

# Some drugs more equal than others: pseudo-generics and commercial practice

Andrew J Probyn

## Abstract

This article analyses the impact of the Department of Health and Ageing's brand price premium policy for some products listed on the Pharmaceutical Benefits Scheme. The policy, introduced in 1990, allows pharmaceutical companies to charge patients an out-of-pocket expense for post-patent brands of pharmaceuticals. One of the policy's intended goals was to increase consumer awareness of price differentials between competing brands, with a view to encouraging greater use of cheaper generic products. More than fourteen years since its introduction, it is debatable whether the policy has achieved this aim. This article looks at how the brand price premium policy can be exploited by global pharmaceutical giants to entrench big-name brands in the Australian pharmaceutical market and, in some cases, prevent 'true' competition from generic pharmaceuticals. This is being done through the establishment of 'pseudo-generics' that are sourced from the same factory floor as the original product.

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SOME OF THE MOST POPULAR brands on the Pharmaceutical Benefits Scheme (PBS) have identical alternatives sitting alongside them. Not widely known is that these identical alternatives are not 'generics' in the traditional sense of being copied versions of the original, but exactly the

## What is known about the topic?

Some PBS products have identical alternatives, pseudo-generics. It is not widely known that these are not generics in the sense of copied versions of original brands. They are exactly identical, produced by the same manufacturer in the same factory and simply repackaged.

## What does this paper add?

There has been no previous Australian analysis, and very few internationally, of the phenomenon of pseudo-generics.

## What are the implications for researchers and policymakers?

Analysis and policy in respect of the PBS in general and the generics market in particular must — from now on — take into account the role of pseudo-generics. The dynamics of generic competition in Australia remains markedly under-researched.

same, made with the same ingredients, from the same factory, and simply repackaged. As a consequence, Australians are unnecessarily paying up to \$21.51 extra per PBS script for some of the most popular essential medicines. (Organon's antidepressant Remeron in May 2004 had a brand price premium of \$22.76. The brand premium for its identical alternative, Avanza, sold by British Pharmaceuticals, was \$1.25 — an out-of-pocket difference of \$21.51.) Pharmaceutical companies are earning more than \$51 million a year on brand price premiums alone, that is, the extra fee the drug company charges patients who purchase the original, big-name brand.

The average citizen, if asked what he or she believes generic drugs to be, would likely answer that generics are cheaper copies of better-known brands, a sort of no-frills, 'home brand' version of the original. They would probably agree with the contention that generic pharmaceuticals would have the same effect on your body as the better-known brands: but ask them whether they would trust a generic pharmaceutical as much as the

## Andrew J Probyn, BA, LLB.

Andrew Probyn was federal politics reporter in Canberra with the Herald Sun newspaper until 2003 and is now state political reporter for the Australian Broadcasting Corporation in Hobart, Tasmania.

Correspondence: Mr Andrew J Probyn, C/- Australian Broadcasting Corporation GPO Box 9994, Hobart 7000.  
[probyn.andrew@abc.net.au](mailto:probyn.andrew@abc.net.au)

original product and there is a strong chance they would say no.

The perception that generic pharmaceuticals are not as good as the original product is not uncommon, even among some doctors and pharmacists. Their logic might be to suspect the quality of generics: if a drug is cheaper then it cannot be as good. Doctors may therefore feel hesitant about prescribing generics and prefer to stick with what they know. If information on generic equivalents is limited, many doctors may choose to prescribe the big-name brand, or originator product, believing it to be a better option for their patients. But while there may sometimes be good reason behind doctors prescribing certain brands — their patients could be allergic or sensitive to the excipients (that is, the inactive ingredients) in the alternatives, such as a colouring agent, lactose or gluten — more often there is no justification for believing so.

Pharmaceutical companies are well aware of the commercial advantages inherent in the public perception that better-known is best. Take these comments from a major pharmaceutical company spokesman, for example:

It is not uncommon for generic and originator medicines to have different pharmacokinetics. Pharmacokinetics describes the absorption, distribution, metabolism and elimination of the drug from the body. This can mean possible clinical differences between use of originator and generic medicines. The effects of changing from an originator to a generic (or vice-versa) would ultimately depend upon different patient circumstances and would always be at the discretion of a patient's physician. (Excerpt of an email received from a representative at Novartis Pharmaceuticals in November 2002, in response to an inquiry about two of their post-patent products and identical alternatives. Subsequent unattributed quotations are from personal communications and/or interviews.)

The use of consumer-unfriendly terminology such as 'pharmacokinetics', coupled with the

catch-all qualification that it is up to the doctor's discretion, would be sufficient to deter many patients from using the generic.

The mere fact that the Therapeutic Goods Administration (TGA) deems a generic product to be bio-equivalent or therapeutically equivalent to the originator does not seem to be enough to convince all doctors and pharmacists to suggest patients take alternative brands.

