THE FREE MARKET FOUNDATION
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Submission on the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances made in terms of Section 22G of the Medicines and Related Substances Act 1965 (Act No 101 of 1965)

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EXECUTIVE SUMMARY

This document explains fundamental problems with price controls and then examines some international experience of controlling the price of medicines, and the impact these regulations will have in South Africa if implemented.

Drug price regulations, as with any form of price control, will not and cannot protect consumers or ensure lower drug prices. Governments have for over 40 centuries attempted to control prices and in every case the regulations have interfered with the normal market process, have reduced competition and ultimately have harmed the consumer. Consumers are most effectively protected by open competition which gives the maximum power to consumers to punish or reward firms based on their performance.

Government micro management of medicine distribution, wholesaling and retailing, and the imposition of price control on these sectors of the industry can be expected to have similarly negative effects and unexpected consequences. The most serious of these is likely to be the probability that small and outlying outlets, such as those in rural areas, will be most severely affected.

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.

One of government's motivations for requiring a single exit price for medicines is to ensure that "South Africans have access to affordable, good quality medicine". We quote studies showing that, to the extent that comparisons are possible, South Africa's private sector patients do not pay excessively high prices for medicines and the State purchases medicines at extremely low prices, which is confirmed both by the study we quote and the fact that a single exit price of 50% below list price would still be above the price it pays. We come to the latter conclusion due to the fact that the State is to be excluded from the operation of the single pricing system. South Africa would therefore appear to be generally well served by its medicine suppliers and drastic government intervention such as the institution of price controls seems to be unwarranted.

South Africa is not alone in wanting to control or regulate the price of medicines and most advanced economies implement some form of price regulation. 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.

Apart from the negative economic and healthcare effects of these drug regulations, we have serious concerns about the way in which these regulations have been formulated. By granting discretionary powers to unelected officials these regulations violate the principles of "good law". We are of the view that the regulations are *ultra vires* as Section 22G of the Medicines and Related Substance Act 1965 (No. 101 of 1965) does not give the minister or the pricing committee the powers to prescribe the price of medicines. In any event, such far-reaching powers without specified objectives and criteria in accordance with the Guidance Principle (as required by the Constitution) are unconstitutional.

In our view the regulations necessary to give effect to Section 22G of the Act should be confined to regulating "the introduction of a transparent pricing system" and "an appropriate dispensing fee" and "prescribing the method of publication of a single exit price". Seeking to prescribe maximum prices for medicines therefore goes beyond the powers created by the Act itself. The wording of the Act indicates government's intention to compel pharmaceutical companies to abandon the complicated discounts they grant to distributors and wholesalers of their products and there is no evidence of any intention whatsoever to institute price control on medicines. Although we consider discounts to be an accepted and acceptable marketing mechanism, the Act sets out to prevent pharmaceutical manufacturers from utilising them, and the application of Section 22G(3)(a) appears to do that perfectly adequately without the necessity for elaborate regulations that alter the intention that is clearly expressed in the Act, and in addition, will have highly disruptive consequences for health-care and the economy in general. There is therefore also no necessity for the Department of Health to act unconstitutionally by exceeding its powers in the formulation of the regulations required for purposes of implementing Section 22G.

1. Introduction

The government has committed itself to reducing the cost of medicines and healthcare to patients in an attempt to improve welfare and the health of the nation. As part of its plans, the Government Gazette of 16 January 2004 carried draft Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances in terms of Section 22G of the Medicines and Related Substances Act 1965 (Act No 101 of 1965).

While the government may have good intentions in wanting to increase access to medicines and good quality healthcare, its proposals will have many unintended consequences that will in effect reduce access to medicines and compromise South Africa's healthcare system.

This document explains the fundamental problems with price controls and then examines some international experience from controlling the price of medicines. We then go on to explore some of the expected impacts from the regulations in South Africa. Lastly we raise some concerns that we have about the way in which these regulations have been formulated and whether they conform with the definitions of good law.

We urge the pricing committee to give careful consideration to our comments. Improving South Africa's healthcare system is a crucially important goal and yet the way in which these draft regulations undermine that goal requires an almost complete overhaul of these regulations.

The Free Market Foundation 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.

High economic growth is regarded as the key to increasing incomes and living standards and reducing poverty and all the evidence now shows that an economic environment characterised by economic freedom is superior to any other in achieving that objective. Not only does economic freedom result in the highest per capita incomes but it also improves all the other measures of human development, such as higher life expectancy, better literacy rates, improved sanitation, increased water sources and many other desirable social outcomes.

Price controls reduce the efficiency of any industry upon which they are imposed but also ultimately harm their intended beneficiaries. In the longer term, consumers and especially the poor in South Africa will be made worse off by the imposition of price controls and not better off. It is our grave concern for the consequences of the regulations that has impelled us to make this submission.

2. The effect of price controls

The most fundamental problem with price controls, be they for medicines or for any other product, is that they interfere with the normal pricing mechanism and the signals that prices send to buyers and sellers. If consumers appear willing to buy more of a product, then manufacturers will have an incentive to produce more of that good and more manufacturers will enter the market. Because of competition for consumer demand, manufacturers are likely to research the product so as to improve it and provide greater choice for consumers. As prices rise, due to increased consumer demand, we expect supply to increase as the dynamic market adjusts to satisfy the demand. The determination of market prices through continual changes in demand and supply is therefore the basic building block of economics.

Price controls distort that pricing mechanism and interrupt the dynamic demand and supply process. Consumer tastes and needs change continuously and as demand for a particular product rises or falls, so the price rises and falls, sending signals to manufacturers to adjust the supply of the product in a never-ending trend towards an equilibrium price. Government-set prices are usually arrived at after a negotiated political process, but once set, that fixed price cannot adjust to account for the ongoing changes in demand for the product. If a price is set too high by government, the supply of that product will exceed demand. For instance, European governments set the price of many agricultural products above the price that would be achieved through a normal market process. This means that European farmers produce far too much milk, maize and pork to the detriment of consumers in their role as taxpayers.

If government sets the price of a good below the equilibrium price level, consumers are signalled to consume more of the product than manufacturers would normally produce at that price. With increased demand and without any incentive to increase supply, shortages arise which in turn reduce consumer choice and lead to welfare losses. Because not enough of the good is sold, a deadweight loss arises because income is lost to the producer and the consumer is left without the good he or she desires.

2.1 Historical attempts to control prices

Governments have attempted to control prices for a variety of goods and services for almost 40 centuries. From the Babylonian King Hammurabi to US Presidents Nixon and Carter, the desire to meet the needs of certain interest groups by imposing price controls by fiat has been irresistible. Yet in every case, price controls have ended up harming the consumer and imposing significant costs on the entire economy.

