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Dr Sue Hill

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Geneva, February 20, 2006

RE: Request for non-inclusion to the 15th WHO M EML of lamivudine/stavudine/nevirapine, lamivudine/zidovudine/nevirapine and lamivudine/zidovudine fixed-dose combinations tablets. (Section 6.4.2.1, 15th WHO MEML)

Dear Dr Hill,

We are writing to ask the 15th Expert Committee on the Selection and Use of Essential Medicines not to include “lamivudine/stavudine/nevirapine, lamivudine/zidovudine/nevirapine and lamivudine/zidovudine fixed-dose combinations,” submitted by Charles Gilks Coordinator Anti-retroviral Treatment and HIV Care (ATC).

There are nine fixed-dose combinations of antiretrovirals on the market, seven of which are included on the last updated version of WHO prequalification list. Other inclusions are expected soon. Only lopinavir/ritonavir is included in the EML since lopinavir does not exist on its own.

We feel that the reference made in the general text of the 14th EML is sufficient to explain the advantages that the use of fixed-dose combinations may represent: “In order to simplify treatment, facilitate storage and distribution, and improve patients’ adherence to the treatment plan, the Committee recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations.”

For these reasons, we consider the inclusion of only one of the many existing fixed-dose combinations in the list not justified, and only acceptable if all are included. But we also understand that the inclusion of all existing and recommended FDCs may be difficult, as the market and the treatment protocols change very quickly, thus rendering the list outdated. Therefore, countries that base their procurement decisions on the list may have their “management practices directed towards less preferred treatment options¹.” In addition, listing only existing FDCs may discourage manufacturers from producing further FDCs that are recommended by WHO, but do not yet exist.

Yours sincerely,

Fernando Pascual Martínez
Access to Essential Medicines Campaign
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¹ Proposal: policy on fixed-dose combination products, submitted by the Expert Committee Secretariat (<http://mednet3.who.int/EML/expcom/expcom15/others/ProposalFDCs.pdf>)