There is no doubt that brand loyalty and big-dollar promotions play a part in maintaining an originator's post-patent drug market share, but the public perception of generic drugs as being the lesser product has to be a major contributing factor. Health is something most people do not economise on, and if we are sick we are inclined to do whatever it takes to get better. This extends to purchasing medicine. People often prefer to rely on the 'tried and tested' brands that they know will make them better rather than take a brand they do not know.

According to the federal Health Department, generics accounted for 18% of total PBS prescriptions for the 2002–03 financial year. The generics industry itself says its share of the market is more than this. According to the executive director of the Generic Medicines Industry Association, Di Ford, generics account for 23% of prescriptions, by volume, and 12% in terms of value. Whichever figures are right, the use of generics in Australia is low compared with the United Kingdom, where generics account for about 50% of prescriptions, and to the United States and Canada, where generics make up between 40% and 45% of the market.

Australia's relatively low use of generics is explained partly by historically small price differentials between brand and generic products (Lofgren 2004). An important factor is also that Australian doctors do not generally prescribe drugs 'generically' (by their scientific name — as in the UK) but by the brand name. Also, Australia's predominant bulk purchaser, the federal government through the PBS, has not as yet sought to systematically give preference to the cheapest generic alternatives

through mechanisms such as tendering, as is the practice in New Zealand (see Davis in this issue *page 171*).

### **Generics as cross-licensed ‘fighting brands’**

Pharmaceutical suppliers have been able to charge brand price premiums since December 1990, provided at least one brand is at the benchmark price. As well as allowing pharmaceutical companies greater flexibility in the pricing of their products, the brand premium policy, according to the Pharmaceutical Benefits Pricing Authority,

... has the effect of making it possible for prescribers and patients to be more aware of the price of drugs. The policy also allows companies to establish prices taking into account competition and the heightened consumer awareness of price differentials. (PBPA 2003, p. 6)

Put simply, brand price premiums are meant to make consumers aware of how much they pay for their medicines, as well as encourage the development of the generic pharmaceutical industry in Australia. More than a decade after the introduction of this policy, its effectiveness on these two fronts is still debatable.

As of May 2003 there were 303 products with a brand price premium, ranging from 6 cents to \$79.48. (Blenoxane, Bristol-Myers Squibb's brand of bleomycin sulfate, used for lymphoma, is the PBS item with the \$79.48 brand price premium). There were 32.6 million prescriptions dispensed in the 12 months to May 2003 with the weighted average brand premium being \$1.57. This means Australians paid \$51.2 million to stick with the big name brands when generic alternatives were available. For the same period, there were 943 products at the benchmark price, for which there were 37.8 million prescriptions (PBPA 2003). Where consumers had the choice between buying a brand at the benchmark price or a higher priced brand, in 46% of cases consumers decided to do the latter. If price alone were the major factor in

the purchasing of pharmaceuticals, brands at benchmark prices (including generics) would surely have a much higher percentage of the market. The fact that this is not the case seems counter-intuitive, but it goes to show how differently consumers behave when it comes to purchasing pharmaceuticals, compared with other retail products.

Fervent believers in generic pharmaceuticals would no doubt maintain that paying brand price premiums is a waste of money. They would be dismayed to learn that just 10 drugs, for which there are identical, cheaper, alternatives, account for almost 30% of the total brand price premium collected every year.

### **“This is not the business of any newspaper”**

In late 2002 I was working as a federal politics reporter for the *Herald Sun* newspaper in the Press Gallery of Parliament House in Canberra. The health portfolio was a particular focus for me, and I took special interest in the PBS. In October 2002, I received an anonymous fax that named about 20 well-known drug brands and their ‘cross-licensed alternatives’. Not knowing what a cross-licensed alternative was, I made a few calls. A contact told me the cross-licensed products were identical to the big-name drugs listed in the fax (which included Ventolin, Prozac, Zovirax and Losec) but were cheaper. The contact described these repackaged identical alternatives as ‘pseudo-generics’, saying they only existed to fight the true generics and, in some cases, to delay the entry of competitors into the market. Further investigations (and another anonymously supplied document) suggested there were more than 70 items on the PBS that had ‘fighting brands’ or pseudo-generics. While in some cases there were no differences in price between originator and pseudo-generic, the majority of originators had brand price premiums. This was the category of greatest interest. The suppliers of these 70-plus originator products were asked the following questions:

# **I PBS items that have cross-licensed alternatives marketed as generic equivalents, as of May 2004**

Generic name	Big name brand	Alternative brand	Treatment	Saving per script
Felodipine	Agon (TP)	Felodur (AL)	high blood pressure	\$8.50
Brimonidine tartrate	Alphagan (AG)	Enidin (PE)	chronic glaucoma	\$1.22
Naproxen sodium	Anaprox 550 (RO)	Crysanal (MD)	anti-inflammatory	\$3
Cyproterone acetate	Androcur (SC)	Cyprostat (SV)	androgenisation in women; reduction of male sexual urge	\$1.00/\$3.28*
Ipratropium bromide	Atrovent (BY)	Ipratrin (AF)	asthma and bronchitis	92c/96c*
Amoxycillin with clavulanic acid	Augmentin (GK)	Clamoxyl (ME)	antibiotic	96c/98c/99c/\$1.30*
Moclobemide	Aurorix (RO)	Mohexal (HX) & Arima (AF)	depression; panic disorders; phobias	95c/\$1.93*
Betaxolol hydrochloride	Betoptic (AQ)	BetoQuin (IQ)	glaucoma	\$2.01
Norethisterone with ethinyloestradiol	Brevinor (PH)	Norimin 28 Day (KR)	contraceptive pill	\$7.96
Norethisterone with ethinyloestradiol	Brevinor-1 (PH)	Norimin-1 28 Day (KR)	contraceptive pill	\$7.96
Captopril	Capoten (BQ)	Acenorm (AF)	blood pressure/kidney & heart conditions	\$2.45/\$2.46*
Diltiazem hydrochloride	Cardizem (AV)	Vasocardol (HP)	angina	\$2.64/\$3.20*
Cefaclor	Cecilor (LY)	Keflor (AF)	bacterial infections	\$1.03/\$1.04/\$1.05*
Ciprofloxacin	Ciloxan (AQ)	CiloQuin (IQ)	bacterial skin infections	\$2.48
Clindamycin	Dalacin C (PH)	Cleocin (KR)	antibiotic	\$1.47
Methyprednisolone acetate	Depo-Medrol (PH)	Depo-Nisolone (KR)	anti-inflammatory	74c
Medroxyprogesterone acetate	Depo-Provera (PH)	Depo-Ralovera (KR)	cancer; endometriosis; long-acting contraceptive	\$3.36
Paraffin	Duratears (AQ)	Poly Visc (IQ)	severe dry-eye syndrome	\$2
Erythromycin	Eryc (MX)	DBL Erythromycin (FA)	antibiotic	\$1.20
Timidazole	Fasigyn (PF)	Simplotan (GP)	antibiotic	\$2.50
Metronidazole	Flagyl (AV)	Metronide (HP)	antibiotic	\$1.98/\$2.07*
Flutamide	Fugerel (EX)	Eulexin (SH)	hormonal treatment for advanced prostate cancer	\$49.39 (I)
Azathioprine	Imuran (GK)	Thioprine (AF)	immune suppressant	\$1.50
Verapamil hydrochloride	Isoptin SR (AB)	Anpec SR 240 (AF)	blood pressure	\$1/\$2*
Cephalexin	Keflex (LY)	Ibilex (AF)	bacterial infections	\$1.26/\$1.28/\$1.37*
Triamcinolone acetonide	Kenacomb Otic (BQ)	Otocomb Otic (BC)	ear drop anti-infective	\$1.10
Polyvinyl alcohol	Liquifilm Tears (14mg) (AG)	PVA Tears (PE)	severe dry-eye syndrome	\$1.22
Polyvinyl alcohol	Liquifilm Forte (30mg) (AG)	PVA Forte (PE)	severe dry-eye syndrome	\$1.22
Diphenoxylate hydrochloride	Lomotil (PH)	Lofenoxal (KR)	diarrhoea	\$1.84
Gemfibrozil	Lopid (PF)	Jezil (AF)	cholesterol	\$3.49
Omeprazole magnesium	Losec (AP)	Acimax (AL)	peptic ulcer	\$1.50
Levonorgestrel with ethinyloestradiol	Microgynon 30 ED (SC)	Levlen ED (SY)	contraceptive pill	\$9.88
Naproxen	Naprosyn SR (RO)	Proxen SR (MD)	anti-inflammatory	\$1.68/\$1.77*
Levonorgestrel with ethinyloestradiol	Nordette 28 (WV)	Monofeme 28 (WX)	contraceptive pill	\$9.24
Norethisterone	Noriday 28 Day (PH)	Locilan 28 Day (KR)	contraceptive pill	\$4
Temazepam	Normison (SI)	Terntabs (FM)	sedative	\$1.06/\$2.12*

