Global Snapshot: HCV epidemiology & response

Introduction:

Globally, an estimated 170 million people (or 3%) are living with the hepatitis C virus (HCV), resulting in over 350,000 liver-related deaths per year, and representing a critical public health crisis that requires an urgent response. The 63rd World Health Assembly Resolution on viral hepatitis urges countries to take the necessary measures to effectively control viral hepatitis, including HCV. Such measures include HCV education, surveillance, prevention, diagnostics, treatment and care. But few countries, particularly in the developing world, have adequate HCV control programs in place. The response to HCV has been slow and is further hampered by the fact that treatment (pegylated-interferon-alfa) is priced too high for most individuals and their governments to afford.

This briefing aims to capture a global snapshot of the extent of the HCV problem (epidemiology) and the cost of pegylated-interferon in various countries. The information was collected through surveys and interviews with session one panelists who represent country and regional experts on HCV, and serves as a primer to session one's panel.

Global epidemiology of hepatitis C:

While HCV continues to disproportionately affect marginalized groups like people who inject drugs (PWID), and people living with HIV (PLHIV), HCV prevalence among the general population has been documented at epidemic proportions in many countries. Since HCV surveillance is not routinely conducted in most developing countries, the following table lists epidemiological data collected by session one panelists in preparation for this meeting, the majority of which are not based on population-based studies, but site-specific ones.

	General Population (prevalence %)	PLHIV (prevalence %)	PWID (prevalence %)
Asia			
Thailand	3.2-5.6[i]	7.2-10.1[i]	89.8[ii] (90-95[i])
India	1-1.9[iii]	NA	41[ii] (26-93)[iv]
Vietnam	0.4 - 4.3[v]	35[v]	74[v,ii]
Indonesia	0.2 - 3.9[v]	34[v]	60-98[ii] (77[v])
Malaysia	2[vi]	30-50[vi]	67-81[ii] (80-90[vi])
Pakistan	4.9[xiii]	NA	84[ii]
Latin America			
Brazil	1.38[vii]	11.4[vii]	63.9[ii] (17.1[vii])
Eastern Europe/Central Asia			
Russia	1-7[viii]	NA	49-96[ii]
Ukraine	2-4.4[ix]	70[ix]	60-73[ii] (91[ix])
Georgia	6.7-9.5[x]	48[x]	58.2[ii] (48-54[x])
Africa			
Egypt	15 (15-59 age group)[xi]	NA	35-63[ii]
Ghana	NA	1[xii]	NA
Congo	2.1[xii]	NA	NA
Burkina Faso	4.2[xii]	NA	NA
Cameroon	13.8[xiii]	NA	NA
Burundi	11.3[xii]	NA	NA
Senegal	>1[xii]	1.6[xii]	30-50[ii]
Benin	4.1[xii]	3-14%[xii]	NA
Mali	3.4[xii]	6.7-20[xii]	NA

Treatment Costs: Pegylated-Interferon & the pipeline

Country	**$ Roche (Pegasys) 48 weeks**	**$ Merck (PegIntron) 48 weeks**	**$ Other source 48 weeks**
Thailand	4,896 USD[i] (102 USD/vial)	4,896 USD[i] (102 USD/vial)	NA
India[iv]	15,000-16,000 USD	15,000-16,000 USD	Virchow (ViPeg) 4465 USD[xiv] (5000 INR/vial)
Vietnam[v]	28,000 USD*	28,000 USD*	Nanogen (PegNano) 4368 USD
Malaysia[vi]	8500-10,000 USD	8500-10,000 USD	Boceprevir 30,000 USD**
Indonesia[v]	17,000-18,500 USD	17,000-18,500 USD	NA
Brazil[vii]	9,520 USD	9,600-11,390 USD	Boceprevir 27,100 USD Telapravir 25,100 USD
Russia	17,000 USD	20,000 USD	NA
Ukraine	18,000 USD	16,000 USD	NA
Georgia	19,000 USD	15,000 USD***	NA
Egypt[xi]	2624 USD	2624 USD	Minapharm (Reinferon Retard) 1968 USD
Pakistan[xv]	6,528 USD (136 USD/vial)	NA	NA
Burkina Faso[xii]	17,200 USD****	17,200 USD****	NA
Cameroon[xvi]	9950 USD*****	NA	NA
Benin[xii]	17,280 USD	NA	NA
Democratic Repulic of Congo[xi]	17,280 USD****	17,280 USD****	NA

