FREE MARKET FOUNDATION

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Free Market Foundation Submission on the Medical Schemes ACT

To: Committee 1 (Triple Challenges of Inequality, Poverty and Unemployment)
High Level Panel on the Assessment of Key Legislation

By: Free Market Foundation

1. The Free Market Foundation

The Free Market Foundation (FMF) is an independent non-profit public benefit 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 by membership subscriptions, donations and sponsorships.

2. Introduction

The triple challenges of inequality, poverty, and unemployment cannot be seen as distinct from the healthcare needs of millions of impoverished South Africans. The government has in various ways attempted to address healthcare concerns, most recently, with the proposed introduction of the National Health Insurance (NHI) programme, which the FMF believes is deeply flawed and may result in unintended, harmful consequences.

In this submission, however, the FMF wants to address the Medical Schemes Act (131 of 1998), which introduced open enrolment, community rating, statutory solvency requirements, and prescribed minimum benefits into the medical schemes market.

3. Community rating and open enrolment

Community rating means health insurers must charge the same price to all members regardless of their age, sex, or health status. Open enrolment means they must accept anyone, regardless of age, sex, or health status, into the scheme. This is provided for in section 29(1)(n) and (s) of the Act.

Unfortunately, despite the good intentions underlying these principles, they have the effect of driving healthy and poor individuals out of medical schemes, while incentivizing mostly the elderly to join them. The consequence is that the risk pool of insured people becomes smaller and less healthy, driving up contribution levels and making health insurance unaffordable.

Medical schemes must be able to 'risk rate' individuals and vary their premiums. This places the responsibility of individuals' health in their own hands. This will reward healthy behaviour and not unduly push younger, and, inevitably, poorer, individuals out of the potential benefits of medical schemes.

4. Prescribed minimum benefits

In terms of section 67(1)(g) the Minister of Health may prescribe the scope and level of minimum benefits to which clients of a medical scheme shall be entitled. By 2001 there were 295 conditions which all medical packages had to cover.

While this seems just and fair, the economic consequences of this are harmful. Medical schemes are now unable to tailor packages for certain demographics, such as younger and older individuals, and have to offer the same package across the board insofar as the minimum benefits are concerned. This makes packages more expensive than they otherwise would be, especially for younger clients who do not have the same level of healthcare needs as the elderly.

As Jasson Urbach, the FMF's Health Policy Unit director writes:
"PMBs act as a de facto entry barrier because they prevent actuaries from designing low-income insurance packages... The consequence is that low cost medical schemes that cover the specific basic needs of low-income people cannot be designed accordingly."

Prescribed minimum benefits seem very attractive on paper, but in reality only cause fewer people to buy into medical schemes because they artificially raise the price of medical scheme cover.

5. Statutory solvency requirements

In an effort to ensure medical scheme members are not adversely affected by the insolvency of their scheme, the government introduced statutory solvency requirements whereby the accumulated funds of schemes must be at least 25% of the gross annual contributions to the scheme. While this seems logical, the solvency ratio was not determined with how medical schemes function.

According to the Actuarial Society of South Africa, solvency is an asymptotic function of contribution increase. In other words, the higher the solvency requirement, the greater the increase required to improve solvency by 1 per cent. For example, increasing the solvency requirement from 10 per cent to 11 per cent requires a contribution increase of 1.39 per cent. However, increasing the solvency requirement from 24 per cent to 25 per cent requires an increase of 2.07 per cent in contributions. Increasing the solvency requirement drives up membership contributions disproportionately and this negatively affects the rate of increase in the number of members entering a scheme.

The statutory solvency requirements introduce a considerable regulatory bias in favour of some medical schemes and against others. A scheme that has accumulated reserves that exceed the required minimum is in a better position to attract new members than one that has a shortfall. It will be particularly difficult for new medical schemes to enter the market and rapidly growing schemes will be at a disadvantage relative to slowly growing ones. This is not a desirable situation given the substantial expected future demand for healthcare in the country.

6. Conclusion

In light of the above, the FMF proposes the following:

1. That age, sex, and health status be removed as prohibited criteria from section 29(1)(n) and (s) of the Act.
2. That the prescribed minimum benefits provisions of the Act be removed, or at the very least, exempt low-income benefit options from having to cover PMBs so that medical scheme actuaries are in a position to devise more affordable options
3. That the statutory solvency requirements in the regulations under the Act be determined (if at all) with due regard to the functionality of medical schemes.

