PERSONAL VIEW

Savings from generic drug substitution in South Africa — an arithmetical view

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This paper examines what scale of savings would result if generic substitution, proposed under Section 22F of the Medicines and Related Substances Control Amendment Act of 1997,[1] were to be introduced in South Africa. It also examines whether the savings should be treated as such when weighted against any possible negative consequences generic substitution may have.

Generic substitution and its savings

A generic product is one that has exactly the same active ingredient(s) as the existing branded (original) product. Generic substitution is the replacement by a pharmacist of a drug or medicine prescribed by a doctor with an alternative drug or medicine of the same active chemical composition. It is very different from the use of generic drugs or from the prescription of such drugs by a doctor (generic prescribing), since it empowers a person not actively involved in diagnosis and treatment to change the treatment from one product to another. To determine the level of savings from generic substitution the present study used the same data sources and a methodology similar to the one employed in a study by Scott and Reekie in 1987.[2] The data for the study consisted of the 200 drugs with the greatest sales value for the year 2001 as recorded by the pharmaceutical industry's primary data collector, Intercontinental Medical Statistics, and referred to ethical (prescription-based) products sold in the private sector. These drugs covered 53% by sales value of the ethical drug market in South Africa. The generic products among these drugs were identified by comparing all drugs listed in the 2001 year-end copy of the *Monthly Index of Medical Specialities* (*MIMS*) with one another in order to determine the drugs with the same active ingredients. Savings were determined by applying the percentage difference in price between the cheapest generic and its branded counterpart (for the same strength, pack size, and dosage) to that product's sales value as detailed in the database of the top 200 drugs. Mathematically this is equivalent to calculating the total savings (S) as the summed (Σ) difference in expenditure (at ex-factory prices) between the highest (P^h) and lowest (P^l) price of the generically substitutable product (i) as applied to its total quantity (Q^t) traded assumed to be made up of the pack size for which the extremity in price difference holds.

Simply put:

$$S = \sum_{i=1}^{N} (P^h_i - P^l_i).\ Q^t_i$$

The data used did not include sales of ethical products by provincial (state) hospitals and clinics. However, since these organisations have practised generic prescribing for many years it was considered that the practice of generic substitution would not produce savings in this area. A number of the ethical drugs incorporated in this study can be sold over the counter (OTC), that is without a prescription from a doctor. Since generic substitution relates to the substitution of a product prescribed by a doctor with another product, those drugs already sold OTC will not be substituted. Because of this factor, the savings calculated here from the total submission of all drugs with generic equivalents would exaggerate the savings that would be attained in practice. There would also be another reason for this, namely that not all pharmacists would wish to change a doctor's prescription, nor would all patients be agreeable to changes.

With total substitution of sales of all lower-price (cheapest) drugs in all possible instances — involving in total 46 products — the total savings for the 200 top-selling ethical drugs were found to be 6.1% of their total sales value. This percentage saving is made up of 4.14% of the total sales value (Table I) from the first 100 products and 1.96% from the second 100 products. As indicated by Scott and Reekie[2] and Reekie and Allen[3] this is expected in view of generic manufacturers 'cherry-picking' best sellers. Given the rapid reduction in the proportion of generic product savings as sales values decrease,

Table I. Potential savings broken down by product rank categories

First 100 largest sales value products (Rands)	214 512 471
Second 100 largest sales value products (Rands)	101 696 748
Total savings for the 200 products (Rands)	316 209 219
Savings as % of total sales for top 200 products	6.1
Total number of products that produced above savings (*N*)	46

Calculated from raw data. Estimates are at ex-factory prices.

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Table II. Real health care costs (index 1993 = 100)

Components	1993	1994	1995	1996	1997	1998	1999	2000
Medicines	100.0	89.6	95.3	100.6	79.3	91.4	98.1	94.6
Hospitalisation	100.0	106.9	119.4	123.3	140.7	141.7	157.5	157.0
GPs	100.0	97.6	106.0	110.7	113.8	106.1	109.3	93.6
Specialists	100.0	104.6	114.1	126.1	120.7	123.1	134.3	131.7
Dentists	100.0	95.3	97.6	89.7	83.6	77.1	78.4	64.8
Administration	100.0	103.2	119.9	146.5	132.4	165.5	202.3	242.0

Sources: [6,7]
Actual values deflated by the medical and health expenses CPI (1993 = 100).

it is reasonable to assume that the level of savings from generic substitution will be even lower in percentage terms for the remaining 47% of the market not investigated. A reasonable estimate of the maximum savings to be expected from generic substitution throughout the whole market can therefore also be obtained (conservatively) by using the value of 1.96% for the remainder of the market. This again exaggerates the potential savings for the reasons outlined above. Application of this value to the remaining 47% of the ethical drug market yields a savings value of R91 498 758, giving an overall savings estimate of R407 707 977 (R316 209 219 + R91 498 758). This amounts to 4.1% of the total ethical drug market in South Africa, and is even smaller at 0.5% of total (household plus government) health care expenditure in the country in 2001.[4,5]

The findings here correspond to those of the Scott and Reekie study, which investigated the savings from generic substitution that would apply in South Africa were it to be implemented in the mid-1980s. The study estimated the overall potential saving from generic substitution in 1984, with total substitution of sales of all lower price (cheapest) drugs in all possible instances, to amount to 6% of the total sales value of the top 200 products at the time. This saving came to 3% of the total ethical drug market (at ex-factory prices) in South Africa and to 0.4% of total health expenditure at the time. The consistency of the findings suggests that the savings from generic substitution are neither here nor there. This is further underscored from an inspection, provided in Table II, of the various cost components making up private sector health care costs, as recorded by the Registrar of Medical Schemes, which records data on approximately 85% of all persons covered.

Over the period 1993 - 2000 the costs of certain health care components have been on a downward trend, such as medicines, GPs, and dentists, while other costs have been on an upward trend, such as hospitalisation and specialists, with the costs relating to health care provision being far outpaced by those from the administrative function of the medical schemes / insurers.

Some final remarks

In 2001 the Directorate for Financial, Fiscal and Enterprise Affairs at the Organisation for Economic Co-operation and Development[8] noted that multinational research-intensive firms, which account for the bulk of the South African pharmaceutical market, rely on at most three products to cover their full research and development costs. Formal research from Grabowski and Vernon[9] and Grabowski *et al.*[10] supports this. Evidence from Scott and Reekie[11] and De Villiers and Scott[12] indicates that the case in South Africa does not differ. Generic drug manufacturers do not create innovative products nor do they incur the marketing costs of new product introductions. Generic products come cheaper because they do not embody the costs of innovation, which in real terms have increased, on average, from US$138 million in the 1970s to US$802 million during the 1990s.[13] Therefore, the thrust towards generic substitution, aside from its nugatory savings, also carries the possibility of reducing the levels of drug innovation, as its mandatory nature (by statutory implication) could stifle corporate incentives for funding future research and development. By extension this could increase the risk of closure of the business operations of those firms engaged in research and development in South Africa.

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