Generic name	Big name brand	Alternative brand	Treatment	Saving per script
Norfloxacin	Noroxin (MK)	Insensye (FR)	urinary tract infection	\$2 (2)
Piperazine oestrone sulfate	Ogen (PH)	Genoral (KR)	hormone replacement therapy	\$1.48/\$1.49*
Ketoprofen	Orudis SR 200 (AV)	Oruvail SR (HP)	osteoarthritis; anti-inflammatory	\$1.80
Bromocriptine mesylate	Parlodol (NV)	Kripton (AF)	Parkinson's disease/ prevent breast milk	\$3
Felodipine	Plendil (AP)	Felodur (AL)	high blood pressure	\$2.65/\$2.95/\$4.30*
Medroxyprogesterone acetate	Provera (PH)	Ralovera (KR)	endometriosis; HRT	\$1.65
Fluoxetine hydrochloride	Prozac (LY)	Lovan (AL)	depression	\$4.10
Pilocarpine hydrochloride	PV Carpine (AG)	Pilopt (PE)	chronic glaucoma	\$176/\$1.87/\$1.88/ \$1.91/\$2*
Ramipril	Ramace (ML)	Tritace (AV)	high blood pressure; heart failure	\$4/\$4.01*
Mirtazapine	Remeron (OR)	Avanza (BP)	antidepressant	\$21.51 (3)
Enalapril maleate	Renitec (MK)	Amprace (AD)	high blood pressure; heart failure	69c/70c* (4)
Clonazepam	Rivotril (RO)	Paxam (AF)	epilepsy	\$4.74/\$5.36*
Isotretinoin	Roaccutane (RO)	Isohexal (HX), Accure (AF)	severe acne treatment	\$2.50
Roxithromycin	Rulide (AV)	Biaxig (HP)	antibiotic	\$2.27
Sulfasalazine	Salazopyrin-EN (PH)	Pyralin EN (KR)	Crohn's disease; rheumatoid arthritis	\$1.66
Dexamethasone with framycetin sulfate	Sofradex (AV)	Otodex (QM)	ear drop anti-infective	\$1.50
Prochlorperazine	Stemetil (AV)	Stemzine (HP)	nausea	\$1.95
Norethisterone with ethinyloestradiol	Synphasic (PH)	Improvil (KR)	contraceptive pill	\$7.96
Hypromellose with dextran	Tears Naturale (AQ)	Poly-Tears (IQ)	dry-eye syndrome	\$1.50
Levonorgestrel with ethinyloestradiol	Triphasil 28 (WY)	Trifeme 28 (WX)	contraceptive pill	\$9.24
Levonorgestrel with ethinyloestradiol	Triquilar ED (SC)	Logynon ED (SY)	contraceptive pill	\$9.88
Diazepam	Valium (RO)	Ducene (SU)	sedative	39c (5)
Salbutamol sulfate	Ventolin (GK)	Asmol unit-dose (AF)	asthma	\$2.20
Salbutamol sulfate	Ventolin CFC-Free (GK)	Asmol CFC-Free (AL)	asthma	\$1
Lisinopril	Zestril (AP)	Lisodur (AF)	blood pressure; heart failure	\$1.95
Ranitidine hydrochloride	Zantac (GK)	Rani 2 (AF)	peptic ulcer; reflux	\$2.17
Aciclovir	Zovirax (GK)	Acyclo-V (AF)	genital herpes; shingles; HIV	\$2.09/\$4.28/\$7.19*

\* depending on strength and/or amount of medication

Notes:

1 While Fugeryl is still listed on the PBS it has been discontinued in favour of promotion of Eulexin.

2 Noroxin has a brand premium of \$3.73 and Insensye's brand premium is \$1.73

3 Remeron has a brand premium of \$22.76 while Avanza's brand premium is \$1.25

4 Both Renitec and Amprace have brand premiums: Renitec, \$3.15; Amprace, \$2.45/\$2.46

5 Valium has a brand premium of \$1.30 or \$1.32 (depending on strength) while Ducene's brand premium is 91c or 93c.

AB Abbott; AD Amrad Pharmaceuticals; AF Alphapharm; AG Allergan; AL Alphapharm Medical; AP AstraZeneca; AQ Alcon; AV Aventis; BC Bristol; BP British Pharmaceuticals; BQ Bristol-Myers Squibb; BY Boehringer Ingelheim; EX Essex; FA F.H. Faulding; FM Fawns and McAllan; FR Charles E Frost; GK GlaxoSmithKline; GP GP Laboratories; HP Hoechst; HX Hexal; IQ Iloquin; KR Kenral; LY Eli Lilly MD Macarthur Research; ME Menley & James; MK Merck Sharp & Dohme; ML Marion; MX Mayne Pharma; NV Novartis; OR Organon; PE Pacific EyeCare; PF Pfizer; PH Pharmacia; QM Qualimed; RO Roche; SC Schering; SH Schering-Plough; SI Sigma; SU Sauter Laboratories; SY Schering AG; TP Therapharm; WX Wyeth Australia; WY Wyeth Pharmaceuticals.

- Who was the sponsor of these drugs?
- What is the site of manufacture of the drugs?
- Is the generic version simply a repackaged version of the originator?
- If not, what are the differences?
- Do these differences, if any, have any impact on the pharmacological and/or biological effect the drugs have on the human body?
- Would someone who is taking the originator be able to begin taking the generic without any impact on their health?
- Conversely, would someone who is taking the generic be able to begin taking the originator without any impact on their health?

