CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

Geneva, January 7 2005

MSF briefing note regarding WHO pre-qualification for the 115th Session of the WHO Executive Board

Médecins Sans Frontières (MSF) is concerned about the lack of support from the World Health Organization leadership for the WHO pre-qualification project. The issue will most likely be discussed under agenda item 4.9 of the 115th Executive Board 'Antiretrovirals and developing countries'.

In May 2004 the World Health Assembly adopted a resolution (WHA57/14) in which it asked the WHO Director-General to strengthen the pre-qualification project. The WHA requested the DG:

> *"to take measures to improve access of developing countries to pharmaceutical and diagnostic products to diagnose, treat, and manage HIV/AIDS by strengthening WHO'S prequalification project;"*

Until today this has not happened.

Achieving the goal of access to essential medicines for all requires globally accepted mechanisms for ensuring that these medicines – generic and originator products – are of quality.

The WHO pre-qualification project is one of WHO's key functions in improving access to quality and affordable medicines.

The specific tasks of the pre-qualification project is to assess the quality of essential drugs, produced by generic and originator companies, through the evaluation of product dossiers submitted by companies, and through the assessment of manufacturing sites.

The pre-qualification project publishes and regularly updates a list of the drugs it has validated. This work is carried out by a very small WHO team of 3 to 4 people, most of whom are on temporary contracts.

The WHO pre-qualification project has improved access to quality essential medicines, particularly AIDS drugs. More than 85 products – 45 of them generics – have been pre-qualified to date. However there are still huge unmet needs. WHO does not have a proactive policy to ensure that sufficient sources of prequalified recommended treatments are available.

The project has also contributed to improving standards of generic producers and helped enhance developing countries' capacity to produce quality medicines as well as improving developing countries capacity to monitor and assure quality of medicines.

Before the pre-qualification project, information on the quality of generic drugs used in developing countries was limited. Regulatory agencies in developing countries often lack the capacity to conduct quality assessments. In the case of HIV/AIDS, for instance, many countries would have chosen to use medicines of unknown quality or more expensive originator drugs due to this lack of information on quality of generics. Considering the difference on prices[1] between originator and generic products, there was and continues to be a real need to make quality assessments of generics available.

Since June 2004 several ARV products have been delisted as a result of the outcome of an inspection performed in the contract research organisation in charge of the bioequivalence studies. The delistings illustrate the rigour of the WHO pre-qualification process. However the delisting lead to immediate problems in countries where these drugs are part of the national protocol.

The delisted products are subject to reassessment. Some products have been put back on the list again after new data was submitted. However in general the re-assessment of these dossiers is taking time. WHO needs to take a pro-active approach with companies to ensure that drugs are rapidly reassessed.

The pre-qualification work is gaining importance now that countries have started to make use of the TRIPS/Doha flexibilities to overcome patent barriers to purchasing or locally producing medicines. Funding agencies such as the Global Fund for AIDS, TB and Malaria require that drugs be pre-qualified by WHO. Without a fully functional pre-qualification project these requirements will mean that access to more affordable versions of medicines will be denied.

The World Health Assembly has recognised that WHO's pre-qualification work must be adequately supported. Despite this, the pre-qualification project has not received the internal support and resources it needs to carry out its important task. The project remains severely under-staffed and under-funded and therefore risks not being able to face the growing challenges of AIDS, TB and malaria.

The WHO leadership needs to ensure that the pre-qualification project becomes a permanent and well-resourced function of the organisation.

Campaign for Access to Essential Medicines
Médecins Sans Frontières

[1] Originator WHO recommended first-line ARVs cost about USD 562 per patient per year while a generic WHO pre-qualified first line costs USD 214/year. With the same budget, a country can treat 2.6 more patients using generics.