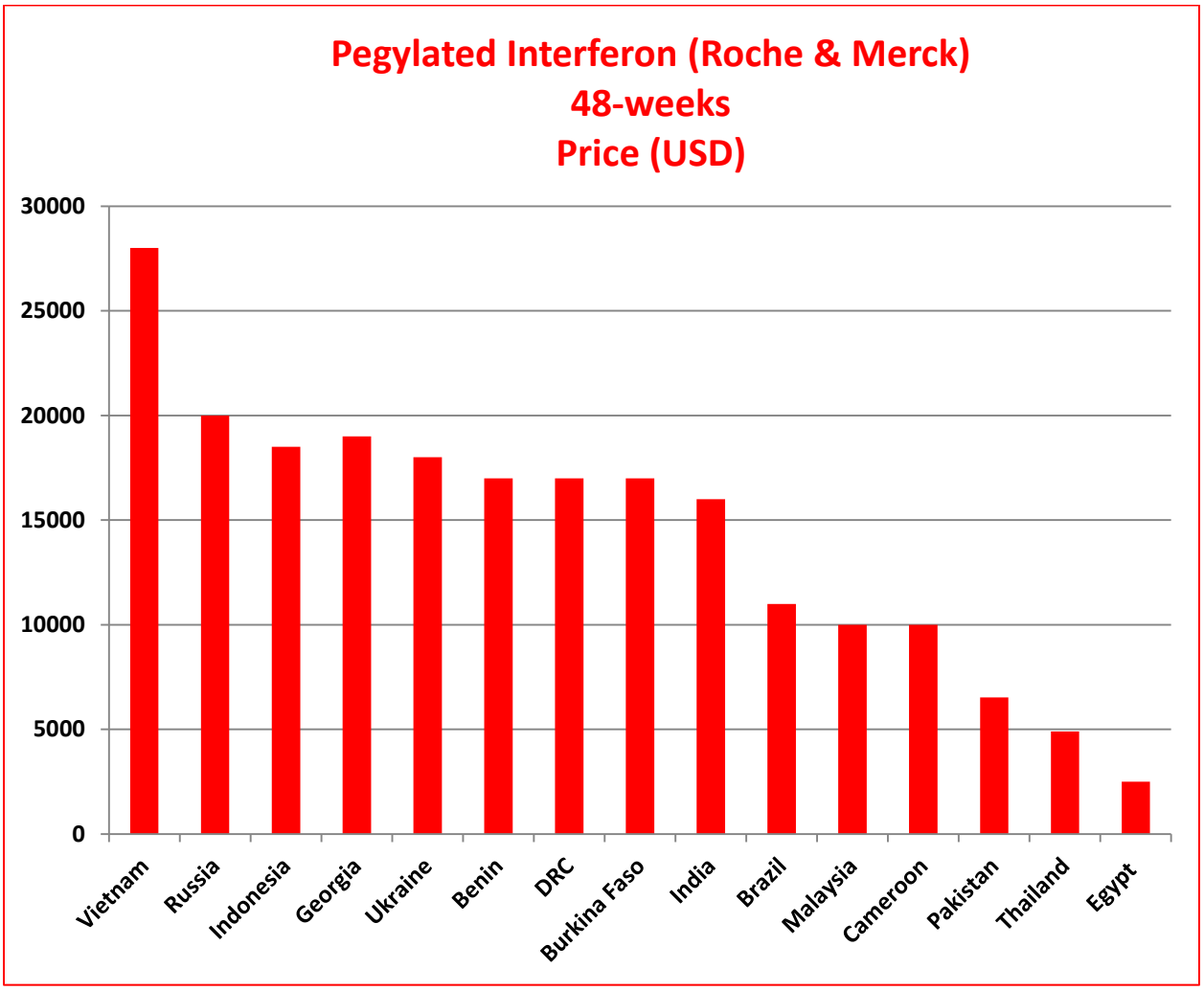
*****Including monitoring and diagnostics costs

