S3 medicines were deregulated.[35]

With information about prospective price differentials and some plausible assumptions about the variance in own-price elasticity in each of these two markets, the extent of consumers' 'willingness to pay' for professional advice for S2 and S3 pharmaceuticals in a deregulated market could be tested. The evidence from 'open sellers' suggests there would be a significant switch in demand to points of sale with lowest prices.[36] Because demand would be highly price elastic in deregulated settings, lower prices could also increase consumption to meet legitimate needs that would have otherwise remained untreated. The Consumers' Health Forum of Australia believes that pharmaceutical costs are a key issue causing needy consumers to delay or not to purchase necessary medication.[37]

The potential lower prices and consumption gains that have hitherto eluded Australian non-prescription customers are a marker for large welfare losses on the $1.5 billion annual expenditure (on 2005–06 figures) on pharmacy sales of regulated S2 and S3 items.[38] These losses are associated with the erosion of consumer surplus and the accrual of supernormal profit now being harboured within the current, regulated community pharmacy industry. This is hard to reconcile with the $2.7 billion net public benefit the Guild's S2/S3 cost–benefit study attributed to regulation.

The Guild's study was defective because it considered only the producer costs of poisons schedule deregulation, neglecting the considerable cost burden imposed upon consumers. It neglected to consider how consumers might reveal their preferences in the event of deregulation and whether they would be willing to pay for professional interventions associated with scheduling—to

which the Guild had attributed an unqualified net benefit. It implicitly assumed all consumers were risk-averse and that professional interventions were likely to be universally valued; it dismissed the burden of the excess cost of pharmaceuticals and the restrictions in accessing them. The TGA's National Co-ordinating Committee failed to recognise or address these issues,[39] and the Guild's coercive model fails to consider the right of individuals to exercise personal responsibility and to make legitimate self-care choices for themselves in a market setting.

Consumer safety

A revealed preference approach, which looks at how consumers actually behave, could be criticised because consumers may misperceive the risks posed by potentially toxic medications, and so undervalue advice from pharmacists. Consumers may be unaware of being a danger to themselves. But if consumer perceptions were incorrect, the best solution would be to provide everyone with adequate facts through product labelling and warnings and adequate access to CMI (consumer medical information) on the internet, so they could make their own informed choices. Experience to date suggests CMI has not always been readily available.[40] In many instances, past experience with a particular medicine, in conjunction with professional advice consumers already possess, is likely to assist in fashioning their choice.[41]

With good information, consumers can make rational risk–price trade-offs for themselves in determining where and for which medicines they shop.[42]

Moreover, despite anecdotal claims to the contrary,[43] there are no systematic epidemiological data to show morbidity and mortality attributable to analgesics and the like are significantly different between Australia and countries that use less-restrictive poison scheduling.[44] Furthermore, there is doubt about whether professional interventions are always needed,[45] and even if justified, their quality has been called into question. It is reported that many pharmacists simply 'do not get involved in OTC medication sales.'[46] Data on S2 and S3 interventions from mystery shopper surveys undertaken as part of the Guild's Quality Care Pharmacy Program are equivocal,[47] and the evidence on interventions from independent research is far from satisfactory.[48] Poor pharmacy staff training too, has become a significant failing.[49] Besides, the quality of advice from registered health professionals (if required) ought to meet absolute standards without the inducement of artificially inflated markups made possible by barriers to competition that masquerade as a 'safety issue.'

Conclusion

Australia relies upon a complex non-prescription poisoning scheduling system, unguided by proper tests of public benefit. This bestows extraordinary privileges upon community pharmacy and is consistent with conditions that encourage rent-seeking behaviour. Although market power associated with professional licensure occurs elsewhere in health, there are doubts if the privileges community pharmacy derives from highly regulated non-prescription poison scheduling have been of much benefit to consumers.

Deregulation of OTC medicines would not necessarily mean community pharmacies would cease selling them. It would simply give consumers greater autonomy and choice over where they purchased them. Pharmacies would continue to provide professional advice if it were valued by consumers, as evidenced by their willingness to pay for it.

In the light of the commitment of the National Co-ordinating Committee to revisit the scheduling arrangements of S2 and S3 OTC pharmaceuticals in 2010, the commonwealth will have an opportunity of reconsidering community pharmacy's privileges and the burden they seem likely to impose upon the majority of consumers.

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