



THE FREE MARKET FOUNDATION

of Southern Africa

progress through freedom

Health Policy Unit

Comment to the Department of Health in response to Government Gazette No 28214 of 11 November 2005 (Notice No 2007 of 2005)

Methodology for conforming with international benchmarks for determining the prices of medicines

The Free Market Foundation (FMF) is a registered Non-Profit organisation that promotes the open society philosophy, the rule of law, and free market policies based on sound economic principles. It works for an economic and business environment that will facilitate the achievement of high economic growth in Southern Africa.

1. Relevant Regulation

5(2)(e) The Minister on the recommendation of the Pricing Committee must determine and publish in the Gazette a methodology for conforming with international benchmarks, taking into account the price, and the factors that influence price, at which the medicine or Scheduled substance that is deemed equivalent by the Minister on the recommendation of the Pricing Committee, is sold in other countries in which the prices of medicines and Scheduled substances are regulated and published and the single exit price of each medicine or Scheduled substance must, within 3 months of publication of such methodology in the Gazette conform with international benchmarks in accordance with such methodology.

2. Introduction

2.1 Approach to the question being asked

Our Foundation follows the practice of going back to first principle in responding to policy questions. This means that before addressing the technical question of how the calculation of a medicine price should be done, the Foundation will examine the question of whether a government-imposed price calculation is economically justified and fundamentally in the best interests of South Africans, including the interests of the poor.

2.2 Medicine price controls have negative consequences

The South African government has committed itself to reducing the cost of medicines and healthcare to patients in an attempt to improve the welfare and the health of the nation. While the government may have good intentions in wanting to increase access to medicines and quality healthcare, price controls will have many unintended consequences that will in effect reduce access to medicines and compromise South Africa's healthcare system.

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South Africa is not alone in wanting to control or regulate the price of medicines. Almost every advanced economy, with the notable exception of the United States, imposes some sort of control over drug prices. However, these regulations result in a wide range of negative consequences for patients. Numerous international studies have shown that drug price regulations result in long delays in drug registration – if the drugs are registered at all. While price controls may bring some benefits to consumers in the short-term through lower drug prices, the medium- and long-term costs in reduced research and development and fewer innovative drugs are considerable.

2.3 International medicine price comparisons are extremely complex

Comparing drug prices around the world is notoriously complex and is often not even useful. Different regulatory regimes and purchasing power, means that drug prices differ across countries for a number of reasons and direct comparisons do not necessarily provide evidence of greater or less consumer welfare in a given country. South Africa has always been able to secure amongst the lowest drug prices internationally for both the private and public sectors without imposing price controls

2.4 Medicine price controls do not necessarily result in lower prices

It should be noted that not only are international comparisons of drug prices highly complex and often misleading, it is not clear that countries that impose price controls necessarily have lower prices. South Africa has been able to secure among the lowest drug prices internationally for both the private and public sectors without imposing price controls. While drug price controls may not necessarily ensure lower overall healthcare costs, the available evidence suggests that they result in a number of unintended consequences. Most notably the presence of drug price controls tends to reduce investment in research and development, delay drug registrations, and can lead to shortages in supplies and illegal trade in medicines.

3. Drug pricing in South Africa

There have been numerous claims in the past that South Africa has amongst the highest prices of pharmaceutical drugs in the world. However, as was noted previously, international comparisons of drug pricing are notoriously complex. Drug price comparisons can vary widely depending on which drugs are included in the study and on whether weights are used to account for the different volumes of medicines consumed.

South Africa has had two distinct markets for medicines and other controlled substances: the private sector and the state sector. Approximately 7 million South Africans are members of medical aid schemes and another 13.5 million have access of some description to healthcare in the private sector. The state sector is thought to provide healthcare services to a potential 33 million South Africans through the various state health facilities.