**PegIntron and Ribavirin are free with purchase of boceprevir

***Through Global Fund R10 tender, price reduced by over 50%. Merck won the tender

****Unclear which product the cost is referring to, or whether both products are available in the country

*****Price reduction accomplished through government negotiations with Roche (price reduced from over 16,000 USD)



As the tables above show, the price of the main medicine used in the current standard of care, pegylated-interferon-alfa, is patent protected and varies significantly between countries. In almost all cases, with a few rare exceptions, it is priced too high, particularly since the cost of treatment is paid for out of pocket in most of these countries. Egypt's price for Roche's Pegasys and Merck's Pegintron, at roughly 2500 USD per 48-week treatment course, is markedly lower than the price of the same medicines in other countries. This may be in large part due to the fact that in Egypt, an alternative supply of pegylated-interferon exists, called Reinferon Retard locally produced by the company Minapharm. The government has been paying for treatment for its citizens and since 2008, 200,000 patients have been treated through Egypt's national treatment program. Other alternatives or potential "biosimilars/biogenerics" for Roche and Merck's pegylated-interferon exist. Such products are locally produced in Vietnam (produced by Nanogen, called PegNano) and India (Virchow Pharmaceuticals, called ViPeg). However, assessing the safety, quality and efficacy of these products has been a major challenge to date, as there is limited expertise at the regulatory level in many countries to assess biosimilarity.

Last year, two new antivirals (boceprevir and telaprevir) for use with pegylated- interferon and ribavirin became available, but have been reported to cost an additional 30,000 USD. Recently, Brazil approved the use of these

medicines for a select number of patients through their national treatment program. Price and patents will continue to limit access as we move toward an era without pegylated-interferon. The most promising pipeline drugs, while significantly more efficacious, will also be exorbitantly priced.

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[i] Personal communication. Karyn Kaplan, Treatment Action Group

[ii] Nelson, P.K., Mathers, B.M., Cowie, B., et al. (2011). Global epidemiology of hepatitis B and hepatitis C among people who inject drugs: results of systematic reviews. *Lancet, 378:* 571-83.

[iii] Sievert, W., Altraif, I., Razavi, H.A., et al. (2011). A systematic review of hepatitis C virus epidemiology in Asia, Australia and Egypt. *Liver International: Official Journal of the International Association for the Study of the Liver.*

[iv] ANPUD. 2011. *Barriers to hepatitis C diagnosis, management and treatment among people who inject drugs in 4 Asian countries*. Available at: http://testandtreathepatitisc.files.wordpress.com/2011/11/anpud-hcv-study-final-report-2011.pdf

[v] Personal communication. Nicholas Durier, Treat Asia, Amfar

[vi] Personal communication, Prof. Adeeba Kamaralzuman, University of Malaya, Malaysia

[vii] Personal communication, Eloan Pinheiro Dos Santos, Brazil

[viii] Personal communication, Sergey Golovin, ITPC-ru

[ix] Personal communication, Ludmila Maistat. International HIV/AIDS Alliance- Ukraine.

[x] Personal communication, Paata Sabeleshvilli, Georgian Harm Reduction Network

[xi] Personal communication, Prof. Gamal Esmat, University of Cairo, Egypt

[xii] Personal communication, Prof. Serge Eholie, Centre Hospitalier Universitaire de Treichville, Côte d'Ivoire

[xiii] Te. S.H., & Jensen, D.M. (2010). Epidemioligy of hepatitis B and C viruses: a global overview. *Clinical Liver Disease, 14:* 1-21.

[xiv] Personal communication. Tahir Amin, I-MAK

[xv] Personal communication. Giten Khwairakpam. TreatAsia, Amfar.

[xvi] Personal communication. Hebhang Toussant, Cameroon. Association Camerounaise de lutte contre les hépatites virales