Attachments

1. Scrap PMBs and let the market work
2. Free Market Foundation submission on MAKING HEALTHCARE AFFORDABLE

Attachment to Free Market Foundation submission on the Medical Schemes Act

Scrap PMBs and let the market work

Prescribed Minimum Benefits (PMBs) are a compulsory package of benefits that medical schemes, currently, are liable to pay in full – regardless of how much healthcare providers may charge for them. In July, the Minister of Health proposed several amendments to the regulations that could limit medical schemes' liabilities.

Proposed is that medical schemes should be liable for payment for services according to the billing rules and the tariff codes (adjusted for inflation to reflect current prices) of the National Health Reference Price List (NHRPL), published by the Council for Medical Schemes (CMS) in conjunction with the Department of Health (DoH) in 2006. Alternatively, schemes may continue to negotiate directly with providers of health services but are not permitted to use cost-saving measures such as co-payments or deductibles.

The DoH's head of regulation and compliance, Dr Anban Pillay, said the draft regulations aim to protect medical schemes from open-ended claims for PMBs because, "There is an unequal balance between medical schemes and providers, who have a blank cheque to charge what they like". Dr Pillay correctly pointed out that PMBs push-up the cost of private healthcare and are making the medical scheme industry unsustainable. He could have also added that community rating, open enrolment and statutory solvency requirements also push-up the cost of private healthcare.

The fundamental problem yet to be properly identified, let alone resolved, is the principle of so-called "social solidarity" contained in the Medical Schemes Act of 1998 (MSA). Consumers have inevitably borne the brunt of this intrusion into private healthcare arrangements since any "social solidarity" principle unavoidably raises the price of medical scheme coverage and in process prevents low-income people from entering the private medical scheme market.

Medical scheme member contributions cover a defined list of benefits which are set out in the member's agreement with the medical scheme. Medical scheme administrators are compelled to guard the interests of all members by ensuring that in carrying out their administrative duties they adhere strictly to the terms of the contract between the individual member and the medical scheme. If they were to obey the current laws and routinely pay the *full* costs for PMB treatments, without there being any limitations, they would end up bankrupting the medical scheme and failing in their duty to the entire pool of members.

The DoH is correct – it *is* unreasonable for government to force medical schemes to pay service providers in full regardless of what they charge. But, more importantly, it is unreasonable for government to dictate what benefits should be included in private contractual agreements. When benefits are determined politically rather than by what individuals want, the benefit package and the costs required to cover them expand and raise the cost of medical scheme coverage.

According to the CMS, the cost of providing PMBs varies between R332 and R1,150 per beneficiary per month, with the average being approximately R510. The average cost per month for babies under one year of age, was R861, and for a beneficiary 85 years or older, R2,548. To increase the number of private medical scheme beneficiaries, the cost of medical scheme coverage needs to be reduced. Government needs either to remove PMBs, or, at the very least, exempt low end market schemes from having to cover PMBs so that actuaries can devise more affordable options.

The DoH's proposal – to use the NHRPL – is a poor idea, even after adjustment for inflation, and a thinly veiled attempt to further control prices within the private medical sector. According to the CEO of the South African Private Practitioners Forum, Dr Chris Archer, the NHRPL was flawed from the start, since it did not

reflect the true cost of providing medical care. Moreover, since 2006, medical costs have increased at a faster rate than inflation due to a number of different reasons – including but not limited to – the fact that the South African population is aging; incomes are increasing (people tend to spend more on healthcare as their incomes rise); the introduction of new technologies and procedures etc.

One of the many fundamental flaws of government controlled prices is that governments cannot react fast enough to new developments. Any price list it introduces will quickly become irrelevant and cause confusion in the private medical sector. Promisingly, Dr Pillay stated, "This is our attempt to solve the problem. We are open to alternatives".

In order to reduce the price of private medical scheme cover and increase the number of people enrolled in private medical schemes the Competition Commission, as a matter of urgency, should be asked to repeal its 2004 ruling that prevents medical schemes from negotiating prices with service providers. If medical schemes, as a group, are permitted to negotiate prices, they will have greater bargaining power to secure more favourable prices with healthcare providers and then pass these savings on to consumers through reduced premiums. This is a normal commercial arrangement where medical schemes, acting on behalf of their members, try to secure the lowest possible prices.