2.2 Implications for micro retailers and poor consumers

Price controls are normally promoted and devised under the guise of assisting the poor and alleviating poverty. Yet in almost every case it is the poor that suffer most from price controls. In South Africa and most other countries, it is the rich that have access to the high volume, low mark-up retailers that can offer cheaper goods in large urban areas. The poor generally shop in low-volume, high mark-up establishments in the townships simply because they are conveniently located. Price controls tend to penalise the low volume establishments that serve the poor, therefore

forcing them to travel to urban centres, incurring costs and inconvenience in order to shop. Price controls are essentially patronising as they assume that poor consumers (on whose behalf the controls are devised) are unable or too ignorant to make valid choices for themselves.

In addition to penalising small volume retailers and businesses and harming poor consumers, price controls act as barriers to entry. In many cases price controls are tolerated or even welcomed by large established businesses because it keeps competition out of the industry. If prices are regulated downwards to a level where the high volume, low mark-up retailer can still remain in business, no other kind of business will be able to compete. Not only does this harm emerging businesses, but it reduces consumer choice and therefore welfare.

2.3 Price controls during apartheid

Given its interventionist and controlling nature, it is not surprising that the apartheid government was particularly fond of price controls. Almost all goods and services were highly regulated during the apartheid years and most of the controls harmed consumers. It is not even clear that the price controls favoured by successive apartheid governments ensured lower prices. For instance after the price controls on soft drinks were removed, prices fell. The first democratically elected government of South Africa increased economic freedom and served the interest of consumers by removing the web of price controls and economic restrictions. To reverse this trend by reinstating price controls would be a damaging and backward move for the country and most importantly for consumers, both rich and poor.

2.4 Price controls always have negative consequences

By interfering in the normal market process, price controls discourage normal price competition and stifle innovation, research and development. Without any normal price signals, manufacturers cannot respond to the needs of consumers and are therefore often unwilling or unable to improve their product and to compete effectively in order to meet the needs of consumers.

It may be argued that healthcare and medicines are somehow different to other goods and that therefore price controls are justified. The market for medicines and healthcare however are subject to the same laws of economics as any other good or service. In fact given the importance of good healthcare for human well-being and the highly damaging effects of price controls it is imperative that price controls are NOT imposed on medicines. Indeed food is more important for human survival and welfare than medicines and the government quite correctly removed the many price controls on agricultural products precisely because of the damaging effects on the economy and on consumers. For many centuries governments around the world have tried to impose price restrictions on food and this has almost always led to reduced supply of food and ultimately famine. The price controls on medicines will have exactly the same impact and in the long run will harm patients and increase the suffering of some of the most vulnerable and needy South Africans.

3. International experience of Drug Price Controls

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.

A range of measures have been used by various governments 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.

The existence of these price and profit controls around the globe may appear to legitimise to some extent the drug pricing proposals in South Africa. 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.

3.1 Comparing drug prices

Recent media attention in South Africa on the issue of drug pricing has claimed that South Africa has amongst the highest prices in the world.[1] Yet 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. Studies performed during the 1990s by Patricia Danzon, among others, at the University of Pennsylvania show that drug prices in the United States (where there are few price controls) vary widely with drug prices in other countries where there are strict price controls. Depending on how the prices are measured, she found that U.S. prices can be lower than prices elsewhere.

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 an active generic drugs market. The US 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.

South Africa has had two distinct markets for medicines and other controlled substances; the private sector and the state sector. Around 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.

[1] Anso Thom "How cheaper medicine will affect you" The Star, Johannesburg, 4 February 2004

Table 1 below gives a country comparison with South Africa of drug prices in the private sector. Among the countries studied, South Africa has either the lowest or second lowest drug prices. The highest prices according to this particular study were consistently found in the United States.

Table 1 Cross-Country Medicine Price Comparison (Private Sector)

	1995		1998		2001	
Pairwise Comparison	**N**	**Price Ratio**	**N**	**Price Ratio**	**N**	**Price Ratio**
SA/USA	20	1.00: 1.57	21	1.00: 4.58	27	1.00: 3.20
SA/UK	21	1.00: 0.75	22	1.00: 1.16	27	1.00: 1.40
SA/Germany	15	1.00: 1.59	11	1.00: 1.06	20	1.00: 1.19
SA/Denmark	19	1.00: 1.00	13	1.00: 1.12	20	1.00: 1.24
SA/Netherlands	22	1.00: 1.16	21	1.00: 1.14	27	1.00: 1.29
SA/Australia	-	-	21	1.00: 0.83	26	1.00: 0.79
SA/Brazil	-	-	14	1.00: 1.17	16	1.00: 1.15

Notes: (i) The comparisons are done for comparable markets defined as such due to similar levels of income, relatively liberal price controls particularly on new product introductions, and the importance intellectual property plays.; (ii) Besides the pricing discussion in the text, compared is the cost of a basket of important sellers extracted from the top 50 (for 1995) and 80 (for 1998 and 2001) products by value in SA relative to other comparable markets, using IMS ex-factory list prices data as it applies to ethical drugs dispensed through pharmacies. The list prices were in the currencies of each country. Prices were compared in Rands at the applicable official exchange rate as it applies for the years.; (iii) N = number of comparable products.; (iv) '-' indicates no data available.

It is important to note that South Africa, which has a slightly lower per capita GDP than Brazil, has lower drug prices in the private sector. This is despite the fact that Brazil has weaker IPR protection and greater scope to issue compulsory licences and override drug patents. Weakening IPR may not lead to cheaper drug prices if it does not encourage generic competition. In addition, weaker IPR may frustrate the ability of the brand name medicine producer to price-discriminate.

The Minister of Health issued a statement on 15 January 2004 to coincide with the release of the proposed regulations on transparent pricing claiming that the regulations are 'a major development in our effort to ensure that South Africans have access to affordable, good quality medicine[2].' Yet the public health sector, which is supposed to serve the poor, 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. Table 2 below details the COMED expenditure based on 8 of 9 tenders considered for 71 commonly used products. The tender prices available to the public sector ensured a saving of almost R280million compared to the IDPIG prices.

TABLE 2 Total Expenditure on 71 Common Products (based on quantity estimates) 2000

Total for 8 of 9 Tenders Considered	**Expenditure**
TOTAL for COMED Tenders at Comed Prices	R 526 870 968
TOTAL for COMED Tenders at International IDPIG Tender Prices	R 806 003 082
DIFFERENCE	R 279 132 114 or 35% saving

Source George Djolov, 2004

[2] Hon. Dr. Manto Tshabalala-Msimang "Regulations on the Prices of Medicines" Department of Health, 15 January 2004, http://www.doh.gov.za/docs/pr/2004/pr0113.html

3.2 The effects of drug price regulations

As we have explained in the previous section, 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, delays drug registrations, and can lead to shortages in supplies and illegal trade in medicines.

3.2.1 Reduced drug access

Patricia Danzon of the University of Pennsylvania has analysed the effects of price regulations on the registrations of new drugs in various countries.[3] 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 (NCE) 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)[4]. 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[5].

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[6].

