THE FREE MARKET FOUNDATION
of Southern Africa

progress through freedom

Submission on

THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2008

The Free Market Foundation

The Free Market Foundation (Southern Africa) is an independent Public Benefit (PBO No 930 017 343) and Non-Profit (No 020-056-NPO) public policy organisation founded in 1975 to promote and foster an open society, the rule of law, personal liberty, and economic and press freedom as fundamental components of its advocacy of human rights and democracy based on classical liberal principles. It is financed primarily by donations, membership subscriptions and sponsorships. The FMF produces a wide range of electronic and other publications, and lobbies for a legal, monetary and fiscal environment conducive to high economic growth and empowerment of ordinary citizens. (www.freemarketfoundation.com).

This Submissions confines itself to problematical elements of the Bill

We are aware that the Department is receiving submissions that go into the provisions of the Bill in great detail. There is always a danger that detailed comment can be misinterpreted as implying acceptance of underlying principles and concepts. This submission is confined to addressing overarching principles of dubious validity and encourages those who study detailed submissions not to presuppose agreement in principle. Individual enterprises in the the health sector, like their counterparts in any other sector, tend to favour government interventions that benefit the distinctive and divergent vested interests of each individually, and the amelioration of measures which harm them. All who are truly efficient and competitive and those they serve would, on balance, benefit most and therefore prefer a freely competitive liberalised and privatised health care market, with government securing maximal value for money and patient benefit by outsourcing what it does not privatise.

Government should transfer its facilities for BEE and greater efficiency

Furthermore, the government, as the biggest owner by far of health care infrastructure, has by far the greatest potential to facilitate BEE and affirmative action by transferring their hospitals, clinics and laboratories to BEE and AA beneficiaries, and improving patient care, by outsourcing and privatising.

Leave the private health sector alone

In short, the time has come for the government to stop concentrating on the comparatively efficient private sector – to leave it alone – and to concentrate on improving the public sector, especially by harnessing the manifestly superior propensity of a freely competitive private sector.

Johannesburg
1sr Floor, Norfolk House, Sandton Close 2,
cnr Norwich Close & 5th Street, Sandton
PO Box 785121, Sandton 2146
Tel: +27 (0)11 884 0270 • Fax: +27 (0)11 884 5672
Email: fmf@mweb.co.za

Cape Town
1st Floor, Equity House,
107 St George's Mall, Cape Town
PO Box 805, Cape Town 8000
Tel: +27 (0)21 422 4982 • Fax: +27(0)21 422 4983
Email: fmf.ct@mweb.co.za

Website: www.freemarketfoundation.com
Non Profit Organisation Registration No 020-056-NPO / Section 18A PBO Exemption No 930 017 343

Price controls cause distortions

This Bill is still informed by the tenacious fallacy that price control, whether in the form of a single exit price or otherwise, reduces prices without causing distortions that disproportionately harm intended beneficiaries. A prescribed single price is based on the fallacy that there is a single product or service being priced. In truth, different quantities of products that are nominally the same, supplied at different times and at different places, are recognised in economics as being different products. A single exit price, therefore, is a single price but not for a single product. It is a single price for a diversity of products and therefore either too low or too high in all cases except rare cases where the price happens to be appropriate. The inevitable effect of a single exit price is to provide a perverse incentive against the provision of small quantities or products accompanied by favourable conditions of delivery, storage or payment and the like. A particular perversion is that bulk discounts for large quantities that would normally be for large numbers of people, particularly the poor people, are unobtainable. In other words, price control, in all its forms, inevitably discriminates disproportionately against those who can least afford it.

Price differentials arise in free or relatively free markets precisely because they are context-specific, and pricing, if appropriate, is in accordance with circumstances and relative preferences. If not, those who price inappropriately are ruthlessly and appropriately penalised by losing market share, reputations and profits.

Government agencies are incapable of setting prices that will not harm consumers

Prices that are determined by consumers in purchasing and refraining from purchasing should guide all production. Such prices are the signals that tell producers what is in demand and what they should produce. Government actions that interfere with prices also interfere with the signals that should guide the activities of producers. Price control removes the ultimate control that consumers should have over production, the consequence of which is that they do not get the goods and services they want at the time they want them.

The notion that there is some mathematical relationship between costs of production and selling prices is fallacious. If someone were to spend thirty years of his life building a motorcar he would probably have difficulty in recouping what he could have earned by doing something else. Prices depend entirely on the subjective value judgements of consumers, which cannot be mathematically simulated. If producers can produce goods at a cost that is lower than the price consumers are prepared to pay, they make profits. If their costs are higher than the price at which consumers are prepared to purchase their goods, they suffer losses.

