Appendix 5: Nevirapine

No significant adverse effects have been recognized in either mothers or babies taking single-dose nevirapine as part of a PMTCT regimen.

Severe liver and skin complications have been noted in patients taking nevirapine as part of a prolonged, combination treatment programme. These complications have not been noted in mothers or babies taking nevirapine as part of a single-dose PMTCT regimen.

Nevirapine resistance has been noted in women taking nevirapine as part of a PMTCT regimen. The clinical significance of this observation is unclear.

In the HIVNET 012 study done in Uganda and the PACTG 316 study done in the United States, mothers received a single dose of nevirapine during labour. In the HIVNET 012 study, 23% of mothers had evidence of nevirapine resistance 6-weeks after receiving the drug. These resistant mutations were no longer present after 13-18 months in 4 mothers studied. In the PACTG 316 study, 13% of mothers treated with nevirapine in labour were found to have nevirapine-resistant virus. In the SAINT Trial done in South Africa, mothers in the nevirapine treatment group received a dose of nevirapine during labour and a second dose after delivery. Data on resistance is not available.

Many types of virus exist in all people with HIV infection. Wild-type virus is the most common. It is the strongest virus, reproducing better than other types. Nevirapine-resistant virus is present in small numbers, even in people who have never been treated with nevirapine. When someone with predominant wild-type virus is treated with nevirapine, wild-type virus is suppressed and nevirapine-resistant virus is able to grow. With single-dose nevirapine, the impact of the nevirapine is relatively short. Because nevirapine-resistant virus is not as strong (or capable of reproducing) as wild-type virus, over time wild-type virus will again become the most common type of virus in circulation. A mother should be able to use nevirapine for future pregnancy PMTCT treatment once wild-type virus becomes the most common virus in circulation. To date, there are no reports from clinical studies testing this hypothesis.

The present data on resistance is incomplete. More research is required on the effect of resistance on:

- The clinical outcome of mothers and their babies
- The ability for NVP to be used on HIV positive women who may have further pregnancies in the future
- The efficacy of any HEART (highly effective antiretroviral therapy) of which NVP is one of the drugs.

However, the incompleteness of the data at this point, does not construe a reason for delaying the expansion of the national PMTCT programme.