Not every pharmaceutical company was helpful, but nevertheless my inquiries allowed the elimination of some brands as being identical alternatives. By the end, a list of about 60 PBS items and their associated fighting brands emerged. Box 1 shows the PBS items that have both brand price premiums and cross-licensed alternatives marketed as generic equivalents, as of May 2004. The savings per script that consumers would receive by choosing the cross-licensed product over the originator range from 39 cents to almost \$50. (Fugerel, a hormonal treatment for advanced prostate cancer, carries a brand price premium of \$49.39. While still on the PBS, it has been discontinued in favour of its cross-licensed identical alternative, Eulexin. In the 12 months to March 2004, there were no scripts issued for Fugerel, 2635 for Eulexin and 3618 for other brands. The next highest brand price premium is for the antidepressant Remeron, which has an identical alternative in Avanza. Remeron attracts a brand price premium of \$22.76, whereas Avanza has a premium of \$1.25 — a \$21.51 out-of-pocket difference. Organon, which makes Remeron, says it encourages people to buy Avanza instead of Remeron. In the 12 months to March 2004 there were 81 scripts for Remeron, 343 082 for Avanza and 178 501 for other brands.)

Secret commercial-in-confidence agreements between the originator drug company and the company that sells a cross-licensed product prevent consumers, doctors and pharmacists know-

ing that some of the products marketed and sold as generic versions of the well-known brands are actually identical to the more expensive brand. Many doctors and pharmacists may know pseudo-generics exist, but we cannot be sure they know the extent of the cross-licensing arrangements. Consumers are even more in the dark.

The only clue to a cross-licensing deal is usually on the packaging, and is a matter of the consumer inferring a connection rather than the manufacturer declaring a connection. For example, Acimax, the identical Alphapharm alternative to AstraZeneca's Losec, notes on its box that 'Acimax' is a registered trademark of AstraZeneca Pty Ltd and that Acimax is supplied by AstraZeneca for Alphapharm.

It is not an easy matter for a consumer to find out whether a generic product is identical to the medication they take. A case in point: when the TGA was asked to explain the difference between Roche's product Valium and Sauter Industries' Ducene, this was the answer I received: "The Therapeutic Goods Administration would not normally reveal information such as the manufacturer of particular products as this would be considered to be 'commercial-in-confidence'." The TGA pointed out there were three alternative brands to Valium, of which Ducene was one.

Roche has six PBS-listed drugs that have identical alternatives: Anaprox 550 (Crysanal); Aurorix (Mohexal and Arima); Naprosyn SR (Proxen SR); Rivotril (Paxam); Roaccutane (Isohexal and Accure); and Valium (Ducene). Roche's anti-acne drug Roaccutane (isotretinoin), which has a brand price premium of \$2.50, is an interesting example. Hexal Australia repackages Roche's product and sells it as Isohexal, while Alphapharm does the same and calls it Accure. The inherent cynicism of this business approach is no better displayed than in the photographs of the three branded drugs provided for the MIMS product identification guide. The photos of the 10 mg pills of each of the three brands are identical: ie, each photo shows the same image. The same is true of the 20 mg images. (Roaccutane 10 mg capsule, picture 1530; Isohexal 10 mg, 1528; Accure 10 mg, 1529; Roaccutane

## 2 Top 10 earners of brand price premium, where identical alternatives exist

Drug	Originator brands	Total brand price premium
1 Omeprazole	Losec	\$2 872 587
2 Salbutamol	Ventolin	\$2 278 692
3 Diltiazem	Cardizem	\$2 034 452
4 Enalapril	Renitec	\$1 480 324
5 Felodipine	Plendil	\$1 193 811
6 Roxithromycin	Rulide	\$1 171 098
7 Ranitidine	Zantac	\$1 121 981
8 The Pill	Various*	\$864 111
9 Verapamil	Isoptin	\$775 849
10 Lisinopril	Zestril	\$764 521

\* Nordette 28, Microgynon 30, Brevinor, Brevinor-1, Triphasal 28, Triquilar ED and Synphasic

Source: Data supplied to the author by the Department of Health & Ageing on request.

20 mg, picture 1532; Isohexal 20 mg, 1531; Accure 20mg, 1533, in *MIMS Annual 2002*, Product Identification Guide, G-28). Asked about the origins of identical alternatives to Roche's products, Roche's managing director Fred Nadjarian said: "This is not the business of any newspaper" and added that such information was for doctors and their patients. But the script volumes for isotretinoin make it abundantly clear that very few doctors — let alone patients — know that two cheaper, identical alternatives to Roaccutane exist. Figures prepared and supplied by the Department of Health and Ageing (DoHA) at my request show that, in the 12 months to March 2004, of the 127 055 scripts for isotretinoin, 74.5% were for Roaccutane, but just 3.9% were for Accure or Isohexal. (94 718 scripts were for Roaccutane, 1021 for Isohexal, 3978 for Accure and 27 338 for other brands). Twenty months before this period — the 2001–02 financial year — prescribing patterns were little different: Roaccutane accounted for 75.4% of prescriptions for isotretinoin, with Accure and Isohexal on 5.6%.

