

HEPATITIS C VIRUS – PREVENTION AND TREATMENT

Health groups - Without prevention programme, millions at risk of infection High prices of medicines means debt or death for people with chronic Hepatitis C

New Delhi, 21 October 2011 - People living with hepatitis C, ITPC-India and treatment activists at a press conference openly questioned the silence maintained by the Indian Health Ministry on its response to the Hepatitis C virus (HCV), which is emerging as a growing public health threat.

According to the World Health Organization, hepatitis C virus (HCV) is a major cause of acute hepatitis and chronic liver disease. Globally, 3 to 4 million persons are newly infected each year. According to the health groups at the press conference, the burden of the disease in India will continue to rise in the absence of prevention and harm reduction measures with vulnerable communities.

“HIV and hepatitis viruses are transmitted in similar ways and it makes public health sense to link HCV prevention efforts to HIV programme” said Eldred Tellis, Director of Sankalp Rehabilitation Trust. *“In addition to HCV screening in blood banks, prevention and harm reduction efforts for HIV and HCV with vulnerable communities should go hand in hand. Unless this is done, HCV infections will rise in India even though HIV transmission rates reduce, particularly among injecting drug users (IDU), the most vulnerable community,”* adds Tellis.

According to the health organisations, there are two main obstacles to an effective HCV response in the country. First is the absence of prevention efforts; second is the lack of political will to treat HCV—among policymakers in the Health Ministry.

Currently, HCV treatment is a combination of two drugs, pegylated interferon and ribavirin. For people who do not clear the virus spontaneously from their body and go on to develop chronic forms of the disease that affects the liver, treatment is currently unavailable in the public healthcare system and unaffordable in the private sector.

The high cost of HCV treatment in India is attributed to the absence of generic competition due to patent barriers. India, as part of its obligations under World Trade Organization’s (WTO) international trade rules, had to introduce product patents on medicines in 2005.

Pegylated interferon alpha 2a and alpha 2b, used in the treatment of Hepatitis C, were among the first set of drugs to come under patent monopoly in India. The patents granted by the Indian Patent Office to two pharmaceutical companies - Roche and Schering-Plough, block the development of more affordable generic versions of the drug. As a result both these companies charge exorbitant prices from patients, ranging from Rs. 14,000 to 18,000 per dose.

“People living with HIV are increasingly being diagnosed with HCV co-infection. Hepatitis C, is the “silent killer,” threatening to undermine HIV treatment efforts”, said Loon Gangte, of the Delhi Network of Positive People (DNP+). *“We need not only AIDS medicines but also access to HCV medicines from the government.”*

“I had to use all my savings and borrow heavily to pay over seven lakhs rupees for my 48 week HCV treatment,” said Nanao Haobam, sharing his experience of living with HCV/HIV co-infection. *“The Indian Government’s silence on this issue is more like telling us – I am sorry you will die because treating you is not cost effective.”*

Neini Wanda E. Pakma, who underwent HCV treatment this year, adds, *“my family had to pay Rs. 5,78,000 over 24 weeks for just pegylated interferon. I am one of the lucky ones to have been successfully treated in India. The high cost of drugs makes it impossible for patients in India with chronic HCV to get the treatment they need.”*

“As a physician we have gone through the frustration of watching people die of AIDS even when effective antiretrovirals existed. But things changed with domestic production of affordable generic antiretroviral medicines,” said Dr. Tokugha Yephthomi, of ITPC - India. *“People are now dying because the price of the HCV drug that can save them is too high. Prohibitive pricing of lifesaving medicines by pharma companies is unethical and unacceptable.”*

According to the organisations, the government has been moving far too slowly on addressing the problems of patients who need HCV treatment. *“When drugs are patented, and pharmaceutical companies fail to fulfil their obligation to make patented medicines available and affordable to patients, the only way to bring prices down is through examining the validity of the patent granted or compulsory licensing which allows generic production of more affordable versions,”* said Loon Gangte. *“Instead of addressing the problem, it's like the government is pretending the death and the sickness that HCV causes are not happening.”*

This press briefing is being organized by International Treatment Preparedness Coalition – India (ITPC-India). ITPC-India was set up in 2008 as a national coalition of people living with HIV, treatment activists, doctors, lawyers and academia.

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Notes for the editor:

Viral Hepatitis resolution adopted by the member states of the World Health Organisation on 23 January 2010 at the Sixty-third World Health Assembly, which recognises Hepatitis C as a public health issue. Available at http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_R16-en.pdf

Hepatitis C in India: <http://www.ias.ac.in/jbiosci/nov2008/465.pdf>

Treatment protocol: Hepatitis C treatment is a combination of two drugs, pegylated interferon and ribavirin. Pegylation means that a small molecule has been attached to interferon to keep it in the body longer, to make dosing more convenient. There are two types of pegylated interferon (PegIFN) - alpha-2a and alpha-2b. Pegylated interferon alpha-2a is a liquid that comes in one vial and is stored in the refrigerator. Everyone uses the same dose of Alpha-2a, regardless of their weight. Pegylated interferon alpha-2b is a powder that has to be reconstituted with purified water, both of which come in separate vials. Alpha-2b is dosed by weight. For people living with HIV, who are co-infected with HCV, the usual course of HCV treatment lasts for 48 weeks, with ribavirin taken daily (pills) and pegylated interferon taken once a week by injection.

Patents: High prices due to the introduction of WTO's product patent regime in 2005 are starting to be experienced in India. On March 3rd 2006, Roche proudly announced it was becoming the first pharmaceutical company in India to receive a product patent under the new patent regime on peg-interferon alfa-2a (IN198952). Sankalp Rehabilitation Trust filed a post grant opposition to the patent, as the technology of combining interferon and other biologically active proteins with PEG has been known for years prior to the patents. The matter will be heard before the Intellectual Property Appellate Board in January 2012. Schering-Plough was granted a patent (IN 207233) on

peg-interferon alpha-2b and has filed infringement suits in 2009 against Virchow Laboratories and Ranbaxy before the Delhi High Court. The infringement suit is scheduled to be heard next on 15 December 2011.

Compulsory licensing (CL): With CLs prices of medicines can be lowered effectively. The case of the CL issued by Thailand for the AIDS drug lopinavir/ritonavir in January 2007 clearly illustrates this. Over the course of one year, the price for LPV/r decreased by as much as 75%, from \$2,200 ppy to under \$900 in Thailand. As per the World Trade Organization's TRIPS Agreement and the 2001 Doha Declaration on TRIPS and Public Health, *India's Patents Act too allows it to implement a progressive compulsory licensing policy in accordance with international trade rules.*