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 longer to access a medicine that is already available in the UK and Germany[7]. These delays do not only harm patients by denying them important medical treatment, but add to the costs of the manufacturing firms that are prevented from selling their new products. This in turn

[3] Patricia Danzon, Y Richard Wang, Liang Wang "The Impact of Drug Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty Five Major Markets in the 1990s" Working Paper 9874, National Bureau of Economic Research, July 2003

[4] Their research showed that the US had 73 NCE launches, followed by Germany (66), the UK (64), Portugal (26), New Zealand (28) and only 13 in Japan.

[5] In a widely publicized case, Robert Bouressa, the Premier of Quebec sought treatment for his potentially lethal skin cancer at the National Cancer Institute in Maryland, US (Rottenberg & Theroux 1994)

[6] John Calfee "Pharmaceutical Price Controls and Patient Welfare" Ann. Intern Medicine, 2001: vol 134, pp 1060 - 1064

[7] Cambridge Pharma Consultancy "Delays in Market Access" IMS Health, Cambridge, December 2002

puts pressure on the companies to recover their lost revenue elsewhere, further distorting medicine prices. In recent years, the volatile foreign exchange rate has affected medicine prices, mostly pushing them up. Manufacturers and importers are likely to be negatively affected by the proposal to only allow an annual increase in drug prices as they will be unable to respond 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. For instance, research has revealed that one new HIV/AIDS drug prevents around 6 000 deaths in the following year and ultimately prevents 34 000 deaths[8]. While it is true that newer drugs tend to cost more than older, off-patent drugs, (by an average of 24 percent) the former can reduce the number of productive work days lost by 21.3 percent[9]. Newer drugs can also 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.

3.2.2 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 one of the most 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.

Perhaps 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 US, which has few price controls. Between 1988 and 1998, the US share of production of best selling drugs increased from 19 to 33 and in 1998 the US 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 US[10].

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[11].

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

[8] Frank Lictenberg, "The Value of New Drugs", The Milken Institute Review, Fourth Quarter 2003
[9] ibid
[10] The Business Journal "Novartis to invest $250m into facility in Boston" 6 May 2002, http://www.bizjournals.com/triad/stories/2002/05/06/daily12.html
[11] Bain & Company, "Addressing the Innovation Divide" January 2004 http://www.bain.com/bainweb/PDFs/cms/Marketing/addressing_innovation_divide.pdf

economy around $22billion. The result is that the drug price regulations, rather than saving the country money, cost it around $3billion[12].

3.2.3 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 percent more doctors and dentists, 15 percent more hospital beds and 12 percent higher health spending per capita than the rural Trent area in North East England[13]. 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% more services than the lowest social class[14].

4. Anticipated Effects of Proposed Drug Price Regulations

Based on the international experience of drug price regulations and the structure of the local industry, distributors and pharmacies, we expect a wide range of unintended negative consequences from the proposed drug price regulations.

4.1 Delayed drug registrations and reduced access to innovative drugs

The evidence suggests that drug price regulations, even in wealthy economies such as Japan, increase the delay in registering new drugs. Manufacturers have greater incentives to register their medicines and comply with the increasingly onerous regulatory requirements in countries where they have greater freedom to price their products without bureaucratic intervention. The registration process in South Africa already delays the registration of drugs, imposing considerable costs on drug companies. The drug price regulations, most particularly Regulations 5 to 10, are likely to increase the delays of drug registration and/or stop manufacturers from registering the drugs at all. The healthcare outcomes are likely to be severe and will reduce patient welfare as well as the ability of physicians to care for their patients.

[12] The costs to the German economy of the drug price regulations were estimated to be: Reduced R&D spending ($3bn); reduced additional innovation ($900m); lost patient value ($200m); lost high value-added jobs and taxes not paid on them ($4bn); lost associated jobs in supply and service industries ($3-7bn); lost government training of high value-added workers ($200m); lost corporate centres, taxes & startups ($5bn); poorer health outcomes ($5bn).

[13] The Economist, "Dying from Inequality' April 4 1987, quoted in Simon Rottenburg and David Theroux, "Rationing Health Care: Price Controls are Hazardous to Our Health" Independent Institute, February 1994.

[14] Julian LeGrande "The Distribution of Public Expenditure: The Case of Healthcare" Economica 45, No. 178 (1978), quoted in Rottenburg and Theroux.

4.2 Reduced drug access

Apart from the delays in registering drugs and the reduced overall availability of innovative new medicines, the drug price regulations will force many pharmacies into bankruptcy and ensure that the distribution of drugs to rural and remote areas will be financially unviable. Regulations 11 to 15 will reduce the income stream and profit margins for pharmacies, wholesalers and distributors to such an extent that it will become impossible to carry a wide range of medicines. Many of these companies will be forced to diversify their businesses by selling cosmetics and other products and reduce their involvement in healthcare products. The lack of profitability in the sale and distribution of medicines will also reduce the incentive for pharmacists to invest in training and skills development, which in turn will harm many patients who seek advice directly from pharmacists.

In rural areas or townships that are not well served with large high volume retailers and pharmacies, poor consumers and patients choose to purchase medicines (and indeed all manner of other goods) from small scale retailers that may have high margins due to their low volume of trade. Yet consumers are acting rationally when they purchase goods from these retailers because they apparently choose to pay a higher price for convenience. Their alternative would be to travel long distances (thereby incurring travel costs) to access medicines from the high volume, low mark-up retailers in urban centres. The regulations will do considerable harm to consumers by undermining their choices as they will drive the convenient (but low volume, high mark-up) retailers out of the over-the-counter medicine business

4.3 Shortages of drugs, parallel trade and theft

The drug price regulations distort the normal market clearing process and effectively increase demand for medicines without providing the economic incentives that serve to match demand with supply. As demand outstrips supply the resulting shortages in drugs will reduce the ability of healthcare professionals to provide high quality care to their patients and will therefore reduce patient welfare. Apart from these shortages, the regulations provide incentives for parallel trade in medicines (selling low priced South African medicine to countries that have higher prices) and will encourage theft of medicines. All of these will greatly reduce patient welfare, most particularly for poor patients that will not be able to pay a premium to access the scarce medicines.

4.4 Reduced Research and Development

South Africa has traditionally been a favoured destination for drug companies to conduct research and development because of the sound scientific base, good infrastructure and range of different population groups with widely different social statuses in which to run trials. The drug price regulations are likely to reduce any incentive to conduct trials and invest in scientific infrastructure and knowledge as the ability to make appropriate returns on the investment is reduced. Drug companies, both local and foreign, invest over R500m in R&D currently and this is likely to gradually fall away. In addition, Regulation 16, which requires detailed and confidential information on the research, manufacture and marketing of medicines to be given to the pricing committee, will reduce R&D in the country as well as the marketing of drugs in the country.