(Prescribing patterns for the 2001–02 financial year mentioned throughout this article were prepared by the Department of Health and Ageing at my request in November 2002). Roaccutane earned Roche \$236 795 in brand price premium in the 12 months to March 2004, on top of the \$14.2 million it got in agreed base price for scripts.

AstraZeneca has three PBS-listed drugs with identical alternatives: Losec (Acimax); Plendil (Agon and Felodur); and Zestril (Lisodur). This company argues that introduction of a fighting brand is a legitimate way of protecting its market share after the expiry of patents. Jeays Lilley, the managing director of AstraZeneca (Australia), said cross-licensed products can help stave off the impact of cheaper generics:

It's fundamental marketing to want to protect your share of the market that you've established over a long time through significant investment in R&D. I don't think it's a cynical approach to life. I think the facts of life are that the profits post-patent are substantially reduced.

Mr Lilley added: "The originator companies build the markets for these brands and the generic alternative is really just sold on the basis of alternative availability. Generic companies don't create markets, they feed off them."

Given that Mr Lilley sees generics as parasitic, it is no surprise that AstraZeneca's desire to protect its products from 'predation' is perhaps fiercest for its peptic ulcer/reflux drug omeprazole, which is the third-highest Government-cost drug on the PBS (\$179.6 million in 2003). AstraZeneca's originator product Losec, for which there were 1.915 million scripts in the 12 months to March 2004, is the single biggest earner in brand price premiums of all items on the PBS (Box 2). This is despite that fact that Acimax — the identical alternative sold by Alphapharm under a cross-licensing deal with AstraZeneca — now secures more than half of total scripts for omeprazole (50.1% of total scripts for the 12 months to March 2004 — Box 3). With Losec commanding a \$1.50 brand price premium, patients paid an

**3 Market share of the top 10 earners in brand price premium in 12 months to March 2004**

Drug	Originator brand	% of market	Pseudo-generic	% of market	Generic brands
1 Omeprazole	Losec	49.9	Acimax	51.0	—
2 Salbutamol	Ventolin	64.3	Asmol	31.7	4%
3 Diltiazem	Cardizem	57.0	Vasocardol	36.0	7%
4 Enalapril	Renitec	43.4	Amprace	5.1	51.6%
5 Felodipine	Plendil	24.9	Felodur	71.2	3.9%
6 Roxithromycin	Rulide	51.2	Biaxsig	48.8	—
7 Ranitidine	Zantac	32.9	Rani 2	52.5	14.6%
8 The Pill	Various*	12.6	(Various)	87.4	—
9 Verapamil	Isoptin	56.3	Anpec	39.7	4%
10 Lisinopril	Zestril	36.5	Lisodur	24.3	39.1%

\*Nordette 28 (Monofeme 28), Microgynon 30 ED (Levlen ED), Brevinor (Norimin 28 Day), Brevinor-1 (Norimin-1 28 Day), Triphasil 28 (Trifeme 28), Triquilar ED (Logynon ED) and Synphasic (Improvil). For savings per script, see Box 1.

Source: Data supplied to the author by the Department of Health & Ageing on request.

extra \$2.9 million on top of the PBS co-payment. This is profit generated by the power of branding and pharmaceutical fame, rather than from any health benefit. Put another way, concession card-holders who pay \$4.60 for PBS scripts (from January 1, 2005) pay an extra 33% if they choose, or are prescribed, Losec over Acimax.

Losec's share of the omeprazole market (49.9%) is on the decline (it was 72.4% in the 12 months to June 30, 2002), but by retaining just under half of the market share with its original product, AstraZeneca looks well placed to continue reaping big premiums on Losec in years to come. It is important to note, however, that other than Losec and Acimax there are no other brands of omeprazole. From a purely manufacturing point of view, AstraZeneca has a monopoly on omeprazole. But to counter Losec's decline, AstraZeneca has poised to step up promotion of another reflux drug, esomeprazole, which is an isomer variant of omeprazole. Importantly for AstraZeneca, esomeprazole (sold as Nexium) is still under patent and therefore has no competition, pseudo-generic or otherwise. Total scripts for esomeprazole in 2003 were 1.62 million (39.4% of total scripts for omeprazole). Government subsidy of esomeprazole scripts in 2003 cost \$81 million, making it the eleventh costliest drug under the PBS.

