



WHAT THE PHARMACEUTICAL INDUSTRY SAYS

WND CONTACTED SEVERAL drug companies and offered them an opportunity to comment on the functioning of the Medicines Control Council (MCC).

Aspen was the only company which agreed to respond. All the others either did not respond at all or declined to do so.

Stavros Nicolaou, senior executive of Aspen Pharmacare, said: 'The department of health has commenced a process aimed at clearing the MCC backlog and improving approval timelines. While these are early days, initial progress . . . is encouraging and we look forward to completion of the process.'

Val Beaumont, executive director of the pharmaceutical industry association Innovative Medicines SA, said South Africans were being protected from substandard medicines. 'We are comfortable that scheduled medicines in SA are being checked for safety and that standards set by the MCC are world-class,' she said.

Beaumont added there was a problem with the speed at which things were happening, but they had a sense that the backlog was being cleared. 'For the first time in years, we are seeing a sense of urgency and focus.'

Kirti Narsai, head of scientific and regulatory affairs at the Pharmaceutical Industry Association of South Africa (PIASA), said they were positive about the fact that the MCC was dealing with the challenges and some patience needed to be exercised.

Questions about MCC appointees

A new Medicines Control Council (MCC) was recently appointed, with a number of new members. However, sources point out that the maximum period for membership of the MCC as per legislation is 10 years. Three of the members, including the chairman, Professor Peter Eagles, have served 10 years and have now been appointed for a third term.

Questions about Prof. Eagles' involvement in discussions or decision-making (in Council or the Complementary Medicines Committee) relating to products sold by Clicks while he was still a non-executive director of Clicks, remain unanswered.

The outcome of the 2007 investigation into allegations that the late Advocate Thomani Mulaudzi accepted a bribe, is being kept secret, while the MCC also failed to clarify whether allegations that the wife of a council member apparently runs or owns the laboratory used by the MCC for testing, are true or false.

THE MCC MESS



iStockphoto

Rx: STRONG MEDICINE

The regulation, registration and control of medicines in South Africa is (still) chaotic. A WND investigation uncovered an MCC trying to pick up the pieces amid a fractured past which includes massive backlogs, political meddling, allegations of bribes and vested commercial interests, lack of control over complementary medicines and quack remedies flooding the country

BY ANSO THOM,
AWARD-WINNING JOURNALIST, HEALTH-E NEWS SERVICE

SA'S BELEAGUERED Medicines Control Council (MCC) is slowly starting to make inroads into its massive backlog, but it will take a long time to repair the havoc wreaked by years of political meddling and incompetence.

Since the 1998 purge of MCC chairperson Peter Folb, registrar Johan Schlebusch and his deputy Christel Bruckner, the quality of the MCC's work has declined dramatically, said Treatment Action Campaign treasurer Nathan Geffen.

Unhappiness with the MCC culminated during the 2009/2010 Christmas break when there was a deluge of media reports about the seven-year backlog.

Since then some progress has been made, and according to a spokesperson from the Pharmaceutical Industry Association of SA, communication between the MCC and the pharmaceutical industry has improved. Other industry sources say current registrar Mandisa Hela is working tirelessly to fix the situation and that she has already made great strides.

In March this year, she was part of a delegation that presented the

health department's strategic plan and budget to Parliament's portfolio committee.

According to minutes from the Parliamentary Monitoring Group, Hela acknowledged the 'slowness in the registration' of new medicines and said she was giving the matter her full attention and was working towards speeding up registration, especially of antiretrovirals.

But the backlog is still huge and there are still no clear results following recommendations by a task team set up two years ago by then health minister Barbara Hogan, Geffen said.

The task team had to examine the legislation and problems linked to drug regulation, transform the MCC and start clearing the backlog.

Geffen is the author of *Debunking Denialism*, which chronicles how the MCC's poor functioning has opened the floodgates for all kinds of quack remedies and questionable drugs.

This includes complete chaos surrounding legislation for complementary drugs. New, life-saving drugs, especially for ICU and cardiovascular patients, are also unavailable as they await registration,

in spite of the fact that many of these drugs have already been approved by respected agencies such as the US Food and Drug Administration and the European Medicines Agency.

In addition, pharmaceutical companies have complained that at times their patent rights have almost expired by the time they receive registration, dramatically reducing their window period to make a profit.

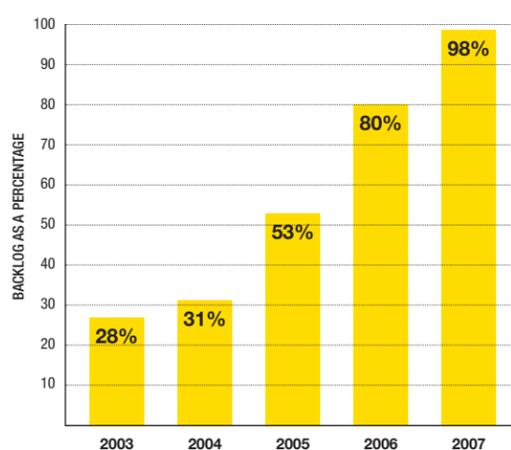
Allegations of bribery and vested interests have added to the MCC's woes.

It is difficult to establish exactly what the current situation is because of a lack of communication. What's New DOC has been trying to interview current Hela since January this year. Countless emails, messages on her cellphone and messages left with her assistant in Pretoria have remained unanswered.

In April, she finally agreed to reply to our list of questions – some of which touched on very sensitive issues (see page 4) – but never did.

'The MCC is an important institution, but it does not have the resources to do its work. It needs more money and competent people,' Geffen said.

REGISTRATION BACKLOG



THE 'TSUNAMI' OF GENERICS