4.5 Reduced manufacturing in South Africa

There has been an increasing trend among the research based drug companies to concentrate manufacturing in various centres of excellence around the world. Because of this and to some extent as a result of mergers, since 1994, 33 drug companies have ceased to produce their products in South Africa. This has not only cost the country jobs, but has reduced the scientific skills and knowledge base in the country and has hampered attempts to increase technology transfer. The drug price regulations will simply exacerbate this trend and if the regulations are implemented in their current form, more and more companies will cease production, imposing significant economic costs on the country.

4.6 Regulations will become increasingly complex and onerous

Once in place, the drug price regulations are likely to become ever more complex and onerous to comply with. During the Nixon administration, price controls began with 3.5 pages of regulations but before long they grew to over 1,500 pages. Regulation cannot emulate all the various factors affecting supply and demand that are normally captured in a free market pricing system. This leads to ever more complex and onerous regulations as the regulators try to carry out the functions of the normal market mechanism. In addition to this, the fact that a new bureaucracy will have significant powers over the commercial decisions of private companies will generate a great deal of rent-seeking behaviour from vested interests. This generally reduces choice for consumers and harms patient welfare.

4.7 Disrupted patient-doctor relationship

The relationship between patient and doctors could be disrupted by the regulations, particularly Regulation 24. Patients normally discuss the appropriate therapy for their needs and financial circumstances with their doctor, pharmacist or other trusted healthcare professional. Regulation 24 undermines that relationship, however, as the Director General may determine that a price for a drug is unreasonable. However a doctor may conclude that for his or her personal circumstance the drug that has been declared over-priced represents the best treatment for the patient, despite the view of the Director General. What is the doctor to do under such circumstances? The regulations appear to treat South Africans as a homogenous group and not as individuals whose circumstances and requirements differ vastly.

4.8 Fewer Empowerment Opportunities

Price controls tend to favour the large incumbent industries that have sunk costs and economies of scale. Prices tend to be set at levels that keep the high volume, low mark-up businesses operating, albeit at lower profits. However the regulations also protect these industries by making it virtually impossible for any other new competitors, that would have higher margins, lower volumes and no economies of scale, from entering the market. Not only does this harm consumer choice, but it reduces the opportunities available to emerging entrepreneurs. As these regulations will protect the large incumbent industries they would seem to be directly at odds with the government's stated policies of increasing black economic empowerment.

4.9 Reduced price competition

As explained above, it is not necessarily true that countries that do not have drug price regulations have higher prices. While drug prices in the US are higher for some drugs, they are lower for others and the fact that there are few price regulations means that there is very active competition among generic drug producers. The fact remains that competition is a far more effective way of protecting consumers than price controls. The price regulations may end up reducing price competition among manufacturers and in the long run harming the consumer by fixing prices above what would otherwise have been achieved in an open competitive market.

5. Government's approach to health care

South Africa's health care system is troubled. Articles appear in the press about doctors and nurses leaving the country, rising health care costs, a shortage of doctors and nurses in public hospitals, deteriorating health care standards, theft and fraud in the public health system, non-responsive public ambulance services, the regulation of private health care and medical schemes, compulsory service for medical graduates, certificates of need required by medical practitioners and for new private medical facilities and equipment, and much more. Government planners appear to believe that all the problems of the health care system can be solved by extending the public health care system and imposing strict controls and regulations on the private health sector. Much of this is

done in the belief that the extension of the public health sector is required by the constitution. This is a matter of interpretation and an alternative interpretation follows:

5.1 An alternative interpretation of the Constitution

In terms of section 27(1)(a) of the Constitution of the Republic of South Africa everyone has the right to have access to health-care services, including reproductive health care. Section 27(3) stipulates that no one may be refused emergency medical treatment.[15] Section 27(2) stipulates that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

In response to these constitutional stipulations, government has committed itself to providing basic health care as a fundamental right, providing quality health care to all South Africans, and achieving a unified national health system.[16]

While the rights mentioned in section 27 are limited by section 36, which makes them dependent on the availability of resources, there are different interpretations about what this means. There is a general assumption that the cost of all the socio-political rights contained in the Bill of Rights are to be borne by taxpayers "subject to the availability of resources"; however, one could argue that the real meaning of sections 27 and 36, taken together, is that government has a duty to adopt policies that will create an enabling environment for the most rapid possible growth of health-care services so that everyone has access to health care. As there is compelling evidence that greater economic freedom provides the best environment for human development, the constitutional injunction could require the South African government to free the economy in order to comply with the constitution. It could also mean that government has to use the most cost-effective methods of providing a health-care safety net for the indigent, which government would best achieve by purchasing health care for the poor from competitive private providers.

Section 36 (1) of the Constitution stipulates that "The rights in the Bill of Rights may be limited only in terms of laws of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including..." four listed factors, the last of which is section 36 (1)(e) "less restrictive means to achieve the purpose". An open and democratic society that has as its core values "the advancement of human rights and freedom" and supremacy of "the rule of law" (section 1 of the Constitution) requires a substantially different approach to health care than is currently contemplated by the Department of Health.

The essential characteristics of nationalised health services are that they are built on authoritarian compulsions and prohibitions. Patients are denied choice and health professionals are denied the right to freely practise their trades and professions. The measures necessary to establish such dictatorial regimes are contrary to the principles of an "open society", "the rule of law" and "the advancement of human rights and freedom", and as such may not survive a constitutional challenge. They are certainly contrary to the fundamental philosophy and spirit of the aspirational provisions of the Constitution.

Moreover, a fully nationalised health system would probably fall foul of section 27(3) as it could not avoid the lengthy queues experienced in Canada and the UK, which constantly deny patients emergency medical treatment.

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[15] The Constitution of the Republic of South Africa, 1996 (Act 108 of 1996).
[16] Republic of South Africa, South African Year Book 2002-2003 (Pretoria: Government Communication and Information System, 2002), pp. 339-340.

A fully private health-care delivery system, on the other hand, would meet all the requirements of the Constitution, including the right of every citizen to have access to health-care services. It would also meet the requirements of section 27(3) because no one will ever be denied emergency treatment in a private health system. The real health-care challenge is then to ensure medical treatment for those who are not able to pay.

5.2 An alternative approach to provision of health care

Government could more rapidly improve health care for all South Africans if it concentrated it's limited resources on supplying health services to the poor while leaving the private sector to provide for those who can afford to pay for their own health care. This process could be accelerated if government were to purchase health care for the poor from competing private sector providers. In this way competition in the private sector would be enhanced and the private health sector would grow rapidly. As the South African population becomes more affluent an increasing percentage of the people would be able to afford to join medical schemes or pay out of pocket for their own health care, so lifting the burden on taxpayers.

As has been shown above such an approach to health care would be totally constitutional and we believe will also provide the best long-term results for the people of South Africa. However, if the private sector is to play its proper role in the process it should not be hampered by unnecessary burdensome regulation and intervention in its day-to-day business functions. The proposed regulation of the pricing of medicines is regarded as an unnecessary intervention, as well as being a measure that will have substantial negative consequences.