As many people use both private and public health services, especially those that purchase traditional and other natural medicines but use public hospitals when they need surgery or specialised treatments, there is a considerable overlap. There are also many people that hardly ever use medication or other health services, so determining the respective health-care contributions of the public and private sectors is very difficult. Any discussion of drug prices in South Africa should take into account the price discrimination that has traditionally occurred, with drug manufacturers selling drugs at relatively high prices to the private sector and at greatly discounted prices to the state sector. The fact that manufacturers have been able to price-discriminate has meant that overall, drug prices in South Africa are amongst the lowest in the world

Indeed, the South African public health sector has access to among the cheapest medicines in the world. Through the Co-ordinating Committee for Medical Procurement (COMED) tendering system for drugs, the government has been able to ensure that medicines for the state sector are around 35% lower than the World Health Organisation's (WHO) International Drug Price Indicator Guide

(IDPIG). The IDPIG is compiled from actual international tender prices for the supply of generic drugs to agencies and vendors in poor and middle-income countries.

4. International Experience of Drug Price Controls

Various governments have used a wide range of measures to control drug prices and restrict the amount spent directly on medicines. In most cases these controls are exerted over drugs sold to the public sector for national health systems. Governments can either regulate the drug prices directly (which occurs in France and Italy) or indirectly (as happens in Germany and Japan) by restricting the amount that can be reimbursed via a social security system. Countries can also choose to limit the profitability of companies as is done in the United Kingdom. For a detailed listing of the various controls imposed by selected countries around the world see Table 1 below.

Table1: Regulation Around the World – Various means of regulating prescription drug prices in other countries

Country	Control prices at launch	Control Reimbursement Prices	Reference Pricing	Profit Controls	Positive/Negative Listings	Drug Budgets for Doctors
Austria	√	√			√	
Belgium	√	√			√	
Denmark			√		√	
Finland		√			√	
France	√	√			√	√
Germany		√	√		√	√
Greece	√	√			√	
Ireland	√	√			√	√
Italy	√	√			√	
Japan		√		√	√	
Netherlands	√	√	√		√	
Norway		√	√		√	
Portugal	√	√			√	
Spain	√	√		√	√	
Sweden		√	√		√	
Switzerland		√			√	
United Kingdom				√	√	√

The existence of these price and profit controls around the globe may appear to legitimise to some extent the desire to formulate a methodology for conforming with international benchmarks of the prices of medicines. However, comparing drug prices in different countries is highly complex, and claims that drug prices are lower in countries that control prices are misleading and often inaccurate. In addition to the inconsistencies in comparing drug prices, a number of unintended consequences arise when governments interfere in the market for medicines. All such relevant issues should inform the decisions of the medicine pricing committee.

Apart from the different regulatory regimes and disposable income in different countries (which will affect the price at which a company markets any product, let alone medicines) the composition of a country's formulary will affect the average price of medicines. For instance, the use of generic drugs, which are often sold at a fraction of the price of branded or patented drugs, can greatly influence the cost of drugs to consumers.

Some countries, most notably France and Italy, do not have active generic drugs markets. The United States on the other hand has a large generics market that drives down the price of

medicines very rapidly once drugs are off-patent. The competition between generic drug producers drives down drug prices over time and therefore studies that fail to account for the generics market will not give an accurate picture of overall drug prices. The fact that branded and patented medicines are subject to price controls in France and Italy means that the market for generics is limited, as price-sensitive consumers that would otherwise purchase generics will simply continue to buy the branded drugs. In effect the price regulations in France keep the prices of off-patent medicines artificially high while US consumers benefit from the vigorous competition in the generics market.

5. Reduced drug access

Patricia Danzon of the University of Pennsylvania analysed the effects of price regulations on the registrations of new drugs in various countries. Her research shows that due to the dangers of parallel importation from countries that have regulations that ensure low drug prices, medicine manufacturers prefer to delay or cancel the launch of a particular product in price-control countries.

Danzon found that between 1994 and 1998 there were 85 new chemical entities (NCEs) launched in the UK and US. Out of a maximum possible registration of 2,125 registrations of these NCEs in 25 countries, only 55% (1,167) were actually registered. The research showed that those countries with lower expected prices or smaller expected market size experience longer time lags and delays in new drug registrations.

