

# MEDICAL MALFUNCTION:

## Four neglected areas of medicine regulation

### Introduction

The regulatory system for the manufacture and distribution of medicines has four key problem areas. These problems have remained unattended to for many years, an astonishing ten years in one case, because of neglect, carelessness or inflexibility on the part of the Health Ministry, and in some cases because the Minister's political and personal objectives have dominated.

The delays in reaching resolution on these four matters have been inordinate:

Subject	Time delay
Medicines Control Council restructuring	Ten years
Prescribing powers for nurses	Four years
A workable system for retail pharmacists	Three years
Regulations for alternative medicines	Three years

These weaknesses have consequences for both the quality of medicines available to South Africans, and their ability to access medicines. It has also led the Minister of Health into a number of scandals, including over vitamin salesman Matthias Rath, and the backyard co-called miracle Aids cure, Ubhejane.

Now that the Health Minister is once again in the driving seat of her department on a full time basis, these four weaknesses must be urgently attended to.

### 1. Medicines Control Council

The Medicines Control Council as it is currently constructed is both hugely inefficient and subject to extremely destructive political pressure. The Council needs to be strengthened and restructured in order to fulfil its mandate, but plans to do so have been delayed for an astonishing ten years.

In 1997, a government task team recommended disbanding the MCC and creating a new, independent regulatory authority. This issue quickly fell away again, however, after the embarrassing forced withdrawal of the enabling legislation in the South African Medicines and Medical Devices

Regulatory Authority Act, after the Act was put in place without the necessary regulations.

More recently, in 2005, a group chaired by Health Ministry special advisor Professor Ronald Green-Thompson began considering, among other issues, whether to place the MCC outside of the Department of Health. But the matter remains unresolved, and in the meantime the MCC has continued on an extremely problematic course.

In 2006 the Council was widely condemned for turning a blind eye to the activities of the Matthias Rath Foundation, which had the sympathy of the Minister of Health despite the fact that it was blatantly conducting unapproved clinical trials and selling unapproved medicines.

Although the Foundation was in breach of a number of laws, the MCC initiated an investigation into its activities only after massive pressure from the TAC, the DA and others. The report on the investigation, initially promised within six weeks, has never materialised although nearly two years have passed.

The Council has repeatedly been criticized for its inefficiency, and it is argued by the industry that employees are often under-trained and inexperienced because the council is unable to pay competitive salaries.

Applications for approval of new medicines can take up to three years – well behind international standards. One troubling hold-up concerns a key ingredient in tik, pseudoephedrine, which is currently available in many common flu remedies. In July 2005 the DA wrote to the Council asking them to consider changing the classification of this product to make it less easily obtainable. Earlier this month, in response to a DA question, the Health Department stated that the MCC was still “considering various options” for limiting its availability.

While the Council dithers, hundreds of thousands of South Africans continue to ruin their lives in pursuit of this deadly substance.

There are also some concerns about the independence of the council in relation to the private sector, with the Chairman of the MCC also being the president of the South African Pharmacy Council, an active lecturer at a pharmacy school and also a member of the board of a company that owns a number of retail pharmacies.

To become more effective and properly independent, the MCC needs to be urgently lifted out of the public service and set up as an autonomous, self-

funding institution along the lines of the South African Revenue Service, with clear specifications about lines of accountability and independence.

## **2. Alternative medicines**

South Africa is awash in miracle cures, with sellers of these products claiming to be able to cure anything from colds to Aids. Many of these products are manufactured in garages and back yards with no controls over conditions, quality or hygiene. They are frequently sold by individuals with no medical or pharmaceutical knowledge, and on the basis of no supporting evidence. This stands in stark contrast to the system that exists for conventional medicines.

Because of the absence of any regulatory system to govern these products, it is not possible for consumers to make any distinction between those products that are effective and those that are not.

One critical example is Ubhejane, sold by a former truck driver, Zebelon Gwala, and touted as a cure for Aids. Despite preliminary testing having shown that this product is of no particular benefit in fighting Aids, its manufacturer continues to fund luxury cars and a expensive life-style on sales of this product.

It is currently only possible to tackle these charlatans through the back door, using provisions in the Health Professions Act and the Medicines Act. The DA is using these provisions to try to stop the deceptive touting of Ubhejane as an Aids cure, but this is cumbersome and inefficient.

Draft regulations to provide for such a system under the Medicines Act were published in July 2004, almost three years ago, but nothing has been seen of them since. The department claimed earlier this month that they are still "being reviewed" and failed to commit itself to any time-frame for their release.