6. Legal (Jurisprudential) Concerns

The draft regulations appear to go beyond what is envisaged and permitted under the Act and the Constitution, and provide for granting the Minister of Health and the Director-General of the Department of Health excessive discretionary powers. These powers are not accompanied, as required by the Constitution and the Principles of Good Law, by clear objectives or criteria according to which they may or must be exercised. Such extensive law-making powers should be created by statute and not regulation, or, if delegated, should be accompanied by unambiguous objectives and criteria. Given the potential for counter-productivity, and economic disruption and distortion, such regulations should not be implemented unless preceded by a full and independent Regulatory Impact Assessment (RIA) in accordance with internationally accepted guidelines.

In order to explain why, in our view, the draft Regulations are at variance with Constitutionality and/or the principles of good law, it is necessary to summarise them. The recognised jurisprudential principles according to which all laws, legislation, regulations, guidelines, directives, policies, political and administrative practices, etc. (collectively called "laws"), must (to be Constitutional) or should (to be good law) conform, include:

6.1 Constitutionality

All laws must be consistent with and informed by the letter, values and spirit of the Constitution. The Constitution is not an obstacle to decisive government. Its purpose is to ensure good law and good government. Accordingly, it is essential jurisprudentially, and desirable socio-economically, for all laws to comply with the Constitution, and promote the values that inform it.

6.2 Rule of law

Separation of powers – The rule of law is fundamental to South African law. It is enshrined in the first Chapter and first section of the Constitution. It is a binding Founding Provision. Section 1(c) provides for the "Supremacy of the constitution and the rule of law". Despite its pivotal importance

for South African law, there is little understanding of what it means, especially for many law-makers. This is one of the legacies of the apartheid era. True transition requires the cultivation of a clear understanding of what the rule of law means in practice; its implications for conceiving of and drafting legislation and regulations.

The "the rule of law" is distinguished from "the rule of man". What that means is that substantive laws must be *legislated* made by an elected, transparent and accountable *legislature*. They must be *executed* by the *executive*. It is not an alternative way of making laws. It is not an alternative legislature. Its *regulatory* function is not and should not be just another way to make laws. It is exclusively the delegation of power needed to execute and implement legislation. Apart from the philosophical reasons for this "separation of powers", to prevent the over-concentration of power, there are profoundly practical reasons for it. The legislature operates in accordance with elaborate procedures prescribed by the Constitution, and followed according to Parliamentary convention. These procedures are appropriate for law-making in a democracy. They ensure transparency, accountability, debate, participation and due consideration. They ensure that substantive laws are made by elected politicians.

Regulations, on the other hand, can be gazetted arbitrarily. That they are sometimes preceded by public discourse, or presented to the cabinet, is a matter of discretion, not a requirement of the Constitution generally or its rule of law provision. For this reason regulations should be confined to formalistic measures needed to implement substantive legislation adopted by legislators.

A second practical reason for rigid adherence to the separation of powers principle is that it is the only sustainable way to contain the natural propensity of officials to draft laws that shift power over time from politicians to officials. Their spontaneous inclination is to promote their interests, namely to formulate laws that enhance their powers, status and incomes. Doing so gradually transfers the *de facto* legislative function from politicians and parliament to the executive, thus eroding democracy itself. Only if there is critical awareness and vigilance amongst politicians, will the erosion of their powers, the rule of law and democratic values be averted. Most mature democracies and, increasingly, developing countries, ameliorate the problem by having all laws drafted and screened by an autonomous central drafting agency, with trained experts in Constitutional Law.

There is no rigid or obvious boundary between legitimate legislation and regulation. But there are clear values and principles embodied in the rule of law that should be appreciated, respected and observed automatically; as a national mindset or ethos. Regulators – usually ministers in their *executive* capacity – should not "sail close to the Constitutional wind". They should not get away with as much as they can. There is no need for regulations to test the limits, and they should seldom if ever be the subject of legitimate Constitutional challenge. Acts should be drafted so as to contain all substantive law. Legislators must decide and debate in public what laws they want. Excessive discretionary power is undesirable in practice. It is an inferior way of making law. It is unsound philosophically; at variance with democratic values.

The separation of powers component of the rule of law has two dimensions. It prescribes and proscribes what may or must be in statutes, on one hand, and in regulations on the other. A statute or a regulation may be *ultra vires*, the former for one and the latter for two reasons. If an Act purports to delegate more power than allowed, it is, to that extent, unconstitutional, regardless of whether the power delegated putatively is used by the executive. Regulations are unconstitutional if they exceed what is authorised by their parent statute, and, even if they accord with it, they are unconstitutional if the delegated power is excessive or ambiguous. We explain below to what extent the draft regulations appear to be in violation of the separation of powers requirement, and to what extent they are not authorised by the principal act.

Objective criteria – The Constitutional Court has ruled that it must be clear from legislation why powers are delegated – to what end are they to be executed. They must also be accompanied by objective criteria for implementation. Delegated power cannot be implemented according to the arbitrary whim of the executive. Statutes must provide clearly and unambiguously for how officialdom must or may exercise powers and perform tasks, and what, precisely, citizens must do to remain within the law. Citizens should not find themselves at the mercy of arbitrary or discretionary power. They should be able to establish with certainty from relevant statutes what their substantive rights and obligations are. What they must do procedurally for the implementation of laws is the legitimate substance of regulations. Typically, regulations would prescribe formalities: forms to be completed, office hours, registration fees, and the like.

As explained below, the Act does not specify the purpose for which it purports to delegate the power under which the draft regulation is contemplated. Neither the Act nor the draft regulation has objective criteria for implementation. To that extent they appear to be unconstitutional. Even if they are constitutional – if the Constitutional Court interprets the Constitution generously, they are certainly undesirable according to the principles of good law.

Certainty – A requirement of the rule of law is certainty: people are entitled to "know where they stand" so to speak. This is an obvious derivative of the rule of law. If there is no certainty, discretion rather than law rules. Uncertainty in law creates real or suspected injustice, and increases the probability of bureaucratic inefficiency. There are provisions in the regulations that create uncertainty, to which we return below.

These are not all the elements of the rule of law; only those that are presently relevant.

6.3 Due process

The purpose of due process is to ensure that, as the saying goes, "for justice to be done it must be seen to be done". For there to be due process various factors must be present, some of which are prescribed explicitly in Section 33 of the Constitution and some of which are implicit. The concept of due process goes beyond the administrative justice clause of the Constitution, into aspects that are also not immediately relevant. What is directly relevant to the draft regulation is the requirement that administrative action must *inter alia* be "reasonable". Section 33 provides that "Everyone has the right to administrative action that is lawful, reasonable and procedurally fair". Although this provision has not yet been the subject of Constitutional Court interpretation, there is Counsel Opinion to the effect that, to be reasonable, administrative action, including regulations, and especially the process leading thereto, must entail a reasonable and *bona fide* consideration of likely costs, benefits and other impacts, that is, something amounting to a Regulatory Impact Assessment or a Cost-benefit Analysis.