Governments that interfere with consumer judgements regarding prices therefore inescapably disrupt production and supply of goods and services. While there may appear, in the short term, to be consumer advantages, the long-term consequences are harmful.

The Public Interest

Section 7 (pg.9) provides that the Minister must decide every registration, and must do so “in the public interest”. Firstly, there is no set of objective criteria constituting “the public interest”. Not only is this obviously so, but the point has been confirmed by the courts.

The rule of law requirement that there must be legal certainty, and that discretionary power must be accompanied by an unambiguous purpose for which it is granted and objective criteria according to which it must be exercised. A decision in the so-called public interest

cannot be debated precisely because it is, at best subjective, and at worst meaningless, and should therefore be accepted as unconstitutional.

Apart from the absence of objective criteria and a stated purpose, the measure is wholly unworkable and impractical, unless the Minister does not take this considerable responsibility seriously. Presumably the reason why the power is given to the Minister is that it is considered sufficiently important to invoke the Minister's seniority and accountability. There is a decided case in the Pretoria High Court according to which a Ministerial power is granted on the assumption that the Minister will apply his/her mind purposefully. This does not only require the Minister to consider the scientific, social and other merits in each case, but to examine countervailing arguments. Clearly the Minister cannot and will not do this and the power should rest with a person or persons who will.

There should be a right of appeal to an independent court

Furthermore, the power is not subject to dispute. To minimise the perverse incentive for abuse and corruption, especially amongst officials on whose advice the Minister acts, there should be at least one right of appeal to a truly independent court or tribunal.

The call on the Minister to act "in relation to the state" is not clear

The public interest requirement calls on the Minister to act in "relation to the State". What this means is unclear. Products are not separately registered when they are "in relation to the State". Does it mean that the Minister's registration decisions must be as if registration is always in relation to the State, even if it is not, or does it mean that the listed criteria apply only for registrations that have some "relation" to the State? Or do the words have some other meaning?

The criteria according to which the Minister is expected to act are vague

In any event, the listed criteria are incoherently vague. It is not clear, for instance, what is meant by "economic interests in relation to health policies" (which must themselves be "in relation to the state"). This could be interpreted by the Minister to mean, for instance, that expensive products for rare diseases should not be registered and only products that promote the economic interests of the State should be. Sound statutory drafting does not allow for a multiplicity of meanings and interpretations.

There is no such thing as a universal "need and desirability" for any product or service. Individuals in need of medication and their physicians are the only people in a position to decide need and desirability. The Minister is placed by these vague criteria in an impossible position. What is the Minister to do if asked to register a perfectly effective but extremely expensive product for a rare disease for which there may be zero demand at present, but potentially one or two people could be critically ill and in need of the product immediately? Would "the public" be "best served" by registration or refusal? There is no objective answer to such real world questions. Do these words direct the Minister to register only medicines for common illnesses, or for all products the Minister regards as effective, or only for those the Minister considers to be good value for money, or anything else conceivable? The wording is far too vague for the Minister and officials advising the Minister to have the slightest idea of what is expected of them when confronted with practical decisions they are expected make on a daily basis, on one hand, and rare decisions with abnormal considerations on the other.

Since all products in respect of which medicinal claims are made must be registered, is the Minister to consider only "scientific" evidence narrowly defined, or must the Minister register products for which there is social, cultural or traditional demand, such as

homeopathic products, traditional African medicines, vitamins, or products that may be effective purely as placebos?

The common law against fraud could adequately deal with many of the issues
One of the problems with attempts at regulation of this kind is that is seeks to reinvent the wheel. The common law is perfectly adequate and has been tried and tested successfully for centuries. It provides *inter alia* that claims may not be fraudulent. Where fraudulent claims are made, they are subject to civil and criminal prosecution. If formal registration is desired, which it is acknowledged has become common practice in all countries, it should have a corresponding logic, namely that suitable government experts should apply their minds to whether false or misleading claims are made and if they are satisfied that this is not so, products should be registered and traded in freely competitive markets subject to such safety rather than economic checks and balances as are necessary.

Where legislation of this kind supplants common law, it usually curtails rather than enhances public protection. It has the effect that someone making false or misleading medicinal claims for a products or service can raise, in their defence, that the government, indeed the Minister her or himself, has approved the product "officially". Instead of protecting people from ineffective or harmful health care products, registration of the kind envisaged will deny them the substantial protection of both civil and criminal law.

