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Cape High Court interdicts Matthias Rath and orders Government to investigate him and stop breaches of the Medicines Act

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Victory for the rule of law and the scientific governance of medicines

Today the Cape High Court handed down a landmark judgment in a court action initiated by TAC and the South African Medical Association (SAMA) against Matthias Rath and the Government of South Africa. The case was originally heard before the Court on 12-14 March 2008.

This judgment unequivocally establishes the duty of the state to enforce the scientific governance of medicines as defined in the Medicines and Related Substances Act 101 of 1965 (hereafter referred to as the ?Medicines Act?). This case has demonstrated how the Minister of Health has wilfully obstructed the rule of law and promoted pseudoscience, resulting in the unnecessary deaths of many people. We call on the President and the ANC to demonstrate their commitment to the rule of law by immediately relieving the Minister of her duties.

This judgment is effectively a stern warning to all purveyors of untested and unregistered medicines, especially those selling so-called ?cures? for HIV/AIDS. Zeblon Gwala, ?inventor ? of the quack AIDS-remedy *Ubhejane*, the makers and financiers of Comforter?s Healing Gift and Secomet products as well as Tine van der Maas should pay particularly close heed to it and cease their unlawful activities.

TAC thanks Advocate Geoff Budlender and our attorney William Kerfoot of the Legal Resources Centre for their efforts which resulted in the successful outcome of this case.

For background on the case, click here.

To view the judge's order, click here.

To download the full judgment, click here.

Summary of the judgment

[THE SUMMARY NEEDS FURTHER WORK AND NUANCE. WE WILL UPDATE IT ON TUESDAY 17 JUNE AFTER THE LONG WEEKEND. - EDITOR]

On the basis of the TAC/SAMA application the following fundamental questions were put before the Court:

- Whether the Rath respondents had unlawfully distributed medicines in contravention of the Medicines Act

- Whether the Rath respondents had conducted unauthorised clinical trials in contravention of the Medicines Act

- Whether the Rath respondents had published unauthorised, false and misleading advertisements concerning vitamins, multivitamins, and certain products produced by Dr. Rath and the entities associated with him; and

- Whether Government had taken reasonable measures to investigate and put an end to such activities.

In deciding on the first question, whether Rath and his associates had unlawfully distributed medicines in contravention of the Medicines Act, the Court first had to consider the definition of the term ?medicine? as laid out in section 1 of the Medicines Act and whether or not Rath?s products fell within the legal scope of that definition. The Court found that the definition of ?medicine? in the Medicines Act places particular emphasis on the purported ?use? of the substance in question: ?In my view the use of a particular substance is the determining factor in deciding whether or not it is a medicine? (para 42). The Court, after analyzing advertisements and media claims made by Dr Rath and his associates in which medicinal properties were attributed their products, decided that:

?the substances are medicines in that the first and second respondents distribute them for use for medicinal purposes. It is therefore necessary to bring them under the ambit of the definition of ?medicines? in order to control and regulate their use. Members of the public, because of statements about their medicinal efficacy, will start using the substances on the basis that, when taken, they will cure or reverse the course of AIDS. *The control and regulation of these substances is necessary in order to prevent confusing messages being sent out to the public about the treatment of AIDS.* In the circumstances I find that VitaCell is a medicine within the meaning of the Medicines Act? (Para 45, our emphasis).

The court did not find that Rath's distribution of his products was unlawful merely because they are distributed. What was deemed to be unlawful were the claims made in advertisements associated with Rath's product distribution, i.e. the claims that rendered VitaCell a medicine. The court therefore interdicted the Rath respondents from making claims that VitaCell reverses the course of AIDS. This point is dealt with in further detail in answer to question three.

In reaching a decision on the second question, whether Rath and his accomplices were found to have conducted unauthorised clinical trials, the Court ventured into new legal terrain because ?the term ?clinical trial? has never been judicially considered in South Africa? (para 72). In the absence of relevant South African case law, the Court considered a 2002 decision of the Zimbabwean Supreme Court where ?clinical trial? was defined as:

?a systematic study in human beings or animals to establish the efficacy of, or to discover or verify the effects or adverse reactions of drugs?