Regardless of whether this is mandatory, which it seems to be – the failure to undertake a thorough assessment of the practical implications of a measure is clearly unreasonable and unfair to people who's rights are affected – such an analysis should be undertaken. This is especially true regarding such serious issues as public health, economic policy (price control), and foreign investment (disincentive effects).

6.4 Regulatory Impact Assessment (RIA)

That laws should be justified by *bona fide* and *ex ante* regulatory impact assessments is increasingly regarded internationally as a requisite of good law. Introducing RIAs as a tool of governance is at an advanced stage of consideration in South Africa and Africa generally. The principle was adopted by the Commonwealth heads of Government Summit in Abuja last year. We suggest that the proposed measure should not proceed without an RIA. We believe that it would be

irresponsible to proceed with such an extreme measure without first assessing potential counter-productive and unintended effects. If there has been an assessment, it should be published for scrutiny and comment. The most serious potential implications are for low-turnover-high-mark-up small businesses serving small, remote and poor communities, for whom the costs and inconvenience of travel may be more serious than nominal price, and where effective control is, in any event difficult or impossible to enforce.

6.5 Governance

For law to be good law, there must be a reasonable prospect of effective enforcement, in relatively corruption- and abuse-free ways. To this end, there must be prior certainty that adequate human and material resources will be available for implementation in all departments concerned, especially those concerned with policing and enforcement. There must be prescribed checks and balances against real or suspected abuse and corruption. This does not appear to be the case.

6.6 Are the Pricing Regulations Ultra Vires?

The Principles of Good Law raise four crucial questions. Firstly, are the relevant provisions of the Act Constitutional? Secondly, if they are, do they empower the Minister to make the contemplated Pricing Regulations? Thirdly, if they do (that is, if there is technical compliance with the *letter* of the law), do the Regulations comply with Constitutional values, especially explicit references in it to the need for laws to promote Constitutional values? And fourthly, do they satisfy other non-obligatory requirements of Good Law?

We assume, for present purposes, that the need for laws to promote Constitutional values is "non-obligatory". This may be excessively generous to legislators. The Constitutional Court may well decide, when called upon to settle the matter, that laws *must* promote Constitutional values to be valid. There seems little doubt that the Act and the draft Regulations are in conflict with some Constitutional values in important respects, such as the need for good governance and such value as personal liberty. In this Submission, we confine ourselves to explicit and unambiguous jurisprudence.

The proposed Regulations appear to fail on all counts.

6.6.1 Section 22G does not authorise Ministerial price-fixing

It should be noted that regulations cannot be considered in isolation. For the regulations to be lawful, the provisions under which they are made must be lawful *and* they must be confined to that which the Act specifically authorises. Under Section 22G, the Minister may make regulations on "the introduction of a transparent pricing system" and on "an appropriate dispensing fee". The pricing system must include a "single exit price". This does not mean that the Minister may determine that price. The section under which the regulations are proposed does not delegate the power to determine prices explicitly, only to *regulate* the introduction of transparency and to *prescribe* the method of publishing single exit prices. Public statements by the Honourable Minister to the effect that manufacturers must set and adhere to single exit prices are, it seems, a correct interpretation of the section. Provisions in statutes must, according to the laws of interpretation, be interpreted strictly, so that the power to regulate prices cannot be read into the section.

6.6.2 Parts of Section 22G may be void for vagueness

Even if one assumes that that the Minister has price-fixing power, the power may be void for vagueness. The Act does not define "single exit price". The regulations seek to address this obvious *lacuna*, but it is the Act which must do so. The intention of laws must be apparent from the laws themselves. All concerned seem *ad idem* on what it means, which may mean that it can be regarded as a matter of trite knowledge. If it is a matter of requiring manufacturers to charge one-

price-for-all, it will be clearer than if it is a regulated price, in which case all sorts of complications present themselves, such as what may be included: VAT, distribution costs, storage fees, interest on credit, etc.

Another potentially fatal flaw in the Act is that it does not specify objectives. Why is the Minister given these powers? To what end are they to be exercised? A wide range of arbitrary possibilities exists. She could, for instance, be expected to fix prices so as to promote foreign investment, or to protect local industry, or to ensure that medicines are sold in small poor remote communities. The prevailing assumption that she must fix prices so as to make medicines radically cheaper is not apparent from the section, whence it would have to come. This assumption implies that Parliament wanted to benefit a select few disproportionately, namely higher income urbanised people near large (high turnover) retailers, at the expense of (a) people in small, poor or remote communities with low turnover retailers, or no retailers at all, (b) marginal retailers who cannot survive sub-economic prices, (c) investors who will reduce product range, service and perhaps quality, (d) empowerment entrepreneurs who might otherwise have become retailers, and so on. Depending on arbitrary assumptions about intended direct and indirect consequences, the Minister might reach vastly different conclusions. Without the "guidance principle" (see below) as determined by the Constitutional Court, the relevant provision of the Act appears to be unconstitutional.

If it is assumed that the Act confers price-fixing power, *and* that the power should be used to fix prices far below market-determined levels, the Act makes no provision for distribution costs. Pharmacists mat charge only the exit price and a dispensing fee. That leaves nothing for distributors and wholesalers. The Act is ambiguous here too. It allows for distribution and wholesale costs, but says they may not be added to end prices. Who then is to pay them? Either distributors and wholesalers have to work for free, or they must be paid by manufacturers. That means real (effective) prices will be well below exit prices. In other words, either the explicit provisions of the Act will be ignored, which would be an extreme manifestation of bad law, or the price control contemplated is more extreme and punitive than intended.

6.6.3 Section 22G has no guidelines or criteria as required by the Constitution

Where discretionary powers can be delegated lawfully, they must be accompanied by objective criteria or guidelines for decision-making. Clear objectives can suffice, but usually there have to be criteria according to which decisions may be made. Section 22G has no such objectives or criteria. It appears to violate the "guidance principle". In the absence of statutory guidance, it is doubtful that the draft regulations will pass Constitutional muster.

6.6.4 The regulations appear to violate the requirement of a separation of powers

If all these assumptions are compounded and conflated into a single assumption that (a) relevant provisions of the Act are *not* void for vagueness, that (b) the powers delegated are *not* Constitutionally excessive, that (c) the legislator's objectives *are* sufficiently clear, that (d) that the absence of guidance is *not* a fatal flaw, the final Constitutionality hurdle concerns the extent to which the draft regulation exceeds the *per se* law-making capacity of the executive branch of government. In other words, regardless of all the other considerations if all else is in place – are the regulations allowed under the rule of law? Do they go so far as to violate the principle of the separation of powers? The Constitutional Court has been generous in its interpretation. It has tended to condone a great deal of law-making power in the hands of the executive. Perhaps it is concerned about the extraordinary implications of a more consistent application of the principle in the context of thousands of laws inherited from the apartheid regime, which transferred all important law-making powers to Pretoria. Almost every law from the past blatantly violates the separation of powers principle. Perhaps it is mindful of the awesome task it would take upon itself were it to try to stem the tide of new laws in violation of the principle.

