The Secretary 4 March 2015

20th Expert Committee on the Selection and Use of Essential Medicines
World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27
Switzerland

Dear Sir/Madam,

We, the undersigned organizations, strongly support the application made by MSF/Médecins Sans Frontières to include daclatasvir in the Model List of Essential Medicines of the World Health Organisation (WHO).

HIV and hepatitis C virus (HCV) co-infection has a global prevalence of 16%, representing up to 4-5 million people living with both viruses.[1] Those with co-infection progress to serious liver disease and cirrhosis much more quickly and more often than those infected with HCV alone. Despite the progress made in the HIV response due to the scaling up of antiretroviral therapy, people with HIV-HCV co-infection remain at significantly increased risk of overall mortality than those with either infection alone.

The vulnerability and high prevalence of HCV infection among people who inject drugs in many countries in our region - including India, Indonesia, Thailand, and Vietnam - are well documented. Many of these individuals are unable to access treatment due to the high cost of the medications and the lack of clinicians appropriately trained or willing to treat co-infected patients. However, it has been shown that people with HCV infection in resource-limited countries can have treatment success rates similar to those in developed countries.[2] There are also emerging data that, if given the opportunity to access treatment, clinicians and co-infected patients in our region can successfully achieve HCV cure.

Daclatasvir, a new direct-acting antiviral used in combination with other HCV medications, is an effective drug that has been associated with high cure rates across multiple genotypes, and has few side effects. Recent approvals of daclatasvir by the European Medicines Agency have created the opportunity for an interferon- and ribavirin-free regimen for the treatment of HCV.

However, although rapidly becoming available in high-income countries, there has been no indication that the manufacturers of daclatasvir are seeking to register the drug or offer compassionate use programs in the countries where we work. Putting daclatasvir on the list will enable all stakeholders to move forward with treatment advocacy activities, in order to avoid the type of delays in access experienced with antiretroviral therapy for people living with HIV that occurred in the early 2000's.

This application from MSF is a critical effort to improve access to effective HCV treatment for those most vulnerable to the worst consequences of this infection. A decision to add daclatasvir to the Model List of Essential Medicines would be a necessary first step for our governments to even consider the addition of this drug to our own national essential medicines lists, and would give us as civil society and treatment advocates the opportunity we need to engage in negotiations with our governments to fund HCV treatment programs with direct-acting agents.

We strongly encourage you to approve MSF's application and begin creating the foundations for broader access to HCV treatment and cure in the countries with the greatest global disease burden.

Sincerely,

(1) AIDS ACCESS Foundation, Bangkok, Thailand

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[1] Alter MJ, **Epidemiology of viral hepatitis and HIV co-infection,** Journal of Hepatology, 2006, (Suppl. 1):S6–9.

[2] Ford N, **Chronic hepatitis C treatment outcomes in low- and middle-income countries: a systematic review and meta-analysis,** Bulletin of the World Health Organization, *Published online: 3 February 2012.*

(2) Asia Pacific Network of People Living with HIV and AIDS (APN+), Bangkok

(3) Asian Network of People who Use Drugs (ANPUD), Bangkok

(4) Center for Supporting Community Development Initiatives (SCDI), Hanoi, Vietnam

(5) Community Network for Empowerment (CoNE), Manipur, India

(6) Delhi Network of Positive People (DNP+), New Delhi, India

(7) Hepatitis Coalition of Nagaland (HepCoN), Nagaland , India

(8) Indian Drug Users Forum (IDUF), India

(9) Indonesian AIDS Coalition (IAC), Jakarta, Indonesia

(10) Perssaudaraan Korban Napza Indonesia (PKNI), Jakarta, Indonesia

(11) Sankalp Rehabilitation Trust, Mumbai, India

(12) Thai AIDS Treatment Action Group (TTAG), Bangkok, Thailand

(13) TREAT Asia/amfAR-The Foundation for AIDS Research, Bangkok, Thailand

(14) Union C, Kathmandu, Nepal

(15) Vietnam Network of People Living with HIV (VNP+), Hanoi, Vietnam

(16) Western India Harm Reduction Network, India

(17) Dr. Hafiz Aziz ur Rehman, Pakistan

(18) Mr. Leslie Ong, Bangkok, Thailand

(19) Mr. Paul Cawthorne, Bangkok, Thailand