With this definition in mind, the Court analyzed the purpose of the activities of the Rath respondents in order to determine their intention. The Court found that the fundamental purpose of Rath?s activities at clinics in South African townships was, ?to establish the efficacy of VitaCell on people with AIDS? (para 74). Indeed Rath himself had admitted that he and his colleagues had conducted a ?clinical pilot study?, the purpose of which was to study the effects of vitamins and micronutrients in people living with HIV/AIDS, but denied that this study could be characterised as a ?clinical trial?. The Court, however, ruled otherwise:

?it seems to me that they were carrying out a clinical trial. Although they deny that they conducted clinical trials, that denial, in my view, is, however, entirely inconsistent with their own repeated statements none of which they denied having made. It appears to be an attempt to escape liability for their widely proclaimed conduct now that its legality is

being challenged. In my view, the Rath respondents? activity (conducting a clinical pilot study) viewed subjectively constituted a clinical trial.....*Their conduct was unlawful in that they did not have a permission to run clinical trials*? (para 75, our emphasis).

On whether or not Rath and his associates unlawfully made false and misleading advertisements, the Court had difficulty reaching a definitive decision, concluding that the ?dispute cannot be resolved on papers? (para 82). However the Court did rule that Rath and his foundation, by publishing adverts attributing medicinal properties to VitaCell without having secured MCC approval, had acted unlawfully. Rath and his foundation were ordered to ?stop making claims about the medicinal effect of their products until their products in respect of which medicinal claims are made have been submitted to the MCC to review the efficacy, quality and safety of those claims? (para 82).

Having found that Rath and his accomplices had acted unlawfully, the Court was now compelled to decide whether the Minister of Health and the Director General of the Department of Health had taken reasonable measures to prevent this unlawful conduct. In terms of the National Health Act, the Court found that the Minister and her Director General, ?are under a duty to take reasonable measures to prevent the first to fifth respondents from conducting unauthorised clinical trials and to prevent the first to seventh respondents from publishing advertisements concerning medicinal effects of VitaCell on people with AIDS pending the submission of VitaCell to the MCC to review its medicinal claims? (para 88).

The court found that the state had not sufficiently investigated TAC's allegations, particularly those concerning the conduct of unauthorised clinical trials.

The final order issued today by the honourable Judge Dumisani Zondi is as follows:
"

- *It is declared that the clinical trials conducted in South Africa by and/or under the direction of the first , second , fourth and fifth respondents are unlawful.*

- *The first, second, fourth and fifth respondents are interdicted from conducting unauthorised clinical trials in South Africa*

- *The first, second, fourth and fifth respondents are interdicted from publishing advertisements concerning the medicinal effects of VitaCell on persons with AIDS pending submission by the aforementioned respondents of the VitaCell to the MCC to review its medicinal claims.*

- *It is declared that the eighth (Minister of Health) and the ninth respondents [Director General, Department of Health] are under a duty to take reasonable measures to:*

4.1 present the first, second, fourth and fifth respondents from conducting unauthorised clinical trails

4.2 prevent the first, second, fourth and fifth respondents from publishing advertisements concerning the medicinal effects of VitaCell on persons with AIDS pending the submission by the aforesaid respondents of VitaCell to the MCC to review its medicinal claims

- *The eighth and ninth respondents are ordered to take reasonable measures to investigate the matters referred to in paragraph 4 hereof and, in light of the facts revealed by such investigation, to take further reasonable action in accordance with their duty.*

- *The first, second, fourth and fifth respondents are jointly and severally ordered to pay 90% the costs of the applicants in these proceedings*

- *The eighth and ninth respondents are jointly and severally ordered to pay 10% of the applicants? costs in these proceedings*

- *The applicants are ordered to pay the costs of the twelfth respondent [Members of the Executive Council for Health, Western Cape Province] including costs consequent upon employment of two counsel?*

Importance of the judgment

Many people in South Africa still present far too late to the public health system, with advanced AIDS. Many patients try all kinds of alternative remedies before finally seeking help from their local clinics. Many never take the opportunity to live longer, healthier lives by using scientifically proven antiretroviral medicines because they are hoodwinked into trying unproven elixirs. Charlatans and quacks abound; some of the more notorious ones are Zeblon Gwala who distributes Ubhejane, Tine van der Maas who claims garlic and an African potato solution treat numerous diseases, Freddie Isaacs who distribute Comforters' Healing Gift and Stephen Leivers who distributes Secomet. In the centre of Cape Town and other cities, numerous unproven remedies are sold as cures for AIDS, including one called Ozone Rectal Therapy. The Minister of Health has fostered this situation by creating the illusion that people with HIV ha ve a reasonable choice to make between antiretrovirals versus alternative remedies and by failing to enforce the Medicines Act.

Charlatans operate in every society, but they usually operate on the fringes. In South Africa, charlatanism has become mainstream. This judgment has unequivocally established that the Minister of Health has a duty to enforce the Medicines Act and to uphold the scientific governance of medicine. Her failure to enforce the act has hampered the rollout of antiretroviral treatment and resulted in many deaths and we ask that she be relieved of her duties.

- AIDS Denialism
- Experiments on People Interdict

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