Medical schemes must also be able to negotiate effectively with service providers. To achieve this, actuaries must be allowed to devise policies that cater for the individual healthcare needs of each beneficiary and not be forced to include procedures and conditions that consumers do not want.

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Free Market Foundation submission on MAKING HEALTHCARE AFFORDABLE

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1. The Free Market Foundation

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2. Overview

Please note: The bullet points below are supported by attached documentation.

- If South Africa wants better health outcomes, it must have economic growth. It is intuitive that there is a strong relationship between income and health, not least because greater wealth buys greater access to the basic determinants of health: nutrition, better accommodation and sanitation.
- This relationship was confirmed by a seminal 1996 study by economists Lant Pritchett and Lawrence Summers, who showed the dramatic effect that increases in incomes can have on health. Pritchett and Summers found a strong causative effect of income on infant mortality and demonstrated that, if the developing world's growth rate had been 1.5 percentage points higher in the 1980s, half a million infant deaths would have been averted.
- The FMF maintains that the private supply of competitive health-care services and the incremental extension of private funding is the most effective method of supplying high quality health care to the entire South African population.
- Government should not be in the business of providing healthcare to all South Africans. Rather, government should devote its limited health budget to the supply of services to the indigent, to purchase an increasing percentage of those services from private providers, and to allow and encourage the rapid growth of the private healthcare sector, enabling it to provide services to an increasing percentage of the population.
- The FMF contends that public healthcare is not in fact cheaper than private healthcare and that this assertion misdirects public policy in the healthcare arena.
- Given the revealed preferences of South Africans, to access private medical facilities whenever possible , reforms should focus on enrolling more individuals in private medical schemes. This will reduce the burden on public sector healthcare facilities and free up scarce taxpayer resources so that the government can focus on purchasing the best available care from privately competing healthcare providers.
- Far from marginalising medical schemes, government should be promoting their proliferation because regular, small, fixed payments to a medical scheme make intuitive sense, as opposed to the rare but devastating high out-of-pocket payments required when illness strikes.

- Considering South Africa's relatively small tax base and thus limited available pool of revenue, and given our chronic levels of unemployment as well as our limited number of skilled healthcare personnel, the proposed National Health Insurance scheme is simply inappropriate for South Africa. Moreover, attempting to provide universal coverage is not a particularly good use of scarce resources since each additional rand committed to healthcare expenditure necessarily precludes funding for other objectives, which may be more efficiently utilised at the margin.
- The economic consultancy, Econex, has demonstrated that the proposed National Health Insurance scheme faces a R200 billion shortfall by 2025-26 – almost double the amount initially anticipated by the Department of Health.
- The FMF contends that in order to alleviate the chronic shortage of skilled medical personnel in South Africa, a short-term response would be to allow more skilled foreign health professionals to practise in South Africa. The majority of foreign doctors in South Africa work in rural areas – without them the rural system would be sure to collapse. Foreign doctors with the appropriate skills can alleviate the chronic shortages virtually overnight as opposed to training doctors in South Africa (or foreign nations that have completely different diseases profiles and often don't even speak the same languages).
- A longer-term strategy to alleviate the chronic staff shortages requires the government, and more specifically, the Department of Education, to relax the controls on tertiary education facilities, make entrance to these facilities less restrictive, and allow the private sector to provide a large percentage of tertiary medical education for doctors. If private education facilities are established they could operate on either a for-profit or non-profit basis and would have the potential to relieve a significant part of the burden currently faced by the public sector.