Danzon's research is supported by evidence from Canada, which suggests that drugs that are widely available in the United States are simply not registered and are therefore unavailable in Canada. It is widely reported that US border states regularly treat Canadian citizens that are unable to access treatment at home.

In some cases, the delays in registering new medicines, due to the price controls, benefit domestic drug producers. As John Calfee explains: Advanced nations with pervasive pharmaceutical price controls, such as Japan, have for decades denied innovative drugs to their citizens even as domestic pharmaceutical firms prosper by pursuing low-risk research on products of marginal value.

Apart from the regulated drug prices, which deter the registration of new drugs, the lengthy process undertaken by bureaucracies to determine 'appropriate' drug prices adds to the delays in gaining access to drugs. For instance, in some European countries, such as Belgium, patients can wait for more than 2 years to access a medicine that is already available in the UK and Germany. These delays do not only harm patients by denying them important medical treatment but also add to the costs of the manufacturing firms that are prevented from selling their new products. This in turn puts pressure on the companies to recover their lost revenue elsewhere, further distorting medicine prices. In recent years, the volatile foreign exchange rate in South Africa has affected medicine prices, mostly pushing them up. Manufacturers and importers are therefore likely to be negatively affected by the proposal to only allow an annual increase in drug prices, as they will be unable to respond rapidly and effectively to changes in the exchange rate. This acts as a further disincentive to the marketing of drugs in South Africa.

Allowing patients to access the latest innovative medicines is vitally important. While generic medicines play a crucially important role in any healthcare system, the value of new and innovative medicines and medical technology cannot be overstated. While it is true that newer drugs tend to cost more than older, off-patent drugs, (by an average of 24 percent) newer drugs reduce the number of productive work days lost by 21.3 per cent. Furthermore, newer drugs can reduce the length of time a patient has to spend in hospital. Given that hospital care (which includes the cost of medical staff, equipment, food, linen etc.) is often very costly, any financial benefit from using older, off patent drugs can be extinguished by the cost of extra days spent in hospital.

6. Reduced research and development

Perhaps one of the most important and damaging long-term effects of drug price regulations is the impact they have on research and development. This impact is also somewhat difficult to measure and is often unseen because government and consumers are not aware of the lost innovation that would have taken place in the absence of price controls.

Arguably the most telling evidence of the impact of price controls on research and development is the movement of research from Europe, which has a variety of price controls, to the United States, which has few price controls. Between 1988 and 1998, the United States' share of production of best selling drugs increased from 19 to 33 and in 1998 the United States produced 8 of the 10 top-selling drugs. Some European companies, such as GSK and Novartis, have moved much of their research and development capacity to the United States. John Vernon of the University of Pennsylvania has estimated the impact of price controls on research and development. Using data from the 15 largest pharmaceutical manufacturing firms in the world, Vernon (2003) estimates several models of the determinants of research and development (R&D) over the 1988-to-1998 time-period. The results affirm the central hypothesis that pharmaceutical price regulation diminishes the incentives to invest in R&D. Moreover, the magnitude of the correlation is quite substantial (-0.07 to -0.20), suggesting that R&D investment may be quite sensitive to the degree of pharmaceutical price regulation. The model predicts that investment in research and development could decline by up to 47 per cent.

While price controls may bring some benefits to consumers in the short-term through lower drug prices, the long-term costs in reduced research and development and fewer innovative drugs are considerable. Bain & Company, an international management consultancy, conducted research into the effects of drug price controls in Germany. Germany introduced reference-based drug pricing in 1989 with the aim of reducing drug expenditure. Bain's research revealed that the price regulations reduced the German government's spending on drugs by \$19 billion in 2002. These savings however need to be balanced against the economic costs of poorer health outcomes resulting from the fact that German patients did not have access to the latest innovative therapies. In addition, reduced research and development in Germany, a reduction in jobs and investment, and lower corporate taxes to government cost the economy around \$22 billion. The result is that the drug price regulations, rather than saving the country money, cost it around \$3 billion.

