

MEDICINES CONTROL COUNCIL PRESS RELEASE-12 SEPTEMBER 2003

The Medicines Control Council (MCC) recognises that the protection of unborn babies from transmission of HIV is of critical importance, and is committed to ensuring that medicines are both safe and effective.

Nevirapine has been shown to be effective in reduction of the risk of intrapartum transmission of HIV-1 infection from mother to child. Scientific evidence was provided to the MCC to support this. In 2001, it was registered for this indication, subject to a number of conditions, including the provision of any new information.

On 25 July 2003, the MCC decided that, in the interests of public safety, additional information concerning the way in which Nevirapine should be used for this indication should be presented within 90 days.

Following this decision, it was brought to the attention of the MCC that additional data from South African researchers is available that may support the continued use of Nevirapine for this indication. Additional information regarding the original study has also now been published.

Recognising the importance of the new information, the MCC, on 5 September 2003, adopted a new resolution, which extends the time period for Boehringer Ingelheim (the supplier of Nevirapine) to review existing evidence, and to submit additional data for expert assessment by the MCC. Discussions have been held with both Boehringer Ingelheim and researchers in the field to determine the nature and extent of the new information that is required. An example of important data that must be submitted is the use of Nevirapine in combination with other antiretroviral agents for the reduction of risk of transmission of HIV infection from mother to child.

The MCC wishes to emphasise that Nevirapine remains registered as part of combination therapy for HIV and AIDS, that it is not and has never been "banned", and that it is still approved for the indication of "reduction of the risk of intrapartum transmission of HIV-1 infection from mother to child".

Appropriate treatment of the mother and the newborn child is also imperative, and the MCC urges healthcare professionals to use available interventions to improve the survival and health status of both mother and child.