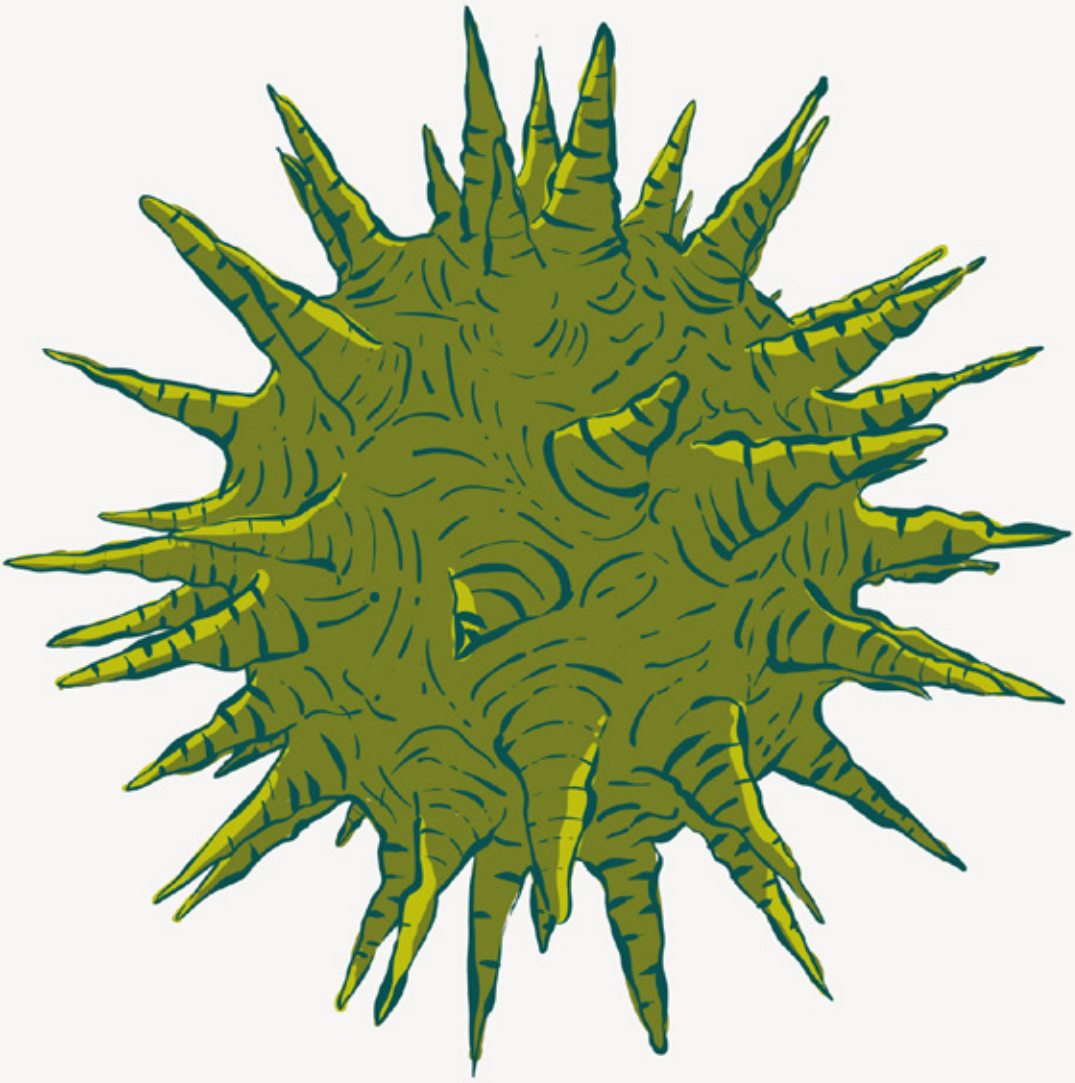
Egyptian Initiative
for Personal Rights



HCV Treatment in Egypt

Why cost remains a challenge?

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The paper benefited from several round-table discussions that were attended by: Dr. Alaa Ghanam, Officer of the Right to Health Program at EIPR, Dr. Alaa Awad: Professor, Gastroenterology & Liver Diseases at Teodorblhars Institute, Dr. Emad El-Azazi: Professor, Pharmacoeconomics at the German University in Cairo, Ms. Dina Iskander: Researcher at Oxfam, and Dr. Mohamed Salem: Researcher at the American University in Cairo.

