Stavudine / lamivudine / nevirapine fixed-dose combination tablets for the treatment of HIV-1 infection

Reviewer's check list for application for addition:

(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 ◎

(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 ◎

If "No", give details.

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

The committee should consider this in context of the other anti HIV products proposed at this meeting.

(9) Additional comment, if any.

This product is a standard combination with wide spread usage. Its toxicity is described as greater than that of other fixed dose combinations with efavirenz as the NNRTI in place of nivirapine. The therapeutic value of having appropriate fixed dose combination products for HIV is considered as very strong. Which of the 4 proposed should be added to the Model List should be discussed at the meeting.

I failed to find the proposed language for the WHO Formulary in this application. I suggest that, in the absence of proposed language in the application, the language used in official documents of countries in which it is registered be adapted for the WHO Formulary.