MEDISYNEBEHEERRAAD

Republiek van Suid-Afrika



MEDICINES CONTROL COUNCIL

Republic of South Africa

DIE REGISTRATEUR VAN MEDISYNE DEPARTEMENT VAN GESONDHEID PRIVAATSAK X828 PRETORIA 0001

Telefoon: Telephone: (012) 312-0000

Faks: (012) 326-4344

THE REGISTRAR OF MEDICINES DEPARTMENT OF HEALTH PRIVATE BAG X828 PRETORIA 0001

22 September 2005

Navrae • Inquiries: Verwysing • Reference:

Adv Brink Rath Foundation Cape Town

Dear Advocate Brink,

CONCERNS RAISED ABOUT THE SAFETY OF ANTIRETROVIRAL USE IN REDUCING THE RISK OF HIV-1 TRANSMISSION FROM MOTHER TO CHILD (PMTCT)

Your several letters refer.

Your concerns about the safety of antiretroviral agents in PMTCT have been noted. We also note that your documentation has not adequately shown that the potential risks of adverse effects of the antiretroviral agents in question are greater, more serious, or on a larger scale than the risks of complications from HIV-1 infection and its adverse effect on the lives of babies and children.

Information which has become available subsequent to the Medicines Control Council (MCC) resolution of 02 July 2004 has also not changed the overall assessment of the risk of HIV-1 infection compared to the adverse effects of antiretroviral agents in PMTCT. (For example, we would refer you to the frequently updated guidelines on the "Aidsinfo" website: www.aidsinfo.nih.gov.)

Yours sincerely,

PETER K EAGLES, PhD CHAIRPERSON MCC

cc. Minister of Health