CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

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Dear Dr. Kazatchkine,

Médecins Sans Frontières (MSF) welcomes the imminent launch of the Affordable Medicines Facility for malaria (AMFm).

We would like to take this opportunity to recommend that the AMFm exclusively endorses fixed-dose combinations (FDCs) of artemisinin-based combination therapies (ACT).

The advantages of using FDCs have been well documented in several disease areas, including tuberculosis and HIV/AIDS.[1] [2] [3] An FDC can benefit patients by reducing the pill burden, thereby increasing adherence. Additionally, combining therapies within a fixed-dose prevents the risk of medication being taken as monotherapy.

FDCs are thus useful both when considering a patient's needs, as well as on the broader spectrum of reducing the risk of populations developing resistance. As you may know, the World Health Organization/Roll Back Malaria (WHO/RBM) recommends the use of FDCs for malaria treatment.

To date, there are two WHO prequalified (WHO-PQ) co-formulations of arthemeter/lumefantrine (Novartis, Ajanta) and others are under assessment. There is only one WHO-PQ artesunate/amodiaquine FDC (sanofi-aventis) but three further products are under assessment. Two FDCs containing artesunate/mefloquine are under assessment by the WHO-PQ programme.

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[1] Connor J, Rafter N, Rodgers A: " Do fixed-dose combination pills or unit-of-use packaging improve adherence? A systematic review". Bull World Health Organ. 2004;82:935-9

[2] Moulding T, Dutt AK, Reichman LB. Fixed-dose combinations of antituberculous medications to prevent drug resistance. Ann Intern Med 1995;122:951-954

[3] Laurent C: Effectiveness and safety of a generic fixed-dose combination of nevirapine, stavudine and lamivudine in HIV-1-infected adults in Cameroon: open-label multicentre trial. Lancet 2004; 364:29-34

One can therefore assume that in the near future there will be two or more WHO pre-qualified FDCs for each of these key ACTs. The growing number of manufacturers of artemisinin-containing FDCs thus provides a viable way for the AMFm to use FDCs exclusively from the outset while ensuring sufficient generic competition.

Furthermore, the AMFm technical proposal has already outlined its acceptance, under certain conditions,[4] of non-WHO PQ products for a period of two years. In addition, if the situation arises where there are not enough FDC formulations available, a time-limited acceptance of co-blisters, similar to the time-limited acceptance of non WHO-PQ products, could be considered.

We believe that by endorsing the exclusive use of FDCs, the AMFm will give a clear message to manufacturers to invest in the development of such formulations, including all necessary quality, safety and efficacy elements.

Such a move would also encourage the WHO Prequalification Programme to consider the review of FDCs as a priority.

An acceptance of co-blisters beyond a limited timeframe, however, would only discourage other potentially interested manufacturers from developing FDCs.

We hope these comments make a constructive contribution to the AMFm and look forward to discussing the issue further with you.

Yours sincerely,

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Médecins Sans Frontières International

CC:

Todd Summers, Chair of the Global Fund Board AMFm Subcommittee
Pr Eyitayo Lambo, Vice-Chair of the Global Fund Board AMFm Subcommittee
Awa Coll-Seck, Executive Director, Roll Back Malaria Partnership
Jorge Bermudez, Executive Secretary, UNITAID - WHO

[4] If there are < 2 or 3 products already WHO-PQ or authorized for use by a Stringent Regulatory Authority (SRA), if such products are manufactured in a site GMP compliant certified after inspection by WHO or by a SRA for the formulation concerned, and the product dossier accepted for review by WHO-PQ or SRA, and recommended for use by an ad-hoc expert review panel (ERP).
Information from: AMFm Taskforce of the Roll Back Malaria Partnership: “Interim report on progress against outstanding AMFm implementation challenges”. (February 2008)