Under Section 3(7), certification or registration is valid for five years. This provision makes sense only if it is assumed that the vague considerations specified are legitimate, in that, however they are interpreted, they could be subject to change for reasons unconnected with the product concerned.

However, if the criteria are appropriate, namely, concerned only with the legitimacy of medicinal claims, then there is no reason for a prescribed period. If a painkiller is registered on the grounds that it has been well established for decades as effective and affordable, it should be subject to reconsideration only if new evidence arises to the effect that there are grounds for deregistration. A health product should be registered if no false claims are made regarding it and should stay registered indefinitely in the absence of evidence to the contrary.

Price controls on pharmacists
Price control imposed on pharmacists and perpetuated in the Bill is as counter-productive and irrational – and disproved by centuries of needless mischief – as the single exit price. Maximum price control on pharmacists, as with all maximum price control, has the following inevitable consequences:

1. Marginal suppliers are driven out of the market, such as pharmacists serving small or low-income communities, and pharmacists working on tight profit margins, in other words, pharmacists that needy people need most.
2. Marginal consumers are denied access to healthcare. Consumers with rare diseases, or consumers who were previously served by marginal pharmacists driven out of the market by price control, are primary victims. Very wealthy people have needlessly high-cost access to medical care over long distances including foreign countries. The poor are pure victims with no such luxury.
3. Medicines that have a short shelf life or are expensive to maintain, perhaps under refrigeration, cease to be available. It was no surprise to see a report last year to the effect that snake serum was no longer available at any hospital in Johannesburg.

4. Medicines for which there is low demand will no longer be available simply because it is not viable for a pharmacist to incur the cost of holding stock.

Price control of the kind applicable has the effect of ensuring only that high-turnover, low-maintenance medicines are available, and then only from those outlets that survive the regulatory assault on health care.

Exempting officials from liability for damage provides a perverse incentive

Section 25 exempts officialdom and contractees from liability for damage caused in good faith. This is a perverse incentive for them to act irresponsibly. Especially where relatively unconstrained administrative discretion is created, accountability is one of the essential checks and balances. It is anomalous that legislation that seeks to impose accountability and transparency on freely contracting parties seeks to exempt those endowed with abnormal power and discretion from that responsibility. This is reverse logic.

The Chief Executive Officer, in terms of Section 3 (pg.7), has neither a fixed term nor tenure, which means that reappointment creates a perverse incentive to make politically popular rather than objectively sound decisions.

Violation of the Rule of Law

Since there is so much in this Bill and in health legislation generally that is in violation of the rule of law, it is assumed that the statutory drafters and officials concerned are unfamiliar with what it means in practice. In the new post-apartheid South Africa, everyone is for the rule of law, or thinks they are and say they are if asked. However, one of the most disastrous and tenacious legacies of apartheid, the essence of which was the destruction of the rule of law, is that there is virtually no spontaneous understanding of when laws and policies are consistent with it. In order to appreciate which aspects of the Bill and much extant health care legislation are inconsistent with the rule of law, clarification on what it is and how it applies to legislation follows.

It is increasingly and distressingly forgotten by statutory drafters that the first section of the Constitution lays down a justiciable “foundational” provision to the effect that all law and practice in South Africa must be consistent with the rule of law. There are many provisions in the act this Bill seeks to amend and in the amendment itself that are inconsistent with the rule of law, particularly to the extent that they violate the principle of the separation of powers and that they establish administrative discretion without accompanying unambiguous objectives, and objective criteria for decision-making.

We do not in this submission examine each example – there are many – but urge the Department of Health to refer the Bill back to its legal advisors with an instruction to ensure that every provision is consistent with the letter and spirit of the Constitution, particularly the rule of law and Section 35 according to which all administrative action must be fair and reasonable.

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, and is not mere puffery, but a binding Foundational 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 lawmakers. 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* by an elected, transparent and accountable *legislature*. They must be *executed* by the *executive*. It is not an alternative way of making laws. The executive 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 lawmaking 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 regulations can be in violation of the separation of powers requirement, to the 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 regulation is contemplated. The Act does not contain objective criteria for implementation of regulation. To that extent regulations could 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 Bill that create uncertainty.

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

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 Bill 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 whose 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).

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.

Conclusion

We propose that this Bill should be sent back to the drafters for revision, particularly those sections that are in conflict with the Rule of Law, are impractical, and will have detrimental consequences for patients and their health care providers.

Prepared by:

Leon Louw
Director,
Free Market Foundation

And

Eustace Davie
Director
Health Policy Unit

Free Market Foundation
PO Box 785121
Sandton
2146
South Africa

Tel +27 (0)11 884 0270
fmf@mweb.co.za

15 May 2008