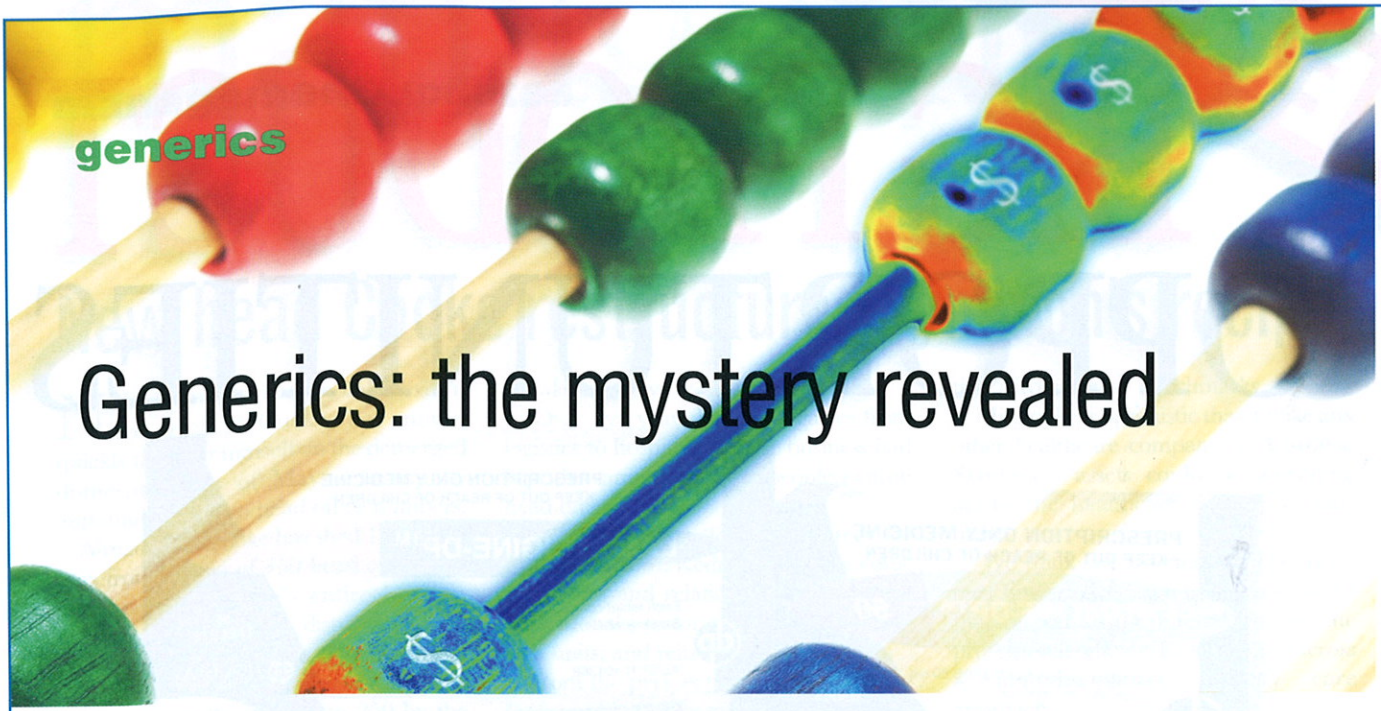


# Generics: the mystery revealed

Concerns about the sustainability of the PBS has seen the Federal Government force structural change, including mechanisms aimed at increasing the use of generic medicines. MARK NICHOLSON* discusses what these changes mean to the business of pharmacy and why it should respond

WITH ink hardly dry on the Fourth Community Pharmacy Agreement, the Government's attention has now turned to the issue of generic medicines. Unfortunately, the Government's view of health is as a cost centre and this will not change so long as the PBS continues to rise and Treasury officials remain focused on the 2002 *Intergenerational Report*.

Generics offer the Government its next big cost saving opportunity and the issue is not likely to go away while new entrants into the Australian generics arena plot to obtain a piece of the growing market. This is, in part, because the generic distribution channel is difficult for a new player to crack—there are well-established, long-term operators who have strong alliances with wholesalers and pharmacies alike, and it is time-consuming to negotiate deals with approximately 5,000 independent pharmacy owners.

For pharmacists though, generics (despite the 12.5 per cent price claw back first introduced in August 2005) represent the one clear opportunity pharmacy has to replace declining prescription volume growth. This contribution is clearly reinforced by the information in Table One sourced from the dispensary reports of four Johnstone Rorke (JR) clients, that compares the three months ended 31 October 2005 with same period in 2004.

Therefore, these pharmacies have marginally increased dispensary profitability throughout the last four months despite an average decline in script volume of more than 4 per cent (which accords with recent Government PBS data).

