

## **Nevirapine for the Prevention of Mother to Child Transmission of HIV**

WHO reconfirms its support for the use of nevirapine to prevent mother-to-child transmission of HIV.

The Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda has recently released the final report (dated March 2003) from the reassessment of the trial procedures and results in the HIVNET 012 trial conducted in Uganda.<sup>1</sup> This trial, the first to demonstrate the safety and efficacy of nevirapine to prevent mother-to-child transmission (MTCT) of HIV, was started in Uganda in 1997 and the results were published in 1999<sup>2</sup>. A single dose of nevirapine given at onset of labour plus a single dose to the newborn within 72 h of birth reduced the risk of HIV transmission down to 13%, almost 2-fold lower than a short course of zidovudine started during labour. Concerns about the trial were raised in March 2002 when claims emerged that certain serious adverse events had not been properly reported. The Division issued a statement with the final report that concludes: "In summary, the re-monitoring of the study determined that nevirapine, 200mg orally given to the mother at delivery and 2mg/kg given to the neonate within 72 hours, is safe and effective. However, the conduct of the study lacked the necessary documentation to support a request to the FDA to consider this study as a stand alone pivotal trial." Nevirapine has been registered in the USA, countries of the European Union and numerous other countries for the treatment of AIDS (in combination with other antiretroviral agents), and is also registered for MTCT prevention in many countries worldwide. Nevirapine is recommended by the US Public Health Service Task Force for MTCT prevention among women in labour who have had no prior therapy<sup>3</sup> and is included for both treatment and MTCT prevention purposes in the WHO Model List of Essential Medicines, which is updated on a regular basis.

In October 2000, WHO in partnership with UNAIDS, UNICEF and UNFPA, convened a technical consultation to review all available evidence on the safety and effectiveness of short-course antiretroviral drug-based interventions to reduce the risk of MTCT<sup>4</sup>. The consultation concluded that all regimens which had been shown to be safe and effective in controlled clinical trials could be used in MTCT-prevention programmes. These regimens included zidovudine alone or in combination with lamivudine, as well as nevirapine.

Since the consultation, further research conducted in South Africa has demonstrated the safety and efficacy of nevirapine as well as the zidovudine and lamivudine combination.<sup>5</sup>

Scaling-up MTCT-prevention programmes in resource-limited settings to reach more HIV-positive mothers and prevent any further infants being infected with HIV is a major challenge, to which many governments, non-governmental organizations, international aid agencies and WHO are committed. While nevirapine is only one of several regimens which has been shown to be safe and effective, the low cost and simplicity of use of the regimen makes it particularly attractive.

## Recommendations

WHO continues to support the use of nevirapine in MTCT-prevention programmes. WHO agrees with the National Institutes of Health report and the accompanying statement, which emphasize that there is no evidence that the scientific data from the HIVNET012 study demonstrating the safety and efficacy of nevirapine are invalid.

Each year, about 800,000 infants become infected with HIV, mainly through mother-to-child transmission. WHO and its partner United Nations agencies recommend that MTCT prevention using antiretroviral regimens such as nevirapine should be included in the minimum standard package of care for HIV-positive women and their children. WHO is not aware of any information that should lead to a change in this recommendation.

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