HCV Epidemiology

Egypt has the highest prevalence rate of hepatitis C virus (HCV) in the world, making it the most challenging public health problem facing the country. Studies show that [1]4.7% of the Egyptian population carry HCV antibodies1 and 9.8% have an active infection.[2]

> *Upon exposure to HCV, the immune system responds by producing antibodies against the virus. These antibodies remain and could be detected even after HCV is cleared from the body.*
>
> *An active infection develops when the virus starts to increase in count and cause damage to the liver. This is when patients develop symptoms of hepatitis, seek medical help and get diagnosed.*

Some age groups suffer prevalence rates of up to 50%. As for the geographical distribution of anti-HCV in persons aged 10-50 years: the Nile Delta and Upper Egypt have rates of 28% and 26% respectively.[3]

Incidence rates are estimated at 2-6 per 1000 per year, that is, at least 170,000 new cases every year, which means maintaining a prevalence rate of 5-15% in the foreseeable future.[4]

Liver mortality in Egypt reaches 40,000 per year, making 10% of total mortality, and comes second after heart diseases.[5]

1- Esmat, G. Hepatitis C in the Eastern Mediterranean Region. Eastern Mediterranean Health Journal, 2013, 19(7). Available at: http://www.emro.who.int/emhj-vol-19-2013/7/editorial-hepatitis-c-in-the-eastern-mediterranean-region.html

2- El-Zanaty, Fatma and Way, Ann. 2009. Egypt Demographic and Health Survey 2008. Cairo, Egypt: Ministry of Health, El-Zanaty and Associates, and Macro International. Available at: http://www.measuredhs.com/pubs/pdf/FR220/FR220.pdf

3- Egyptian National Control Strategy for Viral Hepatitis 2008-2012. Available at: http://www.pasteur.fr/ip/resource/filecenter/document/01s-00002i-03t/nsp-10-april-2008-final.pdf

4- Egyptian National Control Strategy for Viral Hepatitis 2008-2012. Available at: http://www.pasteur.fr/ip/resource/filecenter/document/01s-00002i-03t/nsp-10-april-2008-final.pdf

5- El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

Untreated chronic hepatitis C infection can cause liver cirrhosis, an irreversible damage of the liver. In severe cases of cirrhosis, liver failure can take place. Liver failure occurs when the liver loses most of its functions. Liver transplant is the only treatment then.

Hepatitis-associated liver cirrhosis progresses to liver failure in one in five patients, and to liver cancer in one in twenty patients.[6]

6- NHS. 2013. Complications of Hepatitis C. Available at: http://www.nhs.uk/Conditions/Hepatitis-C/Pages/Complications.aspx

Cost as barrier to HCV treatment

1. High out-of-pocket expenditure on medicines

Pharmaceuticals and health-related products constitute 54.3% of what Egyptians privately spend on healthcare.[7]

In 2009, total expenditure on pharmaceutical amounted to EGP 21,000 million (USD 3,559 million), and constituted 34.2% of total health expenditure. Of this figure, private out-of-pocket expenditure on pharmaceuticals was nearly 77% of total expenditure on pharmaceuticals.[8] This high percentage demonstrates how challenging access to medicines in Egypt can be and how burdensome it could be for families not covered by any kind of insurance.

2. Socioeconomic nature of HCV in Egypt

The HCV epidemic in Egypt is of a socioeconomic nature. It is mostly prevalent among lower social and economic segments of the population. Historically, it started by the parentral anti-schistosomal (bilharzia) treatment campaigns undertaken in the 1960s and 1970s in rural areas using improperly sterilised glass syringes (tartar emetic injections).[9] This is behind the high HCV prevalence rate in rural compared to urban areas; 12% and 7% respectively.[10] HCV prevalence also varies with wealth: 12% in the lowest wealth quintile compared to

7- CAPMAS (Central Agency for Population Mobilisation and Statistics). 2011. Most important indicators for income, expenditure and consumption. Retrieved November 19, 2012, from: http://www.capmas.gov.eg/pdf/studies/pdf/enf2012.pdf

8- Ministry of Health and the World Health Organisation. 2011. Egypt Pharmaceutical Country Profile. Retrieved July 30, 2013, from WHO Essential Medicines and Health Products Information Portal: http://www.who.int/medicines/areas/coordination/Egypt_PSCPNarrativeQuestionnaire_27112011.pdf

9- Esmat, G. Hepatitis C in the Eastern Mediterranean Region. Eastern Mediterranean Health Journal, 2013, 19(7). Available at: http://www.emro.who.int/emhj-vol-19-2013/7/editorial-hepatitis-c-in-the-eastern-mediterranean-region.html

10- El-Zanaty, Fatma and Way, Ann. 2009. Egypt Demographic and Health Survey 2008. Cairo, Egypt: Ministry of Health, El-Zanaty and Associates, and Macro International. Available at: http://www.measuredhs.com/pubs/pdf/FR220/FR220.pdf

7% in the highest quintile.[11] In Egypt, 26% of the population live with less than USD 1.6 per day (the national poverty line).[12] That said, and with this level of poverty in the country, it could be concluded that hepatitis C is a socioeconomic condition, hitting the poorest segments of the population. The challenge does not only lie in the cost of treatment, but also in diagnosis which remains inadequate given the high illiteracy rates and low HCV awareness levels.

3. Budget limitations: challenge of national treatment programme

Treatment of HCV is costly. Given the size of the problem in Egypt, it is being addressed as a national health priority. However, budget limitations remain the main barrier to expanding treatment.

The National Committee for the Control of Viral Hepatitis was established in 2006 with the mandate of developing a National Control Strategy for Viral Hepatitis. The first strategy was developed for 2008-2012, with an annual budget of USD 80 million. Treatment was based on pegylated interferon (peg-INF) in combination with ribavirin (RBV).

