FREE MARKET FOUNDATION

Submission

Medicines and Related Substances Amendment Bill

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The Free Market Foundation

The Free Market Foundation of Southern Africa (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.

Most of the work of the FMF is devoted to promoting economic freedom as the empirically best policy for bringing about economic growth, wealth creation, employment, poverty reduction and human welfare. As a think tank the FMFs fundamental approach to policy questions is consumer-based. Individual consumer choice is placed at the centre of any policy recommendations that the FMF espouses. Consumer satisfaction is generally achieved by an absence of barriers to entry into the provision of goods and services, allowing consumers a choice between the offerings of freely competing providers, and the absence of regulations that impose avoidable costly burdens on the providers of goods and services.

Executive Summary

The Medicines and Related Substances Amendment Bill ("The Bill"), seeks to provide for the objects and function of the South African Health Products Regulatory Agency (SAHPRA). It is proposed that the SAHPRA will function as an organ of state within the public administration but which falls outside the public service. The FMF is of the view that it is neither necessary nor appropriate to establish an entirely new entity, with much greater responsibilities given the country's chronic shortage of skilled personnel and lack of financial resources. The FMF is also concerned about the independence of the proposed regulatory authority given the weight of the Minister to determine the composition of the Board which has direct authority over the SAHPRA.

The Bill proposes that the SAHPRA act through its Board which is appointed by the Minister of Health. The Bill states, "The Minister must appoint a chairperson and vice-chairperson of the Board…" and the Minister may dissolve the Board if he or she "…loses confidence in the ability of the Board to perform its functions effectively and efficiently". The Bill states, "The Board after consultation with the Minister must appoint a suitably qualified person as the Chief Executive Officer of the [SAHPRA]". This suggests that the Minister will have wide ranging powers to influence decisions of the Board that has final authority of the regulatory authority

The SAHPRA has been touted as the solution to the extensive delays that currently characterise the Medicines Control Council (MCC.) Proposed amendments to the principal act include measures to shorten the registration time for medicines by allowing mutual recognition agreements between SAHPRA and other regulatory authorities. However, although this proposal is likely to improve efficiencies, mutual recognition agreements act as a band-aid to more systemic problems that currently beset the MCC. South Africa has a very limited set of skilled personnel to conduct the required analyses. The answer is to conserve these scarce resources and rely on other skilled entities to do the work.

It is envisaged that the SAHPRA will also have much wider scope than the incumbent MCC. For example, it will also be responsible for the regulation of medical devices and complementary medicines. But why should a new regulatory agency with a much wider scope be any more efficient or effective than the existing MCC given the chronic shortage of skilled personnel and dearth of financial resources? South Africa needs to adopt practical, sensible polices that conserve our scarce resources. Such policies will not only attract investment, but will also give South African patients access to the world's latest available drugs in a timely fashion without exposing patients to risk.

Comments on the Bill

The FMF welcomes the opportunity to provide comment on "Medicines and Related Substances Amendment Bill". The rationale for creating the South African Health Products Regulatory Authority (SAHPRA) is to improve the efficiency of the largely dysfunctional Medicines Control Council (MCC) and to regulate previously "unregulated" products.

Functions of Authority

2B. (1) The Authority must, in order to achieve its objects-

(b) ensure that the process of evaluating and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously

It is most encouraging that the SAHPRA seeks to increase efficiencies by evaluating and registering products in a timeous fashion. Indeed the speed of medical innovation worldwide in recent years has been remarkable. Latest developments in the pharmaceutical sector have helped to increase life expectancies and allow people everywhere to enjoy more prosperous lives. These unprecedented advancements in technology have given scientists access to powerful tools to develop new procedures and new drugs. To our detriment here in South Africa, the regulatory environment has failed to keep-up with innovation.

In other countries, drug regulators have devised innovative new ways to deal with the ever-changing spectrum. For example, they have devised different drug application pathways based on the severity of the disease that the drug purports to address. The United States Food and Drug Administration (FDA), for example, in addition to the *Standard Review* procedure for new drug applications, has introduced a *Priority Review* process for promising new drugs that treat serious diseases such as HIV/AIDS, heart failure, Alzheimers, cancer, etc.[1]

The *Standard Review* application procedure is applied to drugs that offer, at most, only minor improvements over existing marketed therapies.[2] A *Priority Review* designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A *Priority Review* means that the time it takes the FDA to review a new drug application is reduced. Amendments made in 2002 to the Prescription Drug User Act (PDUFA) set the goal for a *Standard Review* of new drug applications to be accomplished within ten months and the goal for completing a *Priority Review,* within *six months*.

