

Writing a Letter of Support for Including Pegylated Interferon in the World Health Organization's Essential Medicines List: Guidance for Civil Society Submissions

Civil-society groups have an important but limited opportunity to advocate for the inclusion of pegylated interferon on the World Health Organization Essential Medicines List: **Deadline Mid-February!**

A. What is the World Health Organization Essential Medicines List?

The World Health Organization (WHO) Essential Medicines List (EML) is a list of medicines the WHO considers essential to a basic health care system. Medicines on the list are considered to be the most “efficacious, safe and cost-effective” medicines for treating priority diseases.

Currently, there are more than 350 drugs on the list. The WHO EML is considered a model for countries to use to develop their own list based on national health priorities.

WHO defines essential medicines as “those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.”¹

B. Why is it important for a drug to be included on the WHO EML?

Many governments refer to WHO recommendations when making decisions on health spending. A drug included in the WHO EML may be more likely to appear on a country's national EML and given priority for coverage under a national health care scheme, for example.

Together, the drugs on WHO's EML comprise safe, effective treatment for the majority of the world's communicable and noncommunicable diseases, from HIV/AIDS to cancer. The list is updated every two years to accurately reflect changing global health priorities.

C. How is the WHO EML different from a national essential drugs list?

Often, the WHO EML informs treatment guidelines and policies on national drug coverage in both developed and developing countries. Over 150 countries have published their own list of medicines considered essential for treating the diseases that they have prioritized. A national list helps health authorities optimize their resources so that they are able to provide the best possible health care services and treatment, which is particularly important in resource-limited settings.

¹ http://www.who.int/medicines/services/essmedicines_def/en/index.html.

D. Why submit a letter of support for pegylated interferon to be included on the WHO EML?

An estimated 160 million people—or three percent of the world’s population—have been infected with the hepatitis C virus (HCV). The epidemic continues to grow; each year, 5 million people are newly infected. Although hepatitis C can be treated and cured, more than 350,000 people die from HCV complications each year.

The current standard of care for hepatitis C virus is pegylated interferon (PEG-IFN) and ribavirin (RBV). Yet in most countries, HCV treatment is not being provided. Although generic ribavirin is available in many countries, the high price of pegylated interferon is prohibitive. Most governments of low- and middle-income countries are unable to provide it, making it inaccessible to all but the wealthiest citizens.

In 2010, the WHO created a resolution that established viral hepatitis as a global health priority. Pegylated interferon is not yet included on the WHO EML. ***In order to stimulate price reductions and increase access to HCV treatment, PEG-IFN must be included on the WHO EML.***

Your letter can help convince the WHO technical committee to include PEG-IFN on the list. It should therefore provide information that highlights the epidemiological situation in your country/region, patient need, and how inclusion of PEG-IFN on the EML would increase patient access and impact the epidemic. **The committee is technical, and responds to evidence-based information rather than political arguments for PEG-IFN’s inclusion.**

E. Deadline for submitting a letter of support for MSF’s application for pegylated interferon to be included on the WHO EML:

By mid-February 2013, ideally, as the technical committee will make its decision mid-April 2013.

F. The original, official MSF application for PEG-IFN to be included on WHO EML can be accessed at:

http://www.who.int/selection_medicines/committees/expert/19/applications/peginterferon/en/.

G. Who can submit a support letter?

Any organization (patient groups, professional associations, an advocacy network, government agencies, or other stakeholders concerned about HCV treatment access

may submit a letter. For example: regional or global networks (hepatitis, HIV, harm reduction, etc.), a country's department of disease control, an official from the ministry of health in a country with a high disease burden, national research or related academic institutes, or even another WHO agency such as a regional office representing countries with a high disease burden that would be positively affected by the addition of the medicine on the EML.

H. How do I submit a letter of support?

The support letter, on your organization's letterhead and signed, scanned, and e-mailed as an attachment, or snail-mailed, should be addressed to:

The Secretary of the 19th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27 SWITZERLAND
E-mail: emlsecretariat@who.int

Tip: The WHO secretariat suggests that support letters state details of the country or region's hepatitis C disease burden and explain how an inclusion of PEG-IFN would change the paradigm in the country/context. Evidence-based rather than political arguments for the inclusion of PEG-IFN will be effective, as the committee has no political mandate.

Submissions may be made in English, French, or Spanish. If submitting in another language, you would ideally attach an English translation or summary.

In order to keep a record of all submissions of letters of support, please send a copy of your letter to Karyn Kaplan, Director, International Hepatitis/HIV Policy & Advocacy, Treatment Action Group (TAG) – New York: karyn.kaplan@treatmentactiongroup.org.

I. Sample letters

See **Appendix A**, below, for “Sample letter from Thai AIDS Treatment Action Group (TTAG).”

See **Appendix B** for sample letters (not for PEG-IFN, but for NECT, a sleeping sickness combination therapy) from WHO agencies, government agencies, and others.