It is apparent that there is a lack of political will on the part of the Minister to proceed with the introduction of these regulations. One can only speculate that this reluctance stems from the Minister's open support for alternative treatments and her public encouragement of purveyors of supposed miracle cures, including Matthias Rath and Zebelon Gwala.

Manufacturers of products that claim curative properties must be able to back up their claims with evidence of effectiveness, and they must be required to state exactly what their products contain. It is inexplicable that in

the midst of the disease burden we face in South Africa, it should continue to be so easy to profiteer from desperation and misery.

### **3. Prescribing by nurses**

Allowing suitably trained nurses to prescribe medicines is currently national policy, but the lack of clarity over the conditions under which they may prescribe and the drugs they may prescribe means that the policy is an empty shell. This is placing severe constraints on the delivery of many health services, and in particular antiretroviral drugs for people with Aids and pain relief for terminally ill patients.

A provision in the Medicines Act enabling nurses to prescribe under certain conditions was brought into effect in May 2003. But there is still no appendix to the schedules showing which medicines a nurse can prescribe. The corresponding enabling provision in the new Nursing Act (s56) is also not in effect and no regulations have been issued in this regard. There is a possible way around this through s38A of the old Nursing Act, but this area remains plagued by uncertainty.

Over the past few years the medical brain drain in the public sector has worsened while the demand for health services has escalated – predominantly as a result of the antiretroviral roll-out. If we are to have any hope of meeting the target of 80% of those in need on ARV treatment, then nurses are going to have to form the backbone of the ARV rollout in the future, and they cannot do so without powers to prescribe antiretrovirals.

This argument is made not only by the DA but was also, for example, emphatically argued for in a recent Medicines sans Frontières document on human resources, *Help Wanted*, where the organisation argued that unless there are immediate and dramatic interventions, the 35 000-person waiting list for antiretrovirals will grow massively over the coming years.

Palliative care is another area where prescribing powers for nurses are needed. Only 5% of people with terminal illnesses have access to a formal palliative care service. We could massively increase access to pain relief for dying patients by giving nurses at clinics, where the majority of terminally ill patients seek help, the ability to administer morphine and other high-schedule pain relief drugs – which can currently only be administered by doctors.

Despite the desperate urgency for the delegation of prescribing powers to nurses, there is a distinct lack of clarity about what nurses may or may not

do and there are few processes in operation to refer patients to nurses for prescriptions or to back this up with training and support.

#### **4. Retail medicines**

After three years of court battles, the pricing system for retail medicines now in place is still massively controversial and in no way represents a negotiated agreement between pharmacists and the state. Three years after the Health Minister first promised dramatic cuts to the cost of drugs, price reductions have not come anywhere close to matching the Minister's promises, and pharmacists remain deeply unhappy with the unilateral imposition of new pricing regulations.

In May 2004 the Minister of Health promised consumers savings of between 40 and 70 percent on the price of medicines through new regulations for medicine pricing by pharmacies. As the controversy grew, however, it became increasingly clear that the Minister was attempting to use pharmacists as the sacrificial victims of a public relations campaign based on lower drug prices.

First, the Minister simply failed to consult the pharmacists, who were to bear the full brunt of the proposed price cuts. She included no practising pharmacists on the pricing committee that determined the new prices in the first place. In determining its regulations, the pricing committee did not do an economic impact assessment or test its hypotheses with case studies, and it largely ignored the alternatives proposed by industry players.

The Minister pronounced in March that 162 new pharmacies had opened up in the past year. But the reality is that the department has been granting licenses indiscriminately to a range of new players in the industry as part of what appears to be a war of attrition against pharmacists.

Of the 162 new licenses, nearly half went to retail chains, and many others were for doctors' consultancies and hospital dispensaries. All of these players are able to off-set losses in pharmaceutical sales against gains in other aspects of their businesses. Although the department is obliged to grant licenses to doctors only when no pharmacy service exists in the area, this requirement has been largely ignored. The consequence is that entire regions have been swamped with businesses that are economically unsustainable on their own.

There are valid reasons for regulating the price of medicines, but we need to accept that government involvement inevitably creates distortions. Any

interventions must therefore be carried out only with the best possible information and with the aim to do the least harm. The Minister of Health has complied with neither of these precepts.

In order to restore a sense of order to this industry, she needs to re-engage with pharmacists to develop a more workable plan for the industry. A less inflexible and dogmatic approach might help with the development of solutions that would benefit both pharmacists and the State.

For example, by sanctioning public-private partnerships between public hospitals and private pharmacies, whereby pharmacies operate as collection points for medicines otherwise dispensed at public hospitals, pharmacists would be able to increase volumes and take the pressure off massively overburdened hospital pharmacists.