DRUG COSTS

UPDATE ON THE PHARMACEUTICAL INDUSTRY

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The *Sunday Times Business Times* published a supplement on the pharmaceutical industry on 30 November 2003. This has been an extremely dynamic environment and one that will be affected by impending legislative change. The objective of the survey was to provide some insight into the current status of the industry – special attention was paid to costs of medication, generic medication and antiretroviral therapy. This article aims to provide a summary of the publication and provide background information where necessary.

GENERIC MEDICINES

Generic medicines are copies of branded (original) medicines that are produced and sold at lower costs once the originator's patent protection period has lapsed. Multinational companies invest significantly on the research and development of new medicines. It is quoted that, of a batch of 10 000 molecules investigated, only one will make it to market, with a research and development cost of hundreds of millions of dollars. In order to allow the originating multinational pharmaceutical company to recoup research and development costs, a 20-year patent protection period is allowed. This period is often significantly reduced as extensive safety testing needs to take place before marketing of the new medication.

Once the patent has lapsed, producers of generic drugs are able to manufacture generic copies of the medication. These are invariably sold for a much lower price, bringing about a saving for the consumer.

While much is said about the spiralling costs of medicines, there has been a reduction in the prices of many medicines. This has been brought about largely by the emergence of generics and its effect on costing models. It is acknowledged, however, that multinationals need to be afforded some protection, as they play a major role in the development of innovative new medications.

It is widely accepted that generic medications have a role to play in providing high-quality, affordable health care. Uptake of generic medication in South Africa still lags behind that of other developed markets.

Country	Generic medication as a % of market
South Africa	19%
UK	70%
USA	75%
Germany	74%

The comparatively low use of generic medicines in South Africa has been attributed to mistrust on the part of doctors and patients, who have historically held the view that these medications are inferior because they are cheaper. The generic market is growing rapidly in South Africa, however, and it is anticipated that impending legislation will expedite this process.

MEDICATION PRICING LEGISLATION

Amendments to the Medicines and Related Substances Control Amendments Act (Act 90), intended for implementation in May 2004, have been made to provide a transparent costing model for medication, with the objective of reducing medication costs.

The new legislation will set a single factory exit price for each medication — this price list will be in the public domain. Medicine dispensers (doctors and pharmacists) will not be able to add a mark-up, but will instead charge a regulated professional fee for their service. In this way the consumer knows how much is being paid for the medicine and what is being paid for the dispensing and distribution.

Currently dispensers of medicine receive a percentage mark-up on medications — this clearly provides an incentive to use more expensive medicines in order to maximise profit margins. The price list, as well as the professional fees, will be determined by a pricing committee appointed by the Minister of Health.

There has been mixed reaction to the impending legislation, with some applauding the initiative as a bold step by the Government, while others criticise the practicality of the legislation.

Supporters believe that the legislation will provide a transparent pricing system that will not tolerate perverse incentives, back-handers and excessive profit margins. Detractors feel that implementation is likely to encounter a few practical difficulties and ignores the high likelihood of cost shifting. If an individual/pharmacy is currently earning a specific quantum of revenue, and this is cut, it is not impossible that profits will be recouped by increasing costs in non-regulated areas. In this case, the consumer pays the same (or more) and does not necessarily receive that appropriate care. If this has an adverse effect on the health of the patient, total health care expenditure increases.

It appears that there is still a lack of clarity about final implementation details, and the industry will need to wait for further information and assess the situation at the time of implementation.

ANTIRETROVIRAL THERAPY

The issue of the provision of affordable antiretroviral therapy (ART) received special focus in the survey, with an emphasis on generic medications in South Africa.

There has been good news on the issue of generic antiretroviral medication, with widespread availability of these drugs being predicted in the near future. This has been brought about through agreements between multinational pharmaceutical companies and generic medication manufacturers. On the one hand the need for affordable ART is too great to apply the patent protection period of 20 years, and on the other, the multinationals need to reap some benefit in order to fund further research and development.

A rational solution to this problem has been arrived at through the granting of voluntary licensing agreements by multinationals to generic manufacturers whereby the generic manufacturer is able to utilise the applicable intellectual property for a small royalty fee, or by limitation of the licence to a stipulated geographical region.

Additional good news reported on was the announcement by the Clinton Presidential Foundation of an initiative aimed at reducing the cost of antiretroviral drugs in developing countries. The initiative involves a venture with two Indian pharmaceutical companies and a South African generic medicine manufacturer (Aspen Pharmacare). These companies will be manufacturing generic antiretroviral medication – funding from the Foundation will allow a further reduction in price. A target annual cost quoted is US$140 for HAART.

MANAGING HIV/AIDS IN THE WORKPLACE

BMW South Africa have had considerable success with their workplace-based HIV/AIDS programme. An article on this outlined the comprehensive approach that this organisation has taken, including prevention, voluntary counselling and testing (VCT) and treatment of HIV- infected employees.

Ian Robertson, Managing Director of BMW SA, emphasised the need to see AIDS as a business issue that needs to be addressed with the same vitality as would be the case with other risks facing the business. It is clearly this attitude which has contributed to the success that has been achieved in the programme.

A notable success has been the uptake rate in the company's VCT initiative, with 87% of staff having participated over a period of 20 months. VCT is a crucial element of a comprehensive programme, providing the link between prevention and treatment. Once an individual is aware of his/her HIV status he/she is empowered to act appropriately – if HIV-negative, to take action to remain negative, and if positive, to access management of the condition.

The point is well made in the article that implementation of an effective HIV/AIDS programme in the workplace is not necessarily a costly initiative. Much can be done to manage the epidemic at fairly low cost. In order to assist companies in this endeavour, the South African Business Coalition of HIV/AIDS (SABCOHA) will be launching an HIV/AIDS Workplace Programme toolkit in the first quarter of 2004.

CONCLUSION

The *Sunday Times Business Times* survey of the pharmaceutical industry gave valuable insights into a small but important range of issues affecting the health care industry.