For other sample letters of support (not for PEG-IFN, but for blood products to be

included on WHO EML) may be found here:

http://www.who.int/selection_medicines/committees/expert/19/applications/blood/en/index.html.

J. Additional resources

1. WHO Essential Medicines Fact Sheet:
<http://www.who.int/mediacentre/factsheets/fs325/en/index.html>
2. WHO Essential Medicines List and Formulary:
http://www.who.int/selection_medicines/list/en/
3. Millennium Development Goals chapter on essential medicines:
<http://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf>
4. Médecins Sans Frontières/Doctors Without Borders Campaign for Access to Essential Medicines: <http://www.msfaccess.org/>

Appendix A: Sample letter from Thai AIDS Treatment Action Group (TTAG) to WHO for inclusion of PEG-IFN on the WHO EML

January 15, 2013

The Secretary of the 19th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27 SWITZERLAND
E-mail: emlsecretariat@who.int

Dear Sir or Madam:

This communication is provided by Thai AIDS Treatment Action Group (TTAG) in support of Médecins Sans Frontières/Doctors Without Borders (MSF)'s application for the inclusion of pegylated interferon (PEG-IFN) on the WHO Model List of Essential Medicines (EML). TTAG is a community-based organization that advocates for the health and human rights of people living with or at high risk of HIV and hepatitis C. Through our education and advocacy work across the country, we reach thousands of people living with HIV/AIDS, people who inject drugs, migrant sex workers and people in prison and we influence national health policy.

In Thailand, HCV prevalence ranges from 3.2%–5.6% of the general population. Up to 90% of current and former injection drug users (IDU) have been infected with HCV. At least 10% of Thai people living with HIV/AIDS are HCV coinfecting. People living with hepatitis C suffer a range of problems including disability, poor quality of life, and a higher risk of liver-related death. People coinfecting with HIV/HCV experience more rapid progression of liver disease and death, in spite of HIV antiretroviral therapy (ART) use. Yet hepatitis C can be cured, saving millions of lives and government dollars through averted liver failure, transplantation, and death.

The standard of care for the treatment of hepatitis C is pegylated interferon, an injectable biologic, and ribavirin, a generically available pill. Pegylated interferon is prohibitively expensive in Thailand, and a course of treatment can cost 3 times the per capita gross domestic product (GDP). Access to HCV treatment in Thailand was virtually non-existent until PEG-IFN was included on Thailand's national essential drugs list last year. This allowed the Thai government to conduct price negotiations with the manufacturers and successfully reduce its cost. As a result, the government is now planning to cover HCV treatment under its national health care scheme, though treatment access will remain limited because the cost of brand-name PEG-IFN in Thailand is still relatively high compared with other countries.

Including PEG-IFN on the WHO EML will signal that hepatitis C is a global priority to countries around the world. At the 63rd World Health Assembly, the WHO issued a resolution that clearly states its commitment to enhanced access to affordable and accessible treatment, particularly in developing countries; but resolutions are only useful when they lead to tangible action. Countries must be empowered to promote the right to health and access evidence-based approaches to treating and thereby eradicating HCV.

Including PEG-IFN on the WHO EML will facilitate equitable access to the highest standard of care currently available for HCV.

Yours sincerely,

Paisan Suwannawong
Executive Director

Appendix B: Sample letters from the WHO, government agencies, and others in support of NECT (sleeping sickness combination therapy) for inclusion on the WHO EML

1. Letter #1 attached as .pdf file (NTD Support Letter.pdf) is a letter from the **Director of the Department of Control of Neglected Tropical Diseases, WHO**. According to the WHO Essential Medicines List secretariat, this was likely the most important letter submitted because it came from the WHO disease control experts. It effectively summarizes the problems with existing treatment and describes how the combination treatment (NECT) would alleviate these problems. It also defines the WHO's policy on sleeping sickness, explains how countries have requested WHO support to improve their national responses, and explains how putting combo therapy on the EML would allow the WHO to fulfill its mandate more effectively and shape national-level policy/response on sleeping sickness.
2. Letter #2, attached as a .pdf file (CDC Support Letter.pdf) from the **Centers for Disease Control (CDC), Swiss Tropical Institute, Institute of Tropical Medicine Antwerp**: This makes the same arguments as above, but from the perspective of a leading research/medical institute working in endemic countries.
3. Letter #3, attached as a .pdf file (DRC Authorities.pdf): This letter is from the **DRC-authorities**, in particular the National Control Programme for sleeping sickness (PNLTHA) and the Ministry of Health, who were the prime users of the new treatment. Having these authorities voice their demand for the treatment and their willingness to start using it if it were available, is crucially important. It is in French, but the arguments are mostly the same as in the previous letters.

Treatment Action Group would like to thank all the contributors who helped in the development of this guide.