GlaxoSmithKline (GSK) is another pharmaceutical giant whose cross-marketed products make it many millions of dollars. GSK has two brands in the list of 10 top earners in brand price premium: Ventolin and Zantac. Ventolin (salbutamol sulfate) has a product familiarity that stretches well beyond its asthmatic target group. In commercial terms, Ventolin's familiarity and fame translate to a golden opportunity for charging a brand price premium. Ventolin CFC-free puffers attract a \$1 premium over the identical product it sells to Alphapharm (sold as Asmol CFC-free puffer). Between the two, 2.05 million CFC-free asthma puffers were sold in the 12 months to March 2004, but GSK's Ventolin-branded version secured 67.6% of the market. Asmol accounted for 30% of the asthma puffer market, with other products picking up 2.4%. It is a similar story with salbutamol nebulisers. Ventolin Nebules, which carry a \$2.20 brand price premium, were 54.7% of the PBS scripts in salbutamol nebulisers, with the identical Asmol uni-dose nebulisers on 36.8% and others on 8.5%. All up, GSK's originator branded products in salbutamol sulfate commanded 64.3% of the market in the year to March 2004, earning it \$2.28 million in brand price premium for the period. This makes it the second biggest earner in

premiums, behind Losec. Importantly for GSK, if Alphapharm's Asmol-branded puffers and nebulisers are excluded, the *real* competition (that is, true generics) is located in and arises from only 4% of the market.

Of the top 10 earners in brand price premiums, the generics' share of the market is highest for the ACE inhibitor enalapril, where the generic brands are 51.6%, compared with 43.4% for Merck Sharp & Dohme's originator product Renitec and 5.1% for the identical alternative Amprace, which is sold by Amrad Pharmaceuticals. Merck's spokeswoman Virginia Nicholls confirmed Amprace was not a generic but:

... a second brand of enalapril which we licensed to Melbourne biotech company Amrad in 1989 — well before patent expiry in 2001 — as part of a joint venture to fund Amrad's medical research. The tens of millions Amrad received from Amprace sales helped support 10 years [research and development] of new chemical entities.

Ms Nicholls said Merck believed generics had a 'valid' role to play in the market once patents had expired and also pointed out that no generic manufacturer had yet committed itself to bringing a new medicine to market:

It is important to recognise that only three in 10 medicines produce sales that match or exceed the average \$A750 million plus R&D costs. These medicines must carry the cost of the products that fail in the clinical trials and never make it to market. Amrad is actually a very good example of this: despite the revenue from Amprace and other licensed medicines, a couple of promising therapies that fell down at stage 2 trials were immensely expensive and damaging for the Melbourne biotech, and it's still recovering.

In the Schedule of Pharmaceutical Benefits booklet issued to doctors and pharmacists, Amrad Pharmaceuticals (manufacturer's code AD) has the same South Granville (New South Wales) address and telephone number as Merck. On face value, this appears similar to the cross-licensing deals struck by Aventis Pharma over Cardizem

and Rulide, both of which have identical alternatives sold by Hoechst, a division of Aventis Pharma. It is also similar to the cross-licensing deals that relate to seven brands of contraceptive pills: Pharmacia's Brevinor, Brevinor-1 and Synphasic are up against pseudo-generics sold by Kenral (a division of Pharmacia that shares its address and telephone number); Wyeth Pharmaceuticals' Nordette 28 and Triphasil 28 sit alongside identical alternatives sold by Wyeth Australia; and Schering's Microgynon 30 ED and Triquilar ED compete with pseudo-generics sold by its parent company Schering AG (again, same contact details for both).

Premiums on these seven brands of oral contraceptive pill remain a big earner for Wyeth, Schering and Pharmacia, even though the identical alternatives now well and truly outsell the originators. This is because their brand price premiums are in the higher range, starting at \$7.96 a script and going as high as \$9.88 (as of May 2004). In the 12 months to March 2004, these contraceptives earned their companies a total of \$864 111 in premiums, despite being only 12.6% of the 815 079 scripts for the drugs. The overall use of these seven contraceptives — originator or cross-licensed product — is on the decline: in the year to June 30, 2002, there were just under 906 000 scripts for the drugs, of which 18% were for the originator drug. The total of premiums paid for that period was \$1.4 million.

Analysis of the prescription patterns for the top 10 earners in brand price premiums shows how successful cross-licensing deals can be in limiting the influence of generics. Of the top 10 originators, three do not have any generic competition at all, other than the pseudo-generics (Losec, Rulide and The Pill) and of the other seven, four have kept the generics' share of the market at 7% or less (Ventolin, Cardizem, Plendil and Isoptin). All up, generic competitors with the top 10 biggest earners in brand price premiums secured just 9.5% of the market, with 1.49 million of the 15.6 million scripts in the 12 months to March 2004. The originators accounted for 7.23 million of the scripts (46.3%) and pseudo-generics were on 6.89 million scripts (44.1%).

Brand price premiums are not the consumer's friend. This is not only because they mean patients pay more for originator medicines when an identical alternative exists, but also because brand price premiums go hand-in-hand with cross-licensing deals that are used by pharmaceutical companies to minimise competition from generics. By installing a pseudo-generic by means of a cross-licensing deal, companies can make it financially unattractive for generic companies to move in on the market with their own version of the drug compound. In such cases, brand price premiums effectively become a way for pharmaceutical companies to offset profit losses that arise from the striking of cross-licensing arrangements for the pseudo-generic.

