Lamivudine in combination with zidovudine

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 with qualification ◎ 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) there are well described adverse effects that must be dealt with.

(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 ◎

If "No", is there a special reason why this should be on the Model List?

(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?

Discuss with other FDC antiHIV products proposed at this meeting. Please see below.

(9) Additional comment, if any.

The WHO guidelines state that therapy should be with two nucleoside reverse transcriptase inhibitors plus one non nucleoside reverse transcriptase inhibitor. This product contains only the first two components of this recommended triple therapy. An NNRTI will have to be prescribed separately and concurrently with this product. There are three triple therapy fixed dose combination products being considered at this meeting. Which of these products to add to the Model List should be considered in the context of the entire group and not each one in isolation.

No draft .of language for the WHO Formulary was seen in this proposal.