3. The FMF's alternative solutions to improved health care for all

- Encourage more private hospitals by deregulating the industry and eliminating Certificates of Need. **See FMF submission.**
- Remove price controls, which send mixed messages to the industry. **See FMF submission.**
- Zero rate VAT on all medicines being sold legally within South Africa. **See FMF submission.**
- Remove prescribed minimum benefits provisions. **See FMF submission.**
- Focus on funding the indigent ie finance health care for the poor – preferably via state-sponsored vouchers, which the indigent can spend where they choose.
- Reduce prices and increase health care quality through increased competition.
- Train more doctors and nurses (the number of doctors is limited to 1,300 a year; this number has remained the same since the 1970s despite increases in the population and the disease burden).
- Allow the private sector to train doctors and nurses.
- Encourage income-producing medical tourism.
- Retain skilled South Africans and attract others by removing the limit on skilled foreign doctors.
- Deregulate medical schemes so they can offer their clients exactly what they want.
- Deregulate pharmacies.
- Speed up registration of clinical trials.
- Give those who pay for their own health care a tax deduction.

Attachments

1. Article: Your life at stake: False assertions about hospital costs
2. Article: SA students flee Cuba, next time it will be Russia
3. Article: Streamlining drug approvals

Attachment to Free Market Foundation submission on Health OVERVIEW

Your life at stake: False assertions about hospital costs

Private medical schemes will no longer exist in a decade or so, predicted Health Minister Aaron Motsoaledi at a gathering of the National Editors' Forum in Cape Town. The reason was escalating costs, he said, and then went on to compare with anecdotal evidence the huge cost differences between public and private hospitals.

Private hospitals, for example, he said, charge up to R15,000 for a circumcision while township clinics charge only a "few rand". A private hospital charged R150,000 for a spinal decompression whereas the Steve Biko Academic Hospital in Pretoria charged only R30,000.

Well, for the ordinary, everyday, thinking South African, this anecdotal guide to the relative costs of public and private hospital treatment simply will not do.

Yes, it is true that private medical scheme rates are growing faster than other categories of medical expenses (and CPIX). However, this is not due to the logic of private medical care per se, it's due to the conditions forced on the medical scheme industry by the state. For example, they are not allowed to risk rate or exclude certain pre-existing conditions. They are forced to offer fairly generous minimum benefits to all. These measures very quickly raise costs to levels way above those that a private medical scheme would institute if left alone.

The comparative costs quoted by the Minister illustrate why science regards anecdotal evidence as useless. The examples don't compare like with like and were probably chosen to be maximally misleading. No doubt the circumcision example compares straightforward circumcisions involving normal foreskins, to the most complicated and expensive circumcision operation carried out in a private hospital. The same goes for the spinal decompression. For example, a procedure which puts in artificial discs and involves cutting through the abdomen and moving aside organs to insert expensive hardware is doubtless much more expensive than the more common practice of fusing the vertebrae without an abdominal invasion. And most unforgivably, the Minister was quoting what was charged to the patient (or their medical aid) and not the true cost of the procedure. On top of that, he simply omitted to include in his calculation the huge state subsidy that finances public health. The huge state subsidy financed by taxpayers' money. Does this possibly mean that all public health care is after all actually being funded by the private sector?

To do a fair comparison, we have to compare overall hospital costs per patient, after controlling for the following: differences in the reason for treatment (type of problem), the severity of the condition (number of days admission involved), the risks involved (extra procedures or expertise necessary to counter these), as well as the fact that at public hospitals patients do not have to pay VAT but at private hospitals patients do have the additional expense of funding government by paying this tax.

Innovative Medicines South Africa (IMSA) just happens to have conducted such a study. In a raw comparison, before introducing the controls mentioned above, it found, on average, that private hospital costs were 1.438 times more expensive than public hospital costs. This is the result of the sort of unadjusted, like versus unlike comparison that the Minister used to select his examples from.

However, after equating like for like, they found that private hospital costs were 1.053 times that of public hospital costs.

This figure doesn't take into consideration the differences in the quality of medical care and associated services, like food and bedding. A substantial number of public health doctors are interns, or freshly qualified and doing community service, rather than experienced doctors. Because private health pays more and is more likely to have patients who will sue if something goes wrong, it is more discerning of who it employs. That is why in private hospitals there are more experienced doctors and nurses with better skills on average who know that they are likely to be dismissed if they don't perform.

Private medical care staff tend to have a better professional attitude than those in public health. Private hospitals have better equipment and are better able to maintain stocks of basic necessities like rubber gloves, syringes, swabs, etc. Patients at private hospitals are not subjected to common public hospital problems such as a lack of bedding or decent food.

