## WHEN THINGS GO WRONG . . .

. . . they can spiral out of control. This is what seems to have happened at the Medicines Control Council (MCC).

Medicine regulation in South Africa nearly grounded to a halt in 2007. In 2008, only five of 748 applications were registered and in 2009 only two of 281 applications were awarded registration. Although MCC registrar Mandisa Hela seems to be working round the clock to reduce a seven-year backlog of nearly 3 000 medicines, it is clear that medicine regulation in South Africa is in need of a major overhaul. Health minister Dr Aaron Motsoaledi recently admitted it will take at least two years to clear the backlog.

It's also clear that the matter of medicine regulation in South Africa is a sensitive issue.

When What's New DOC commissioned Anso Thom, a prominent and award-winning journalist from Health-e News Service, to establish the status quo at the MCC (article on page 2), we were hoping to find answers to our many questions. But there were pitfalls. Firstly Hela could not find the time to respond to our questions. Nor did she respond to any of our telephone calls or messages – and we've been trying to get hold of her since January. Secondly, we are unable to acknowledge a number of our sources by name, because many players in the pharmaceutical industry fear retribution if they speak out. However, we can assure you that these sources are formidable.

We hope to bring you the official answers to our questions in the next issue, or maybe the next . . .

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**PS** *And let's hear it for Marí, who on 6 May won a coveted Discovery Health Journalism award in the category 'best trade publication: health journalism' for her What's New DOC article on teens and depression. Congratulations, Marí, we're proud of you! What's more, WND had six finalists in the prestigious health journalism competition – more than any other medical or consumer publication.*

*– Joan van Zyl, assistant editor*

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peddling complementary medicines operate.

She conceded that complementary medicines are not regulated, but said the MCC is looking into ways to strengthen the regulations.

The problem is historical. In February 2002, the health department issued a directive in which manufacturers and distributors of complementary medicines were asked to submit information on their products to the MCC. The aim was to audit the complementary medicines market over a period of six months and then formulate new regulations to better control the industry.

But it seems the audit never took place and eight years later manufacturers are still sending in applications for MCC approval, often claiming this means their products are 'registered'.

Sources say that the MCC is now trying to sort out the problem by cancelling the call-up and formulating regulations, but they find themselves in battle with role players with a stake in the complementary medicines market.

Earlier this year the Health Products Association of Southern Africa (HPA) lodged an official appeal to the decision to rescind the call-up. It fears that if recision is put into practice, it will have a major impact on the complementary medicines industry, effectively making about 15 000 products illegal.

An industry source said negotiations are taking place.

The Simply Slim debacle earlier this year showed why the matter is urgent. After being ordered by the MCC to remove Simply Slim from the market, the manufacturer simply revised it and returned it to the shelves.

Simply Slim, which claimed to be 100 percent herbal, contained more sibutramine that prescription medicines.

'There is no evidence before the MCC that any work has been done on this product; it's unbelievable,' a source said.

Last year, a group of South Africa's top pharmacology experts and academics sent a five-page letter to the MCC warning that the market is being flooded with all kinds of quack remedies and dubious 'medicines'. Neither Eagles nor Hela acknowledged the letter.

The letter warned that the information submitted continues to be accepted by the Medicines Regulatory Affairs Cluster of the health department and as a consequence these products are freely marketed without any regulatory oversight.

They said that in the absence of independent assessment it is not known whether the products contain any active ingredients or toxic health metals, are possibly contaminated with bacteria or banned substances, contain scheduled substances or whether formulations are rational or safe.

Will these problems be solved by the MCC, or its envisaged successor, the MRA? It is clear a dramatic overhaul of medicine regulation is needed to ensure the public has prompt access to new, life-saving drugs – and that it's protected against substandard products.

## Questions the MCC refused to answer

**Below are some of the issues What's New DOC attempted to discuss with MCC registrar Mandisa Hela. In April, she finally agreed to answer a list of questions by email and promised to follow it up with a telephonic interview. She never replied to the questions and also ignored all follow-up attempts to get hold of her. A senior source in the health department said these questions are 'spot on' and cut to the core of the challenges facing the MCC.**

### ALLEGATIONS OF QUESTIONABLE CONDUCT

- Some members of the MCC have very close relationships with representatives of the pharmaceutical industry. How are these relationships monitored?

- Why don't members of committees or the Council routinely recuse themselves from discussions or decision-making when possible conflicts of interest may arise, as prescribed by section 4 of the Medicines Act?

- Is there any record of MCC chairperson Professor Peter Eagles recusing himself from discussions or decision-making relating to products sold by Clicks while he was still a non-executive director of Clicks?

- Is it true that the wife of a Council member runs or owns the laboratory used by the MCC for testing?

- What was the outcome of the 2007 investigation into advocate Thomani Mulaudzi's alleged bribery?

- Is it true that some medicines are registered even though the documentation may only have been given to Council members on the same day as the meeting?

### COMPLEMENTARY MEDICINES

- How can manufacturers and other members of the industry decide for themselves that a product is a complementary medicine and therefore only needs to comply with the abbreviated complementary medicines call-up process? Who double-checks the claim that a product is a complementary medicine and hasn't already been called up for registration as a conventional medicine?

- Is it true that some generic medicines are registered while no bioequivalence studies have been done comparing them with the SA reference product?

- How strict is the MCC when it comes to registration of bioequivalent generic ingredients, as a high number of poor-quality generic ingredients is flooding African markets?

- Will new regulations or new primary legislation be needed for complementary medicines and how will the public be protected in the meantime?

- What is being done to stop charlatans offering unregistered medicines for a range of diseases, including Aids?

### MCC OPERATIONS

- How is the campaign to clear the backlog progressing? What steps are being taken?

- How do you respond to claims by pharmaceutical companies that the backlog is affecting their patent rights?

- Why must drugs already approved by the Food and Drug Administration and European Medicines Agency be reassessed?

- What is being done to improve the efficiency of the Medicines Control Council?

- Which expert committees are making headway and which ones are struggling?

- What has happened to the many millions of rand the MCC has been paid since 2003? Why isn't this money being used to employ more staff or pay more academics to assist on the various committees?

- It is said a member of the Complementary Medicines Committee is using a SCIO machine on members of the public. SCIO is unproven and is a device that is not registered. How can the MCC have such a person as a member of one of its committees?

### GENERAL

- Why have no regulations been published yet for registration of devices? The 2003 Medicines Act includes registration of these devices. How many have been registered in the past seven years? ●