CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

Rue de Lausanne, 78
CP 116 1211 Geneva 21
Switzerland
Tel : +41 (0) 22 849 84 05
Fax : +41 (0) 22 849 84 04

www.msfaccess.org

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

December 19, 2008

Re: Docket Number FDA-2008-D-0530

Dear Sir or Madam,

Médecins Sans Frontières / Doctors Without Borders (MSF) wishes to provide comments on the “Draft Guidance for Industry on Tropical Disease Priority Review Vouchers”.

MSF is an international medical humanitarian organization working in more than 60 countries. MSF provides care to people suffering from tropical and other neglected diseases and therefore experiences first-hand the lack of appropriate diagnostics, drugs and vaccines for many of these diseases.

MSF welcomes the willingness to create new mechanisms to boost research and development (R&D) into neglected diseases but would like to provide the following comments with particular focus on question 6 of the draft guidance (i.e. “Would eligibility to receive a priority review voucher be affected in any way by whether the sponsor intends to market or distribute the qualifying tropical disease product after approval? No, it does not matter if the sponsor decides not to market the product. Eligibility will be based on the criteria outlined in the statute."):

The need to stimulate innovation while at the same time guaranteeing access to the innovative products for populations that most need them is widely acknowledged and has been extensively described, among others, by the Report of the Commission on Intellectual Property, Innovation and Public Health of the World Health Organization. [1] We are concerned that the priority review mechanism does not ensure that health technologies approved for tropical diseases and resulting in a priority review voucher will boost access to medicines in developing country patients. The guidance in its current form does nothing to require that any product developed for tropical diseases is either priced affordably, or even made available in developing countries. A company could simply neglect to register a product in developing countries, or maintain its price out of reach of people who need it or could not market it at all. In that case, the mechanism would be giving pharmaceutical companies a financial windfall, and patients would be getting nothing in return. Innovation by itself is of little practical value to

[1] http://www.who.int/intellectualproperty/report/en/index.html

address tropical neglected diseases if the results are not available to the people suffering from those diseases

To the extent that the FDA has the power to impose conditions, MSF recommends that the granting of a priority voucher is made conditional on a binding guarantee by the applicant to market the drug in developing countries at an affordable price or to establish an open licensing policy for third party manufacturer. Alternatively the FDA could consider the creation of a system for the collective management of licensing rights such as the medicines patent pool currently being established by UNITAID.

If the FDA does not currently have such powers, it should at least monitor, (and if necessary impose reporting requirements on recipients of a PRV) how many products which benefit from a PRV have been registered or made available in the relevant disease endemic countries.

In addition, the mechanism in its current form does not assess if the FDA approval will provide additional public health benefit over the current treatment of tropical diseases in developing countries. This problem is exemplified by the Swiss pharmaceutical company Novartis that is currently seeking FDA approval for artemether/lumefantrine and could be the first possible recipient of a priority review voucher. Artemether/lumefantrine was added to the Essential Medicines List of the World Health Organization (WHO) in 2002 and has been available in the developing world for several years. There is therefore no benefit to patients in the developing world from a U.S. registration - and thus no reason to reward the company. Other companies could come forward with even older drugs for tropical diseases simply because they have never been registered in the U.S. such as antimonial stibogluconate (SSG) for visceral leishmaniasis.

MSF recommends that the FDA, before granting a priority voucher, obtains an opinion by a relevant health authority such as the WHO or the Center for Disease Control (CDC) on the expected added benefit that the new health technology could provide over currently WHO recommended diagnosis, treatment or prevention methods.

We thank you for your consideration of these comments. We will be happy to discuss further if there are any questions. Please contact me in the first instance.

Yours sincerely,

Tido von Schoen-Angerer, MD
Executive Director
Campaign for Access to Essential Medicines
Médecins Sans Frontières / Doctors Without Borders International