The effect on outcome of quality differences is substantial. In "A Comparison of health outcomes in public versus private settings in low- and middle-income countries" Montagu et al report that risk of mortality in private health settings is 60 per cent of that in public health settings.

Private medical care is accused of "over-servicing" for profit. But, even if this is so, it isn't really making private hospital care any costlier than public hospital care. The main factor which leads many astray in their reasoning, including the Minister, is the huge state subsidisation of public hospitals.

Economist Mike Schüssler compiled statistics from independent sources such as Statistics South Africa, the National Treasury and the Council of Medical Schemes reports. He says that on average 100 per cent of the cost in private hospital care is borne by the client whereas only 2 per cent of the cost of public hospital care is charged to the client. If we fail to take all the relevant factors into account and only consider costs passed on to the client at private and public hospitals then average private hospital charges are 60 times public hospital charges.

Just because a public hospital client doesn't pay 98 per cent of the cost of their care, it doesn't mean this cost does not exist. But what it does mean is that someone else (a taxpayer) has to do the paying. The money still comes out of the economy. Channelling this payment via government, instead of it being paid directly to the hospital, no doubt involves a significant portion of those funds being diverted into government itself to cover administration and the like. In other words, the government funding figures will underestimate the actual cost of public hospitals to taxpayers, and therefore the true cost to the country. The IMSA relative cost equation above does not take into account this inefficient channelling of funds through government when estimating the relative cost to the economy of private and public hospitals.

Let's apply the 60 fold ratio of private to public hospital client charges to the Minister's anecdotal examples. If clients paid full costs in public hospitals, his "a few rand" for circumcision could become "more than a hundred rand, if not several hundred", and the costs of a spinal decompression operation could be as high as R1.8 million in public hospitals. Alternatively, if

private care was subsidised to the same extent and didn't pay VAT, a client could be charged as little as R250 for a private circumcision and R2,500 for a spinal decompression. This makes the Minister's case look quite bad.

Schüssler goes on to show that between 2000 and 2008 private hospital charges rose by 74 per cent and, while public hospital charges rose by only 12.8 per cent, the government funding cost per admission rose by an astounding 111.7 per cent. I estimate therefore that full public hospital costs rose by 108 per cent. That is 46 per cent faster than private hospital costs. The difference was especially marked between 2001 and 2006. For that period, the Council for Medical Schemes reports say that private costs per admission rose 22.1 per cent and public (full) costs per admission rose 57.7 per cent. Public hospital costs therefore rose 161 per cent faster than private hospital costs in that period. All of this is in spite of there being only a 0.5 per cent growth in public hospital admissions in the context of an 8.5 per cent growth in population between 2000 and 2008, and a 42 per cent mortality increase between 2000 and 2005. So, in the face of greater urgency, the ability of public health care to reach the poor actually declined by 7.4 per cent in this period.

In sum, reliable statistics show that private hospital care is at worst 5.3 per cent more expensive than public hospital care, but is likely to be significantly cheaper when quality of care and other services, as well as the inefficiency of the government funding channel, are taken into account. For example, if the 60 per cent private versus public health setting mortality rate applies to SA, the cost of saving a life is 36.8 per cent cheaper in private hospitals than in public hospitals. Furthermore, in terms of the cost to the economy at large, public hospital care has been, and is likely to continue, getting more expensive than private hospital care, at a rapid rate. Finally, public hospitals are getting worse, not better, at providing affordable health care to the poor.

A superficial glance at the costs to clients suggests that public health care is cheaper to provide than private care but when you look at the cost to the economy at large and the effectiveness of actually providing care, the opposite is clearly true.

In order to provide more health care at a lower price to the poor, government is undermining the myriad private efforts of South Africans to look after their own health. Less obviously, it is shifting a great proportion of the country's productive efforts away from other important purposes in order to provide a far from satisfactory form of health care.

The declining public admission rates per capita, in the context of high mortality, shows clearly that government's current healthcare policy actually leads to less care for the poor. Even if we were to accept that the health of the poor justifies a drop in overall utility, the anti-private pro-public path chosen by government is a failure. If government is serious about saving the lives of the poor, and improving welfare generally, it needs to take a different path.

Garth Zietsman
Statistician

Attachment to Free Market Foundation submission on Health OVERVIEW

SA students flee Cuba, next time it will be Russia

It came as no surprise that a group of South African medical students have fled Cuba to escape the horrendous conditions they were being subjected to in that country.