Whatever the case might be, its onerous task should not be compounded by a perpetuation of South Africa's legacy of bad law. The executive should be an agent for the promotion of Constitutional and Democratic values and principles, and not propose laws of dubious Constitutional validity or jurisprudential legitimacy. All South Africans of good will should work together to turn this country into a model democracy where it is clear to all its citizens and the rest of the world, especially investors with desperately needed capital and technology, that we take our Constitution seriously, that we understand the values that inform it, and that we want them to be a living reality.

6.7 Checklists

We have added a Principles of Good Law Checklist for ease of reference. Applied to the draft regulations, it is readily apparent that the regulations do not satisfy all the principles of good law. We suggest that all relevant provisions in the act and draft regulations should be tested according to the criteria contained within the Checklists (Appendix A) so as to satisfy the Department of their constitutionally and feasibility.

7 Conclusions

Governments have tried to use price controls since the beginning of recorded history and in every case they have disrupted economies and have ended up harming poor consumers the most. As they stand, the price controls will reduce drug access in South Africa rather than increase it and will harm the ability of medical professionals to treat patients. We have serious concerns about the process under which these regulations were conceived and that they are not consistent with good law. The regulations grant powers to the Minister and Director General that should, according to the principles of good law, be granted by statutory bodies and not by unelected committees or government officials.

In the circumstances, we urge the Department to withdraw the draft regulations in their entirely, and recommend that Section 22(G) of the Medicines and Related Substances Control Act be amended to be unambiguously constitutional.

It is only through implementing sound economic policies and constitutional values that encourage competition and democracy that the interests of consumers, especially disadvantaged consumers, will be met sustainably. This is as much true for the provision of food, clothes and cars as it is for the provision of medicines. We urge the Pricing Committee to consider our arguments in the interests of patients whose rights and access to healthcare will be severely undermined by the proposed regulations.

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Appendix A – Good Law Check Lists attached (Pages 18 to 22
Appendix B – UK Regulatory Impact Assessment Guidelines (as requested during oral hearing)

Appendix A

Good Law Checklist Part 1 - Constitutionality

The questions in Parts 1 and 2 apply to *all* laws (legislation and regulations) made for any purpose whatsoever.

Most answers must, as indicated, be "Yes". In some cases "No" can be justified by very special Constitutionally valid circumstances.

NR	QUESTION	YES	NO	IF "NO", THE SPECIAL REASON
1	Does the legislative body for whom the law has been prepared have the power under the Constitution to pass the law?			Must be "YES". (If "NO" the law will be unconstitutional.)
2	Is the proposed law a law of general application, equally applicable to all?			Must be "YES".
3	Is the purpose of the law set out in the long title?			
4	Is the purpose of the law set out in the preamble?			
5	Does the law comply with the requirements of the rule of law:			
	a) Is the law free of provisions which allow the arbitrary exercise of power by any person?			Must be "YES".
	b) Is the law clear?			Must be "YES".
	c) Is the law precise?			Must be "YES".
	d) Is the law unambiguous?			Must be "YES".
	e) Is the law free of retrospective provisions?			
	f) Does the law conflict with any existing law?			
	g) If the law conflicts with existing laws, does it identify such laws and amend them?			
	h) Is the law compatible with South Africa's international obligations?			Must be "YES".
6	Does the law comply with all the provisions of the Bill of Rights in Chapter 2 of the			Must be "YES".

	Constitution?			
	a) b) c) *<u>Here every clause in the Bill of Rights could be listed (in plain language)</u>*			Varies according to s36
7	If the law limits any of these rights, does the limitation comply with s36 of the Constitution?			Must be "YES".
8	Does the law uphold the separation of powers between legislature, executive and judiciary?			Must be "YES".
9	If the law authorises any person to make regulations:			
	a) Does it define clearly who may make the regulations?			Must be "YES".
	b) Does it define clearly and limit the purposes for which regulations may be made?			Must be "YES".
	c) Does it give guidelines with which the regulations must comply?			Must be "YES".
	d) Are the regulations restricted to administrative and procedural matters?			Must be "YES".
10	If the law authorises any person to exercise discretion:			
	a) Does it define clearly who may exercise discretion?			Must be "YES".
	b) Does it define clearly and limit the discretion?			Must be "YES".
	c) Does it define clearly the purpose for which the discretion may be exercised?			Must be "YES".
	d) Does it give guidelines as to the manner in which the discretion may be exercised?			Must be "YES".
11	If the law sets up a tribunal:			
	a) Why are the courts not used?			
	b) Does the tribunal function free of administrative or executive responsibilities?			Must be "YES".
	d) Does the law define the composition of the tribunal clearly?			Must be "YES".
	e) Does the law define and limit the powers of the tribunal clearly?			Must be "YES".

	f) Does the law require the tribunal to observe natural justice?			Must be "YES".

Good Law Checklist Part 2 - Feasibility

Unlike the questions in Part 1, these questions are concerned with determining whether a law is suitable for its purpose. The answers are a matter of judgement requiring careful consideration and debate.

All the answers should be "YES". A "NO" answer indicates that insufficient consideration has been given to the law.

A	The General Purpose and Objective of the Law	YES	NO
1	Has the purpose of the law been defined?		
2	Has the importance of the purpose been quantified or evaluated?		
3	Does the importance of the purpose justify legislation?		
4	Has the objective (how the purpose will be achieved) been defined?		
5	Are there good reasons to believe that the law would achieve its purpose?		
6	Has an estimate been made of the benefits expected from the law?		
	a) Is the estimate of the benefits realistic? b) Where the benefit has monetary value, has the value of the estimate been quantified? c) Has the estimate been recorded as a matter of public record for later monitoring and performance evaluation? d) For accountability purposes, have the persons (preferably department heads) responsible for the estimation of benefits confirmed their satisfaction with the estimate? e) Has an estimate been made of by when or over what period the benefits are expected? f) Has the estimate of the timing of benefits been recorded as a matter of public record for later monitoring and performance evaluation?		
7	Has a list of alternative methods of attaining the purpose of the law been prepared?		
	a) Have the alternative methods of attaining the purpose of the proposed law been considered and rejected for known compelling reasons? b) Has the repeal of existing law which may be causing or exacerbating the problem been considered as an		

