

**MSF support letter for the inclusion of the nifurtimox as a treatment for second stage African trypanosomiasis (in combination with eflornithine) in the WHO Model List of Essential Medicines.**

Dear Madam, dear Sir,

Médecins Sans Frontières (MSF) has been supporting sleeping sickness control programs in Uganda, Angola, the Congo, Central African Republic and Sudan since 1986. During this period, more than 50'000 patients have been treated in the MSF centres, including more than 30'000 patients in the neurological (second) stage of the disease.

MSF had no choice but to use the arsenic-based melarsoprol for treating second-stage patients between 1986 and 2001. While we recognize that this drug has saved many lives, it has been responsible for the loss of many others. Its high toxicity directly leads to the death of 3 to 5% of patients, many of whom had walked to the treatment centres with few or no symptoms. Moreover, treatment failure with melarsoprol has increased in numerous endemic foci, most likely due to parasite resistance.

Since the early 1990s, eflornithine was known to be an efficient and likely safer alternative to melarsoprol but was not available due to high pricing and irregular production. Thanks to the WHO-Aventis agreement (2001-2006), which has been recently renewed (until 2011), eflornithine is now donated and is being increasingly used in the field. Its improved safety record has been demonstrated in several thousands of patients treated in MSF programs. Unfortunately, the universal use of eflornithine for treating second stage sleeping sickness in Africa is made very difficult by its complicated mode of administration (4 intravenous infusions per day, each lasting 2 hours for 14 days), requiring night shifts for the nursing staff and very heavy logistic means (e.g. transport and storage of materials). This situation led MSF, Epicentre and the Ministry of Health of Congo to launch the NECT study. It was considered as crucial to simplify the use of eflornithine and to combine it with another drug, nifurtimox, in order to improve the treatment's efficacy, prevent the selection of resistant parasite strains and therefore to preserve the few drugs we have to treat this disease. The NECT trial has evolved into a multi-centre study under the sponsoring of the DNDi and has recently been completed. The results are strikingly convincing, showing improved practicability (14 infusions instead of 56!) with similar efficacy and safety profiles of the nifurtimox-eflornithine combination compared to the standard eflornithine regimen.

We have no doubt of the urgency for the nifurtimox-eflornithine combination to become the 1<sup>st</sup> line treatment for second stage *T. b. gambiense* HAT and we are aware that this opinion is shared by most, if not all, actors active in the field of this neglected disease. The introduction of the nifurtimox-eflornithine combination into national guidelines and clinical practice would further decrease the current use of melarsoprol and the unnecessary deaths.

Therefore, MSF strongly supports the application submitted by the DNDi, proposing the inclusion of nifurtimox in the section 6.5.5 Antitrypanosomal medicines (6.5.5.1 African trypanosomiasis, Medicines for the treatment of second stage African trypanosomiasis) in the WHO Model List of Essential Medicines. This will allow for the rapid and large implementation of a really improved treatment protocol (in combination with eflornithine).

For MSF International  
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