In 1996, the Department of Health dreamt up a programme to train doctors in Cuba to reduce the chronic shortage of skilled doctors in SA and avoid the supposedly high cost of training them here. Students, keen to study medicine but unable to get into any of SA's eight government-run medical schools went along with the plan.

Why should we not be surprised that they want to flee the country? Cuba is one of the world's most repressed countries with an economic freedom score of 28.5 out of 100 according to the Heritage Foundation's 2013 Index of Economic Freedom. It is second to last in the world ranking, one place better than North Korea. Cuba's socialist command economy lurches from one crisis to the next under a resolutely Communist economic policy. The average worker earns less than USD25 (R228) a month. Any move towards genuine political or economic freedom is rejected by the Castro regime.

According to SA's Minister of Health, Aaron Motsoaledi, "It costs R750,000 to train a South African medical student in Cuba, but double that to train them here." The problem that South African students going to Cuba have to study in Spanish, and on their return to South Africa have to relearn medical vocabulary in English seemed to be of minor importance.

But our healthcare problem is urgent, so Dr Motsoaledi says, "With the shortage we have got we want to send (them) to any part of the world. It's an advantage, of course, to send them to a country where the language is the same." So now the Minister is contemplating sending SA students to Russiawhere training is provided in English.

How soon will our students be fleeing from Russia? It also ranks poorly (139th) on the Heritage Foundation's Index of Economic Freedom, amongst the likes of Guinea-Bissau (138th) and Vietnam (140th) and slightly ahead of the Central African Republic, which is ranked 142nd.

What Minister Motsoaledi intentionally overlooks in his quest to send our students off to economically and politically repressed destinations is that our very own private sector has already shown a keen interest in training doctors right here in this country. A few years ago, when a private institution applied to establish a medical school in Midrand, Gauteng, it was turned down by government. This naturally quashed any interest by others contemplating the same move.

Apart from the language barrier, are foreign trained returning doctors adequately equipped to handle problems unique to SA? According to the economics consultancy group Econex, SA has a "quadruple burden of disease". As a result Econex states, "The types of in and out-patient treatment, medication, primary and other care needed in South Africa, are not like that of other countries. One implication is, for instance, that more hospital beds, and therefore medical as well as other staff, will be required in a country where there is such a high prevalence of HIV/AIDS, communicable diseases and also injuries".

It is not only more staff we require but also medical personnel. Personnel who gain an acute in-depth knowledge of prevailing local conditions that can be acquired only by obtaining training in this country.

The HIV/AIDS prevalence rate in Russia is 1 per cent. In Cuba, it is 0.1 per cent. In South Africa, it is 17.8 per cent. From this it should be obvious that we require local solutions to heal local problems.

In SA every year, thousands of potential candidates, even those who achieve distinctions in their matric examinations, are turned away because the number of positions available at SA's eight government run medical schools is limited to around 2,000 positions. This number is only fractionally higher than that which was set in the early 1970s, despite our rising disease burden and a population that has more than doubled.

An obvious short-term solution to the chronic shortage of skilled healthcare personnel in SA would be to allow foreign skilled healthcare personnel to practice here, without any restrictions on where they are allowed to work and for whom. A longer term solution would be for the Department of Education to relax the restrictions and allow the private sector to establish private medical schools so that thousands of SA's brightest students can pursue their dream of studying medicine. Whether these schools operate on a for-profit or non-profit basis, their establishment can only alleviate the burden.

South African private hospitals are well-established centres of excellence and world-renowned for their high levels of care. Privately run education facilities, if conducted in co-operation with private hospitals, have the potential to attract internationally recognised lecturers, which, in turn, will increase the available pool of knowledge as well as international students, who quite possibly will continue to work in SA.

Unlike government, the private sector has an immediate economic incentive to ensure that doctors who qualify at their institutions measure up to SA's high standards. Fears that they will not are unfounded.

Privately run medical schools will not solve the chronic doctor shortage overnight, but they will definitely assist the government's long-term efforts to increase the number of doctors practicing in SA.