South Africa has already experienced a major change in the way international pharmaceutical manufacturing companies view the local market as a result of government intervention in the pricing of medicines. In some cases full-scale local representation has been downgraded to agency representation. As a consequence, South Africa is not only losing local manufacture but also the potential participation of companies in finding solutions to 'South Africa specific' health problems, local research and development, local drug trials and the like. As in the experience of Germany, described above, the available evidence suggests that the South African economy and its people will be net losers as a result of the intervention.

7. Market distortions and the black market

Apart from the increased overall costs of healthcare, reduced availability of drugs and reduced research and development, drug price regulations in many countries have exacerbated the parallel trade in drugs and the black market for medicines. Artificially low drug prices in one country provide incentives for entrepreneurs to export those drugs (perhaps illegally) to countries that have higher drug prices. This can reduce income of the drug manufacturer by reducing its ability to price discriminate. It can also lead to poorer health outcomes as the manufacturer has reduced control over the product sold in the higher priced market. With products such as medicines it is often crucially important for the manufacturer to control the supply chain, ensure that the product is safely transported, and that it complies with the various regulations governing its use.

Due to the economic distortions created by drug price controls, patients frequently do not have access to adequate healthcare. In the United Kingdom, rationing of healthcare services due to price controls has created shortages, which more often than not affect the poorer sections of society. The wealthy North East Thames region near London has 27 per cent more doctors and dentists, 15 per cent more hospital beds and 12 per cent higher health spending per capita than the rural Trent area in North East England. Price controls have not resulted in greater equality in access to healthcare in the UK. The rationing of healthcare services has meant that the pattern of healthcare consumption has changed little since 1948 when the highest social class consumed 40 per cent more services than the lowest social class.

8. Conclusions

8.1 Introduction of international benchmarks should be reconsidered

Despite the South African governments best intentions to create a transparent pricing mechanism through the use of international benchmarks this submission has shown that cross-country analyses are notoriously difficult. Furthermore, anecdotal and empirical evidence has proved that the imposition of price controls has a number of perverse and unintended consequences on the functioning of the market. Most notably the presence of drug price controls tends to reduce investment in research and development, delays drug registrations, and can lead to shortages in supplies and illegal trade in medicines. The whole question should therefore be reconsidered

8.2 The fundamental approach to the pricing of medicines should be reconsidered

We therefore wish to recommend that the Department of Health reconsider its approach to the pricing of pharmaceuticals. There appears to be a distinct possibility that, as a result of the introduction of medicine price controls the government sector will, over time, have less access to low-priced medicines than it has had in the past. Evidence from Canada suggests that both the private and public sectors, on the other hand, appear certain to have a lower level of access to newer and better drugs. Pharmaceutical company investment in South Africa has already declined and the loss of investment over time is likely to be enormous. To state the matter bluntly, South Africans, including the poorest members of the population, appear to be scheduled to be substantial net losers as a result of the introduction of medicine price controls.

8.3 Proposed review

The pharmaceutical industry, and health care generally, are vitally important to the welfare of South Africa's people. Considering the gravity of the issue and the potential implications of continuing with the regulations, we propose that the question of price controls over medicines be revisited. We suggest that an intensive study, utilising internationally respected researchers, such as Patricia Danzon, be commissioned to carry out a study and advise the government on the most appropriate policy on pharmaceutical pricing. It is most important that such a study should be dynamic in nature, taking all the factors into consideration, including matters such as the health care of the entire population, research and development into health-care problems specifically affecting South Africans, total investment in health care in South Africa, and the consequences for the South African economy in general. We repeat our call for a Regulatory Impact Assessment to determine the effect of these regulatory issues on South Africa's people. The proposed study of pharmaceutical pricing can form part of such a more general assessment.

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