

# The Medicines Control Council must be allowed to fulfil its duty to protect health

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Created 2011/11/15 - 10:25am

15 November, 2011 - 10:25 ? moderator

## Treatment Action Campaign Comment on Medicines Control Council and others v Adcock Ingram and another: urgent rescission application

*Media Release 9 November, 2011*

According to media reports today, the Medicines Control Council (MCC) instituted urgent proceedings to set aside a settlement agreement purportedly entered into with Adcock Ingram Ltd (?Adcock Ingram?). The settlement agreement relates to the deregistration of certain medicines found to be dangerous to the public, and is therefore a matter of significant public interest. The statement below provides some background to the case.

In April this year the MCC took a decision to cancel the registration of medicines containing dextropropoxyphene (?DPP?), on the grounds that these medicines give rise to cardiac safety concerns which outweigh the benefits of the medicines and are therefore unsafe to the health of consumers. Adcock Ingram is one of the primary manufacturers and distributors of DPP-containing medicines in South Africa. This followed similar decisions by drug regulatory authorities in the United States and Europe.

On 18 May 2011 Adcock Ingram lodged an internal appeal against the MCC's decision. According to Adcock Ingram its internal appeal suspended the decision to cancel the registration of DPP-containing medicines, and allowed it to continue to distribute DPP-containing medicines. However, the MCC disagrees with this approach. In order to ensure that these DPP-containing medicines were no longer sold, it went ahead and issued what is known as a ?Dear Health Care Professional? (DHCP) letter, a letter that is routinely issued by the MCC to inform health care professionals that the registration of the medicine had been cancelled.

This prompted an urgent application by Adcock Ingram on 7 October 2011, for an order suspending the cancellation of the registration of DPP-containing medicines pending the resolution of the internal appeal against the MCC's decision. The effect of this order would be that DPP-containing medicines would continue to be available to the public, despite significant concerns regarding their safety.

Unfortunately, although express instructions were given to the representatives for the MCC and the Department of Health to oppose the urgent application brought by Adcock Ingram, these instructions were ignored and the application was not opposed. Instead, in October 2011, a settlement agreement ? the terms of which were never presented to the MCC or the Department of Health ? was concluded between the parties.

The settlement agreement allows Adcock Ingram to continue to distribute DPP-containing medicines pending the resolution of the internal appeal. It also allows Adcock Ingram access to documents which had previously been refused under the relevant provisions of the Promotion of Access to Information Act, 2 of 2000, and extends further than the relief sought by Adcock Ingram in its urgent application.

The settlement agreement was made an order of court on 25 October 2011. The members of the MCC only became aware on that day that a settlement agreement had been concluded and that it had been made an order of court. As a result, the MCC and the Minister of Health (and others) launched an urgent application to overturn the settlement agreement on the following grounds:

- the settlement agreement was entered into without the authority of the MCC or the Minister of Health, and was in fact completely contrary to their instructions;
- the settlement agreement is contrary to the public interest because there are public health and safety issues at stake; the continued availability of these medicines could be dangerous; and
- the settlement agreement was entered into contrary to the statutory and constitutional duties imposed upon, inter alia, the Minister of Health, the MCC and the Registrar of Medicines. The matter was not capable of being settled in the manner contemplated by the settlement agreement.

This is a matter of public importance. Treatment Action Campaign (TAC) believes that the MCC has an important statutory responsibility to fulfill. This duty should not face interference from pharmaceutical companies who are seeking to protect their profits, regardless of medical evidence that this medicine is dangerous.

The matter will be heard by the North Gauteng High Court on 15 November 2011.

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