The reasons follow:

- generic discounts have increased through competition;
- pharmacists have increased generic substitution rates as patents have expired and the focus on substitution has increased; and
- fixed dispensing fee increases the GP

**Table One: Client Data Average—sample of four pharmacies**

| | 2004 Aug to Oct Average | 2005 Aug to Oct Average | Change |
|---|---|---|---|
| Sales | $901,934 | $861,375 | (4.50)% |
| GP$ | $256,455 | $260,070 | 1.41% |
| GP% | 28.43% | 30.19% | |
| Rx No. | 27,001 | 25,645 | (5.02)% |
| Average script value | $33.40 | $33.59 | 0.57% |

Note: all data is derived from a point-of-sale system which accurately reports true dispensary gross profit (GP)— that is, net of all discounts. The sample pharmacies are reasonably sized located in Queensland, Victoria and Tasmania.

percentage after the 12.5 per cent clawback.

To illustrate this point in more detail, Table Two compares the financial impact of the 12.5 per cent reduction on a branded drug and generic drug while also highlighting the financial incentive for the pharmacist attached to switching a patient.

Accordingly, the question arises as to whether the wholesalers, and indeed the manufacturers, will absorb the additional costs or eventually pass them through to pharmacy.

The financial pressure (evident from Table Two) to replace falling dispensary GP dollars with generic GP dollars is systemic and will not subside. This becomes clearly evident once the drivers of future change are closely analysed.

- The Government's Fourth Agreement offer started at $11.75bn over five years and was finalised at $11.1bn, plus the estimated $500m for professional pharmacy programs (plus $60m left over from the Third Agreement).
- My estimates indicate that pharmacy was paid approximately $1.9bn in the final year of the last agreement (which equates to pharmacy only receiving a compounding 2 per cent per annum remuneration increase).
- That is despite the Government forecasts within the agreement estimating a compounding 3.9 per cent per annum increase (21 per cent over five years) in script numbers and JR client averages indicating pharmacy expenses continue to grow at around 6 per cent per annum.
- Further costs are being removed from the supply chain through the wholesaler mark-up reducing from 11.1 per cent to 7.5 per cent from 1 July 2006 (although initially from the wholesaler's perspective, it is hoped to be largely offset by the $150m Community Service Obligation payment pool).

In summary, costs are growing faster than revenue and over time it would be expected that there will be some change to wholesaler service levels and, ultimately, trading terms.

These changes are all aimed at further flattening the PBS expenditure growth curve despite the fact that the patient co-contribution increases introduced on 1 January (patients started paying 15 per cent more than the previous year) achieved that aim, with the more recent 12.5 per cent generic clawback actually causing a decline.

In addition, the co-contribution effect reduced customer numbers and caused an immediate fall in pharmacy front-of-shop sales. It now appears the retail deflators of rising petrol prices and falling housing prices have exacerbated the decline in front-of-shop sales. The Australian Bureau of Statistics retail data for 'All Industries', and the sub-sector of 'Pharmaceutical, Cosmetics and Toiletries' (see Figure One) and shows in stark contrast how the industry is out of step with the general retail trend in Australia.

Against this backdrop you may be excused for thinking that the pressure for further PBS cost reductions would have abated but, as reported in the 6 Decem-

**Table Two: Financial impact of 12.5% reduction on branded and generic drug**

**Impact on sales$ and GP$—Branded Item**

| | pre 1/8 ($) | now ($) | change ($) | |
|---|---|---|---|---|
| LIPEX 40 | 66.70 | 58.36 | (8.34) | |
| + Mark-up | 6.67 | 5.84 | (0.83) | |
| + Fee | 4.75 | 4.75 | – | |
| Sale value | 78.12 | 68.95 | (9.17) | (11.7)% |
| Gross profit $$: | | | | |
| Fee + mark-up | 11.42 | 10.59 | | |
| W/Saler discount (assume 5%) | 3.33 | 2.92 | | |
| GP$ | 14.75 | 13.51* | (1.24) | (8.4)% |
| GP% | 18.9% | 19.6% | | |

**Impacts on sales$ and GP$—Generic Item**

| | pre 1/8 ($) | now ($) | change ($) | |
|---|---|---|---|---|
| Simvahexal 40 | 66.06 | 57.81 | (8.25) | |
| + Mark-up6 | .61 | 5.78 | (0.83) | |
| + Fee | 4.75 | 4.75 | – | |
| Sale value | 77.42 | 68.34 | (9.08) | (11.7)% |
| Gross profit $$: | | | | |
| Fee + mark-up | 11.36 | 10.53 | | |
| Generic incentive (assume 30%) | 19.82 | 17.34 | | |
| GP$ | 31.18 | 27.87* | (3.31) | (10.6)% |
| GP% | 40.3% | 40.8% | | |

(NB: The dispensing fee used in the above calculation excludes the increase flowing from the new Agreement)

Which means in summary:

| | Generic | Brand |
|---|---|---|
| Consumer saves | nil | nil |
| Brand + wholesaler lose | | (7.93) |
| Generic manufacturer loses | (5.77) | |
| Pharmacy loses | (3.31) | (1.24) |
| Government saves (per above) | $9.08 | $9.17 |

***Note:** In this example the real impact of generic substitution is to double GP$/Profit

ber 2005 *Australian Financial Review*, an interdepartmental committee is considering four options aimed at extracting further savings of up to $850m a year via the generics market.