The market entry of fighting brands sees the taxpayer subsidy of post-patent PBS items fall. On the face of it, this satisfies the Federal Government's desire to keep costs down. But when fighting brands are established alongside brand price premiums for the originator, an end result could be the delayed entry of generic competition, especially where brand price premiums are being used to offset losses following patent expiry. Given that drug prices fall according to the amount of competition, the onus lies with the Government to create the right environment for generic competition. This is perhaps even more important when the only 'competition' is a pseudo-generic. (The Australia Institute's paper *A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement*, November 2003, cites US Congressional Budget Office estimates that when there is one to 10 manufacturing and distributing a particular drug, average prices are 40% lower than the brand name price. Where there are more than 10 competitors, the average generic prescription price is less than 50% of the brand name price. [Lokuge, Faunce & Denniss 2003])

In June 2005, Merck's Australian patent protection for its best-selling cholesterol-lowering drug simvastatin will expire. This will be one of the most significant patent expiries in the PBS's history. Merck currently sells the drug under the brand name Zocor. (Simvastatin is also sold in Australia as Lipex by Amrad Pharmaceuticals, similar to the

commercial relationship between Merck and Amrad and their products Renitec and Amprace.) Globally, simvastatin sales are massive. In 2000, simvastatin sales were worth \$US5.28 billion and in Australia simvastatin is the second-highest cost to the PBS. The 5.2 million Australian scripts for simvastatin in 2003 cost taxpayers \$311.4 million. Another lipid-lowering drug, atorvastatin (sold as Lipitor by Pfizer), is the single biggest cost to taxpayers: total script subsidies for atorvastatin amounted to \$337 million in 2003. In order to protect simvastatin from generic competition for as long as it can, Merck has entered a cross-licensing deal with generic drugs company Arrow Pharmaceuticals. Beginning on November 1, 2004, Arrow will have eight months to cement its fighting brand before any other potential competitor is allowed entry into the market. In the UK, where Merck's patent for simvastatin expired in May 2003, nine companies were granted marketing authorisation for generic equivalents. So much competition saw one British analyst predicting the price of simvastatin could fall by 90%. In Germany, where simvastatin's patent also expired in May 2003, the AOK health insurance group said the drug would be 43% cheaper as a result of its deal with generics company Hexal (Anon 2003).

Simvastatin's patent expiry in Australia will affect the prices of other statins listed on the PBS, including Lipitor and Pravachol (Bristol-Myers Squibb's brand for pravastatin, the sixth-highest Government cost drug on the PBS, at \$108.5 million in 2003), even though their patents are yet to expire. This is because they are within the same reference group, meaning that their prices are referenced to the cheapest product within the particular therapeutic class of medicine. The chief executive of Alphapharm, John Montgomery, told the *Australian Financial Review* that he expected the prices of statins to fall by 30% after June 2005 (Mellish 2004). The newspaper estimated this would be a saving to Government of about \$250 million a year.

The patent expiry of statins will provide an excellent opportunity for the Health Department to review its brand premium policy. Brand premiums are likely on the originators' products and, given

the interest of generics manufacturers overseas in the statin market, the real test will be whether the cross-licensing deals will stave off generic alternatives. For the government and the consumer, this would be bad news.

It is ironic that producers of originator pharmaceuticals are quick to question the quality of generic alternatives when they may themselves be the suppliers of competing products. Brand price premiums, while good for the pharmaceutical industry's bottom line, discourage confidence in generic products deemed interchangeable, by inadvertently promoting the perception that they are second-rate derivatives of the originator product. And while brand price premiums do not hurt Australia's biggest purchaser of pharmaceuticals — the federal government — they do eat into consumers' budgets, often for no more benefit than peace of mind and confidence in the familiar.

The brand premium policy — as it stands now — allows manufacturers to list a pseudo-generic at the current price and place a premium on the originator, even if it is still under patent. This does not result in any savings to Government, and lumps patients with extra costs.

### So what are the alternatives?

Mandating price reductions upon the introduction of an alternative brand is one option. By stipulating that alternative brands must be priced at a certain percentage below the originator or benchmark price, savings would flow to both the consumer and to the government, regardless of whether the alternative brand is a pseudo-generic or a generic. This approach would also work when the originator product is still under patent.

Helpful to the development of policy would be to know how often doctors tick the 'do not substitute' box on their patients' scripts. Surprisingly, the Health Insurance Commission does not keep such data, even though it would shed much light on medical professionals' level of brand loyalty. A spokesman for the Health Insurance Commission, however, said that such information was considered a privileged communication

between the doctor and the pharmacist: "We have no means of collecting or capturing that information: that is a policy set by the Health Department." This policy needs revisiting.

Government embrace of the 'medicines not brands' way of thinking could take many forms. Generic prescribing — that is, the prescription of drugs by their chemical compound — would be the most obvious way of countering the brand culture. More controversial would be the introduction of practice incentive payments for doctors and pharmacists who prescribe or recommend generics. Without policy change, Australia will continue to see emphasis on big-name pharmaceuticals, resulting in market and consumer manipulation and the suppression of true competition.

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