	alternative method? c) Is the proposed law clearly the best way of attaining the purpose?		
8	Will it be possible to implement and administer the proposed law?		
	a) Have all departments and structures responsible for implementing the proposed law confirmed in writing that they have the administrative capacity to do so? b) If not, have adequate arrangements been made for the provision of the necessary capacity before the law is implemented? c) Does the implementation of the law require the diversion of resources from other purposes? d) If so, has adequate provision been made for the continued performance of those purposes? d) Can the law be implemented without additional budgets, or the appointment of more functionaries or officials? e) If not, have the relevant departments, particularly of finance and public services, agreed in writing to the proposed law and its implications? f) Has any special training which may be needed to apply the law been prepared, costed and budgeted?		
9	Will it be possible to enforce the proposed law?		
	a) Have all departments and structures responsible for enforcing or policing the proposed law, particularly the police and the courts, confirmed in writing that they have the capacity to do so? b) If not, have adequate arrangements been made for the provision of the necessary capacity before the law has to be enforced? c) Does the enforcement of the law require the diversion of resources from other purposes? d) If so, has adequate provision been made for the continued performance of those purposes? e) Can the law be enforced without the appointment of more functionaries, police or judicial officers? b) If not, have the relevant departments, particularly of finance and public services, agreed to the proposed law and its implications? c) Has any special training which may be needed to enforce the law been prepared, costed and budgeted?		
10	Will it be possible to comply with the law in the ordinary course of events and is widespread compliance likely or achievable in practice?		
11	Is generalised compliance with the law achievable in practice and likely?		
12	Has a cost-benefit analysis been done of the law?		

13	To ensure accountability, has a senior person or department head taken responsibility for the accuracy and adequacy of the cost-benefit analysis?		
14	Is the expected cost to the State in all its forms of implementing and enforcing the law justified by the expected benefits?		
15	Is the expected cost to the public for compliance with the law justified by the expected benefits?		
	a) Have the compliance costs for every sector or interest group affected directly by the law been estimated separately? b) Do the compliance costs affect poor and wealthy people fairly in proportion to their wealth and income? c) Do the compliance costs affect micro, small, medium and bigger businesses fairly in proportion their wealth and income?		
16	Have all direct and indirect regulatory impacts, including side effects (secondary and unintended consequences), of the proposed law been considered?		
17	Does the expected benefit from the law outweigh likely undesirable side effects?		
18	Have all reasonable measures to minimise undesirable side effects been incorporated in the law?		
19	Is there any mechanism in place to monitor the affect of the law in order to improve its benefits and reduce its undesirable side effects?		
20	Has the inclusion of a “sunset” clause in the law been considered?		
	a) If no sunset clause is included, has provision been made for monitoring the efficacy of the law in terms of its intended objectives, and anticipated cost and benefits? b) If so, does the sunset clause specify unambiguous criteria for its implantation.		

Appendix B

REGULATORY IMPACT ASSESSMENTS GUIDANCE (UNITED KINGDOM)

- **Are you involved in developing a policy to solve a problem domestically or in the EU?**
- **Are you considering options that impact on business, charities or the voluntary sector?**

If you answered "Yes" to both the above questions, you need to construct a Regulatory Impact Assessment (RIA) to assess the costs and benefits of your proposal.

The RIA will help you develop creative, robust, flexible and informed policies that are focused on outcomes - something that we are all committed to as part of the Modernising Government agenda. In the EU context this will help strengthen your negotiating position in terms of information both on the course of action proposed and on alternative approaches. You will also need to include an RIA with any regulatory proposal seeking collective Ministerial agreement and all public consultations.

So where to start

In the first instance you can find out how to construct you RIA by speaking to Bruce Bebbington on 020 7273 8172 or Sandra Pontat on 020 7273 4180 in Performance, Delivery and Strategy Unit. The sooner you start the better. Guidance on the RIA process is also available on the Home Office and Cabinet Office websites:

- http://www.cabinet-office.gov.uk/regulation/scrutiny/ria-guidance.pdf

Hints & Tips

To help you get started here are a few hints and tips

The following is a list of key issues to bear in mind when you are considering a regulatory proposal to solve a problem:

Remember Modernising Government is all about evidence based policymaking

- You need evidence - so collect it
- Pick up the phone and speak to stakeholders - Have early informal discussions with business, charities, and the voluntary sector. They will be able to help get information on the scale of the problem, both in the UK and, if appropriate, more widely. For example, on the number, type, and size of businesses likely to be affected and the potential costs and benefit of your proposals. They may even be able to suggest ways of solving the problem. All of this will be useful for your initial RIA.
- What do we already know – There may already be an existing body of research available for you to call on. But in any event, if you have no data you will need to make some assumptions about the likely impact. This will be essential when you go out to consult formally.
- And remember you will need to Build in time for consultation and implementation - the Cabinet Office "Code on Written Consultation" can be found at:

  http://www.cabinet-office.gov.uk/servicefirst/index/consultation.htm.

and the Small Business Service has issued guidance on implementing regulations at:

http://www.sbs.gov.uk/content/pdf/implementationguidelines.pdf

- Do you need to regulate? - Stop and think

- Think about a range of options – These should include "do nothing" and could also include non-regulatory approaches such as codes of practice and financial incentives, as well as domestic or European legislation.
- Think small first – You should always consider the impact on small firms. The Small Business Service is there to help you use the "Small Business Litmus Test".
- Think about possible unintended consequences - In regulating in one area, you may unintentionally create problems elsewhere.
- Think about consistency with existing regulation – including international trade rules, EC law, and competition policy.
- Assessing your options – How much and who?
- Balance risk, cost and practical benefits - What's the scale of the problem? Who is affected and how? Does the extent of the market failure merit regulation? Who will benefit and who will bear the cost?
- How will the regulatory proposal be enforced? You should consider which government agencies or devolved administrations would enforce the proposed regulation. Have you consulted the relevant organisation? What will be the extra cost on government resources?
- The Better Regulation Task Force Principles of Good Regulation - Does your regulatory proposal/options meet these principles of: Transparency, Accountability, Proportionality, Consistency, and Targeting? More information is available at:

  http://www.cabinet-office.gov.uk/regulation/TaskForce/Principles.htm

Depositing RIA's in the House of Commons and Lords Library

Please ensure that all copies of all RIA's are sent to the following addresses:

Deposited Papers Clerk
Oriel Room
House Of Commons Library
London
SW1A 2AA

Official Publications Library
House Of Commons Library
1 Derby Gate
London
SW1A 2DG

Weekly Information Bulletin Editor
House of Commons Information Office
London
SW1A 2TT

House of Lords Library
House of Lords
London
SW1A 2PW

Contacts:

House of Commons 020 7219 3666

House of Lords 020 7219 3107

Key Contacts:

Performance Delivery and Strategy Unit:
Bruce Bebbington on 020 7273 8172 or
Sandra Pontat on 020 7273 4180

Economics and Resources Analysis Unit (RDS):
Gareth Harper on 020 7273 2373 or
Mark Weiner on 020 7273 4521

Regulatory Impact Unit Cabinet Office:
Marie-Anne Mackenzie on 020 7276 2186 or
Paul Roberts 020 7276 2571

Small Business Service:
Ken Alden 020 7215 4421
Debbie Akinfe 020 7215 8092