At 30 June 2005 the generic medicines market was estimated (refer Genepharm Australasia estimates per annual report) to be worth $1bn out of a possible $2.5bn and growing to around $2bn in 2009. If the *Australian Financial Review* is correct and the Government is able to extract a further $850m from the market, this equates to 42.5 per cent of the 2009 market size estimate or, alternatively represents $170,000 per pharmacy per year to be extracted. Much of community pharmacy would not survive in its current format.

Before extracting savings, the equally difficult proposition for the Government is how the substitution rate can be increased at a faster rate. Whether it be for ethical concerns or consideration of patient trust when it comes to advising customers to switch medicines, pharmacists may find it difficult to match substitution rates of other first-world countries without appropriate customer incentives. Accordingly, do not be surprised if the Government moves to provide customers a greater financial incentive, (apart from the existing Brand Price Premium, Therapeutic Group Premium and Special Patient Contribution methods) to switch.

As a guide, substitution rates for the year ended 30 June 2005 approximate the following:

| | % of $ | % of Rx |
|---|---|---|
| Canada | 14% | 40% |
| United States | 12% | 60% |
| United Kingdom | 18% | 52% |
| Australia | 14% | 26% |

The above information has been extracted from the Genepharm annual report and is based on IMS Retail Drug Monitor and Genepharm Australasia estimates. Further information is available from their annual report and website at www.genepharm.com.au.

Besides indicating how much opportunity exists in Australia to increase substitution rates (and hence the market growth/competition to come) the above table also confirms the efficiency of the Australian PBS. Why? Because in the US, Branded Pharma only account for 40 per cent of scripts dispensed yet take 88 per cent of the drug costs, whereas in Australia they have 74 per cent of scripts and 86 per cent of the costs.

By way of anecdotal confirmation regarding substitution levels, a Johnston Rorke client extracted data for the three months ended October 2004 and 2005, identifying the scripts dispensed with a product from his four highest generic suppliers. The substitution rate against total items dispensed increased from 22.5 per cent to 27.2 per cent over that period. Generic discounts now represent approximately 40 per cent of his net profit !

While it is clear that generics can replace the remuneration lost in the recent agreement (estimated by various commentators to be about $20,000 for a $2m turnover pharmacy), it is concerning that measuring substitution rates cannot be done easily or accurately. While our client's exercise was simple enough, it does not measure a substitution rate against only items that can be substituted.

Accordingly, pharmacists should be lobbying their dispense and point-of-sale suppliers to enable reporting of two important KPIs:

- items substituted against total substitutable items (as both dollar and percentage); and
- items substituted against total items dispensed.

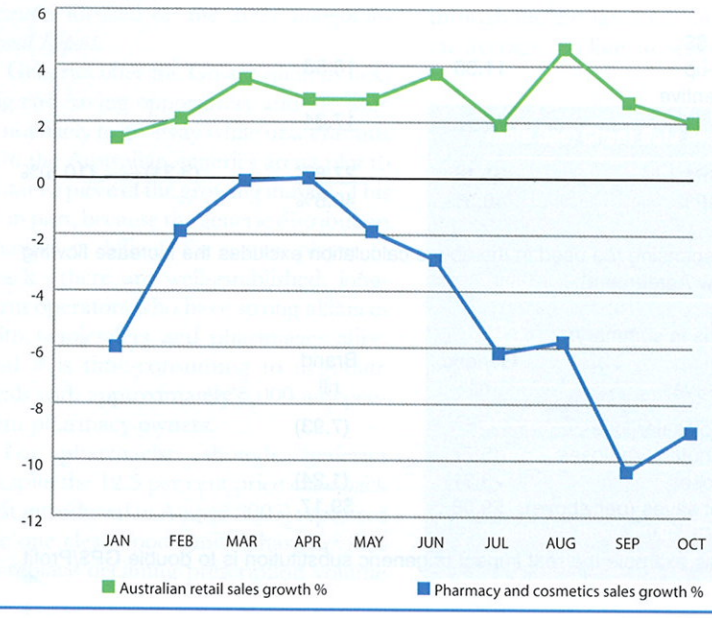
While many pharmacists often quote their substitution rate as that calculated by their generic manufacturer, it is inaccurate as it only represents the percentage of items substituted against the product range carried by that manufacturer. In addition, this exercise is spasmodic and certainly not available on a regular basis. However, at least one of the generics manufacturers now provides a monthly service to extract the dispense data on a memory stick to assist with measuring improvement for the purpose of providing incentives/rewards/additional savings.

