**Reviewer's check list for application for addition: zidovudine / lamivudine / nevirapine fixed-dose combination tablets for the treatment of HIV-1 infection**

**(1) Have all important studies that you are aware of been included?**

Yes x ◎ No ◎

**(2) Is there adequate evidence of efficacy for the proposed use?**

Yes x ◎ No ◎

**(3) Is there evidence of efficacy in diverse settings and/or populations?**

Yes x ◎ No ◎

**(4) Are there adverse effects of concern?**

Yes x ◎ No ◎

If "Yes", (list / describe) well described in the application

**(5) Are there special requirements or training needed for safe/effective use?**

Yes ◎ No x ◎

**(6) Is this product needed to meet the majority health needs of the population?**

Yes x ◎ No ◎

**(7) Is the proposed dosage form registered by a stringent regulatory authority?**

Yes x ◎ No ◎

**(8) What action do you propose for the Committee to take?**

This is a standard combination of three drugs for the treatment of HIV. Each of these drugs is already on the Model List. What is new in this application is putting them all in one dosage form. Since there are 4 fixed dose combination products proposed for inclusion at this meeting, the committee should discuss which should be added to the List.

**(9) Additional comment, if any.**

The value of combination products with several appropriate drugs in a single formulation has been shown for drugs to treat HIV disease. The only question for the committee, in this reviewer's opinion is which of the 4 proposed should be added to the Model List.. No language for the WHO Formulary was not seen in this application.