Jasson Urbach
Director, FMF Health Policy Unit

STREAMLINING DRUG APPROVALS

by Jasson Urbach: Director Freemarket Foundation

Drug regulators worldwide are grappling with the problem of how to approve medicines quicker whilst still ensuring that drugs are safe to be released into the market.

Writing in the New England Journal of Medicine, Hamburg and Sharfstein note, "Critics concerned about haste point out, accurately, that drugs and other products are generally approved on the basis of relatively small studies and that safety problems often emerge when large populations are exposed to the products. Those worried about delay note, correctly, that people with life threatening diseases have no time to wait".

The harmonisation of drug regulators' activities is proving, increasingly, to be the answer to this apparent conundrum. For example, the European Medicines Agency (EMA) has demonstrated that a central drug agency that coordinates all drug approvals has the ability to reach a vast number of patients because there is only one application process and gives the applicants access to all 28 countries of the European Union.

Increased cooperation between major drug regulators has also been occurring. According to LembitRago, coordinator of quality assurance and safety of medicines at the World Health Organisation, "Even the big fish like the FDA and also EMA are increasingly exchanging views and cooperating".

This increased harmonisation is justified by the increased interdependence between nations and the desire for the latest developments to be made available to patients as quickly as possible. The benefits of emerging market economies cooperating with advanced country drug regulators are manifold. In addition to ensuring the safety and efficacy of drugs that are already on the market through an open and transparent communications channel, increased cooperation prevents duplication of efforts. This argument is particularly important for poor, developing countries such as South Africa. The opportunity costs of investing vast resources into the duplication of efforts are staggering.

According to the Department of Health (DoH) Annual Report for 2012/2013, one of the key objectives of the sub-programme Pharmaceutical Trade and Product Regulation is to "Improve the registration of medicines and reduce the time to market by reducing the backlog on medicine registrations". Moreover, according to the Report, the DoH sets itself the target of registration timelines of "28 months for new chemical entities (NCEs) and 15 months for generics". The report, however, reveals that the average registration period for generics was 34 months and for NCEs 36 months. Thus, in an age of tremendous scientific and medical progress that offers new hope to South African patients, the regulator failed to approve both generic and NCEs in a timely manner; reporting a variance of 19 months for generic registrations and eight months for NCEs.

The DoH annual report cites a number of reasons for the variance. Firstly, "[The] lack of evaluators – in-house and external". Secondly, "Difficulty in recruiting evaluators at the remuneration rates paid". Finally, "Registration occurs at MCC meetings, which take place six times a year, based on peer-reviewed evaluators' reports received from five expert committees".

From this we can be led to believe that the staff and part-time assistants that support the MCC in the drug registration process are to blame. Not so. It is the system that is at fault. Consider the high profile case that included the HIV/AIDs treatment called Tenofovir. This particular drug was approved by the FDA in 2001. Only after much local public criticism did the MCC eventually register the drug in South Africa in 2007. This is just one example where the drug approval procedure for a drug already approved by stringent drug regulators in advanced countries has caused pain and suffering amongst South Africa's sick and vulnerable.

There is a simple policy that, if adopted, will improve South African patients' access to the world's most innovative new medicines and vaccines, and thereby allow us to leapfrog up the developmental ladder. South Africa's medicines authority should identify a handful of reference regulatory agencies that it deems competent. For example, it may decide that the United States Food and Drug Administration (FDA), Health Canada, the United Kingdom's Medicines and Health Products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA) and the European Medicines Agency (EMA) are sufficiently stringent regulators.

If the application has yet to be approved by any of those regulatory authorities, then a full dossier must be submitted to the regulator for evaluation and a regulatory decision. If the application has been approved by one drug regulatory agency from the agreed reference basket, an abridged dossier may be submitted for an abridged evaluation and a regulatory decision. If the application has already been approved by two or more of the reference regulatory agencies, then a verification dossier may be submitted for evaluation, and the regulatory decision based on the assessment report provided by a reference regulatory agency.

The primary aim of this proposal is to reduce the time period for patients in South Africa to have access to the latest available technologies. Delaying access to proven, effective drugs results in direct pain and suffering. There are other factors that have a bearing on patient access to quality care and treatment in our country, but our ability to reform the current drug review process ranks among those most easily achieved—but only if South Africa's Minister of Health demonstrates the compassion and the foresight, and sufficient political will to see it through.