



17 November 2011

PRESS RELEASE: HIGH COURT JUDGMENT ON ADCOCK INGRAM'S DPP-CONTAINING MEDICINES

- **Medicines containing dextropropoxyphene (DPP) cannot be prescribed, dispensed or sold pending Adcock Ingram's appeal**
- **Medicines Control Council (MCC) decisions remain in force and must be implemented pending appeals**
- **MCC cannot enter into settlement agreements that undermine its mandate**
- **Transcripts of MCC meetings are confidential documents**

On 15 November 2011, Judge Bertelsmann of the North Gauteng High Court, Pretoria, heard argument and handed down judgment in an urgent application filed by the MCC and others against Adcock Ingram Ltd and Adcock Ingram Healthcare (Pty) Ltd (collectively referred to as "Adcock Ingram").

Amongst other things, the MCC's application sought to ensure that DPP-containing medicines are neither prescribed, dispensed nor sold, in accordance with the its decision of 14-15 April 2011 cancelling the registration of all DPP-containing medicines and pending Adcock Ingram's appeal against that decision.

The need for the urgent application arose after the MCC became aware that it had purportedly entered into a settlement agreement – subsequently made an order of court – that compelled it to do the following:

- Retract its Dear Health Care Professional (DHCP) letter dated 28 September 2011;
- Draft and distribute a letter to all health care practitioners informing them of the order; and
- Hand over "the transcripts and all records of [MCC] proceedings in respect of [DPP]-containing medicines and all documents that served before it on or before 24 October 2011".

Of even greater concern, the order expressly authorised Adcock Ingram to continue selling Synap Forte tablets, Lentogesic capsules and Doxyphene capsules "until the appeal to the Appeal Committee has been finalised".

In resolving to make an urgent application to court to rescind the order, the MCC noted that the matter of settlement had never been tabled before the MCC or its Executive Committee, and that the part of the order that related to the handing over of transcripts conflicted directly with a prior MCC decision that access to such documents can and should ordinarily be denied.

In ruling in the MCC's favour, Judge Bertelsmann made the following findings:

- The lodging of an appeal against a decision of the MCC in terms of section 24 of the Medicines and Related Substances Act 101 of 1965 **does not** suspend the operation of that decision;
- Once the MCC has taken a decision, it must ordinarily implement and defend that decision pending any appeal;
- The MCC is prohibited by law from entering into settlement agreements that undermine its statutory mandate relating to safety, quality and therapeutic efficacy; and
- Transcripts of MCC meetings are confidential, meaning that there is no legal obligation to grant access to such documents.

In light of the order, the MCC would like to confirm the following:

- The MCC's decision of 14-15 April 2011 cancelling the registration of all DPP-containing medicines remains in force;
- The DHCP letter dated 28 September 2011 remains in force; and
- DPP-containing medicines may not be prescribed, dispensed or sold.

Respectfully

Ms Mandisa Hela
Registrar of Medicines