Clearly pharmacists will continue to be challenged when it comes to the issue of generics. The participants are increasing, as are their offers to encourage switching and/or brand loyalty. Recent changes to the market place include:

- Sigma/Arrow merger;
- Sandoz-Hexal global merge and API alliance;
- Alphapharm direct to consumer marketing; and
- new entrants Bellwether Pharma and Genepharm.

As such, it is imperative pharmacies position themselves and their generic supply relationships to achieve both short and long-term benefits for the business and

**Figure One: 2005 Australian retail growth**




Source : ACRS Retail Trends

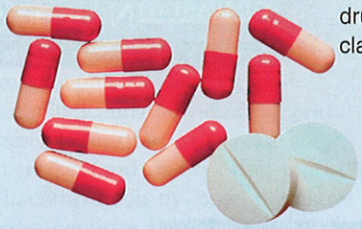
generics

# Bioequivalence: the generic facts

by Mark Hutchings, business development and regulatory manager, Douglas Pharmaceuticals Australia Ltd

TWO medicines containing the same dose of active ingredient are bioequivalent if the rate and extent of absorption of the active ingredient are similar to such a degree that their clinical effects can be expected to be essentially the same. Tests are carried out using an analysis of variance and calculating a 90 per cent confidence interval for the average of each pharmacokinetic parameter, which must be entirely within the 80 per cent to 125 per cent boundaries.

It is sometimes incorrectly claimed that the 80 per cent to 125 per cent limits for the 90 per cent confidence interval mean that there can be a substantial variation in bioavailability between a generic product and the original brand product. However, because the mean of the bioequivalence study data lies in the centre of the 90 per cent confidence interval, the ratio of the means of the data for the generic product to the original brand product is usually close to 100 per cent (a generic/original ratio of 1).



The US Food and Drug Administration's Office of Generic Drugs has conducted two large surveys to quantify the differences between generic and original brand products. The first, conducted on 224 bioequivalence studies submitted during 1985 and 1986, found an average difference of only 3.5 per cent with respect to AUC (Area Under the plasma Concentration versus time curve). The second survey, involving 127 bioequivalence studies submitted to the FDA in 273 applications approved in 1997, found average differences of only ± 3.25 per cent for AUC(0-inf) and ± 4.29 per cent for Cmax (maximum plasma concentration).

This data clearly demonstrates that the current regulatory guidelines are adequate for ensuring that generic products perform as required.

The FDA's review in 1997 concluded: 'Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred.' It also stated: 'Any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another'. Also: 'Additional clinical tests or examinations by the healthcare provider are not needed when a generic drug product is substituted for the brand-name product...It is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class...'.

In other words, irrespective of the therapeutic class, a bioequivalent generic product can be dispensed with confidence in place of the original brand product.

There are several factors, apart from the formulation of a product, which can affect blood concentrations and the clinical effectiveness of a medicine, and pharmacists must be aware of these factors.

For example, changing meal times in relation to the time of dosing can produce variations in blood concentrations for some medicines; storage of some carbamazepine and phenytoin formulations in hot, humid conditions can reduce bioavailability up to 50 per cent; and diurnal changes in gastrointestinal physiology can affect the disintegration of sodium valproate enteric-coated tablets, thereby reducing night-time drug concentrations 30 to 40 per cent compared with day-time values.

Any pharmacist concerned about generic substitution should be more concerned about these other factors which can affect blood concentrations.

The bottom line is that generics can be trusted. However, as with all medicines, patients must be adequately counselled to ensure correct storage and correct dosing.

their customers. The next 12 months will continue to see community pharmacy come to terms with a new paradigm; a good location, high dispensary traffic, helpful staff and minimising expenditure is no longer enough to guarantee growth.

In fact, without turnover growth, my estimates indicate the average pharmacy will need to increase generic substitution by more than 50 per cent from current levels during the next five years (ignoring the impact of any further Government generic claw-back policies) if profits are to remain at their current levels (inflation adjusted).

In order to achieve profit growth, pharmacies will need to develop generic policies and retail strategies that are customer relevant.

The low-price/low-cost operators (there will eventually be only one winner) will continue to pressure margins, which is why differentiated models built around providing healthcare solutions and driven from the dispensary prescription traffic must be developed.

Unfortunately the Fourth Agreement will deliver little or no net profit growth without a significant increase in script numbers. The Government, however, will remain vigilant in dampening script demand.

Generics present a short-to-medium-term opportunity to grow dispensing profits which can be used to offset pharmacy operating cost increases. Therefore, investing now to create new retail healthcare income streams is essential!

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