In the United States, policy-makers have recognised the importance of streamlining the regulatory process to improve access to new medicines. This authority has set an objective timeline on the understanding that delays in the registration of products causes pain and suffering amongst its citizens. The SAHPRA should thus consider publishing registration timelines.

2B. (2) The Authority may-

(a) Liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of –

[1] Available at: http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm. Accessed 25 June 2013

[2] Available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm276421.htm. Accessed 25 June 2013

(i) Matters of common interest; or
(ii) A specific investigation; and

(b) Enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act

It is encouraging to note that the SAHPRA will seek to cooperate with other foreign regulatory authorities. This should be welcomed and applauded. 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 (2009) 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".[3]

The harmonisation of drug regulators' activities is increasingly providing 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 the applicant can obtain access to all 27 countries of the European Union.

There has also been increased cooperation between major drug regulators. According to Lembit Rago, coordinator of quality assurance and safety of medicines at the World Health Organisation, "Even the big fish like the FDA and also European Medicines Agency are increasingly exchanging views and cooperating".[4] According to the FDA, "The European Medicines Agency (EMA) is one of FDA's closest regulatory partners in the area of medical product review. FDA maintains an active robust bilateral relationship with EMA, along with national regulatory authorities throughout Europe".[5]

This increased harmonisation is justified by the increased interdependence between nations and the desire to make the latest available developments available to patients. 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.

[3] Hamburg, M.A. and Sharfstein, J.M. (2009) New England Journal of Medicine, 360, 2493-2495
[4] Willyard, C. (2013) Regulatory Renovation, *Scientific American Worldview: A Global Biotechnology Perspective,* 23-25.
[5] Available at: http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/EuropeanUnion/. Accessed 25 June 2013

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 you could be led to believe that the staff and part-time assistants that support the MCC in the drug registration process are to blame. This is not so. It is the system that is at fault and although the SAHPRA has the potential to resolve these issues the FMF os of the view that gives the country's system lack of resources (both financial and human) unless there is a fundamental change in the way the SAHPRA approves news medicines the problems that have best the MCC will continue unabated in the SAHPRA.

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 leap-frog up the developmental ladder. The following proposal is not a ground-breaking idea outside South Africa. Singapore has already adopted a similar procedure, and other countries have signed mutual recognition agreements with drug regulators whom they deem competent in order to "piggy-back" off their scientific and medical expertise. The FMF proposes that the SAHPRA 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 regulatory authority, then a full dossier must be submitted to the regulatory authority for evaluation and a regulatory decision. If the application has been approved by one drug regulatory agency from an 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 the regulatory authority reference regulatory agencies, 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 access the latest available technologies. Delaying access to these drugs results in direct pain and suffering to South African citizens – and also untold harm to these patients' extended families. While there are other factors that have a bearing on patient access to quality care and treatment in our country, our ability to reform the current review process ranks among those most easily achieved— if South Africa's Minister of Health demonstrates sufficient political will to see it through.

While patients are the focus, the regulatory authority will also benefit from a lower work load, and can re-allocate its energy to higher value-added priorities. This simple reform would enable the regulatory authority to concentrate its limited resources on activities to ensure that drugs already on the South African market are efficacious and do what they purport to do. As part of the agreement, the regulatory authority can insist that it immediately be informed if any problems arise in the reference countries. Similarly, if any issues were discovered in the South African market, the regulatory authority is obliged to inform the reference countries concerned.

This proposal can easily be adapted to meet changing circumstances. For example, the SAHPRA may want to consider offering a conditional approval based on the terms laid out above. A conditional approval of drugs already approved by stringent drug regulators could mitigate some of the risk. The SAHPRA would keep these medicines under tight control whilst it monitored their efficacy over the course of a probation period.

Clause 9 of the Bill

> *Clause 9 seeks to empower SAHPRA to cancel registration of any medicine, medical device or IVD if SAHPRA is of the opinion that it is not in the public interest that such a medicine, medical device or IVD is made available to the public.*

The FMF is of the view that the term public interest has not been adequately defined and is so vague as to render it meaningless. Moreover, given the fact that the Minister of Health shall have an inordinate amount of power over the Board (and since the SAHPRA acts through its Board) the FMF is concerned that the Minister will have undue influence over decisions to terminate registrations.