The strategy aimed to treat 20% of patients by 2012 under subsidized schemes; however, only patients with relatively higher chances of cure had access to treatment, and advanced liver care was not financially feasible under the strategy.[13] Also, children were excluded from this strategy.[14]

Public pressures on the MOH at the time caused it to put too much emphasis on treatment at the expense of other important measures of addressing HCV such as infection control, a fact which exposed the treatment strategy to heavy critique.[15] Clearly this has resulted in budget mismanagement, with hardly any adequate

11- El-Zanaty, Fatma and Way, Ann. 2009. Egypt Demographic and Health Survey 2008. Cairo, Egypt: Ministry of Health, El-Zanaty and Associates, and Macro International. Available at: http://www.measuredhs.com/pubs/pdf/FR220/FR220.pdf

12- Central Agency for Public Mobilisation and Statistics (CAPMAS). 2013. Poverty indicators according to income, expenditure and consumption data 2012-2013. Available at: http://www.capmas.gov.eg/pepo/a.pdf

13- Egyptian National Control Strategy for Viral Hepatitis 2008-2012. Available at: http://www.pasteur.fr/ip/resource/filecenter/document/01s-00002i-03t/nsp-10-april-2008-final.pdf

14- El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

15- El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

treatment coverage. Even with this focus on treatment, and with an annual budget of USD 80 million, only a little more than 2% of HCV patients benefited from treatment, while more than 97% were ignored in terms of protection from the risk of being infected.[16]

This overspending on treatment, while inadequate, was not borne by the government alone. The government contributed only 40% of what the treatment programme actually spent. The remaining 60% got covered by HIO, insurance companies and private out-of- pocket spending.[17]

What the 2008-2012 strategy achieved in four years...

Aimed at HCV control and treatment, the Strategy outlined four priority areas: surveillance and monitoring, prevention, patient management (which includes improved access to treatment and reduction in prices of medicines and expanded subsidisation of antiviral therapy), and finally research.[18]

Over a period of four years, 190,000 patients were admitted to the treatment programme (out of nearly 10.2 million with HCV antibodies, and 6.8 million patients with chronic HCV infection). By the end of 2011, only 114,000 patients achieved negative sustained virologic response (SVR). In other words, only 2.8% of patients with chronic HCV were admitted for treatment; however, only 1.67% of patients with chronic HCV were actually treated (negative SVR).[19]

The 2008-2012 strategy focused on treatment, prioritising it at the expense of prevention. This was reflected in budget allocations within the strategy.[20]

16- Iskander, Dina. 2013. The Right to Health: a case study on Hepatitis C in Egypt. MA thesis submitted to the American University in Cairo. Available at: https://dar.aucegypt.edu/bitstream/handle/10526/3748/Thesis%20IHRL%20%20Dina%20Iskander%20Dec2013.pdf?sequence=3

17- Iskander, Dina. 2013. The Right to Health: a case study on Hepatitis C in Egypt. MA thesis submitted to the American University in Cairo. Available at: https://dar.aucegypt.edu/bitstream/handle/10526/3748/Thesis%20IHRL%20%20Dina%20Iskander%20Dec2013.pdf?sequence=3

18- Egyptian National Control Strategy for Viral Hepatitis 2008-2012. Available at: http://www.pasteur.fr/ip/resource/filecenter/document/01s-00002i-03t/nsp-10-april-2008-final.pdf

19- Iskander, Dina. 2013. The Right to Health: a case study on Hepatitis C in Egypt. MA thesis submitted to the American University in Cairo. Available at: https://dar.aucegypt.edu/bitstream/handle/10526/3748/Thesis%20IHRL%20%20Dina%20Iskander%20Dec2013.pdf?sequence=3

20- Iskander, Dina. 2013. The Right to Health: a case study on Hepatitis C in Egypt. MA thesis submitted to the American University in Cairo. Available at: https://dar.aucegypt.edu/bitstream/handle/10526/3748/Thesis%20IHRL%20%20Dina%20Iskander%20Dec2013.pdf?sequence=3

The new strategy (2014-2018)

A new national strategy for the control of viral hepatitis is currently under development, with a higher budget compared to the previous one. The new strategy has received support from several partners including the WHO, Institut Pasteur and CDC.[21] The MOH launched the Plan of Action for the Prevention, Care and Treatment of Viral Hepatitis2014-2018 (only the executive summary was released), as well as the new treatment programme using Sovaldi®.[22]

Treatment will be provided through 26 designated government centres, to be increased to reach 40 centres. The cost of treatment is expected to be distributed among several entities, including patient co-payment: 38% by MOH, 51% by the Health Insurance Organisation (HIO), 3% by the private payments and 8% by cash payments at the centres.[23] [24]

The treatment programme will cover 50,000 patients in its first phase, launched in October 2014. In February 2015, the MOH expects 100,000 more treatment courses to be delivered.[25] The target is to ultimately treat 300,000 patients annually.[26]

Now with the introduction of oral DAAs, the new strategy will cover both INF-based and INF-free treatment regimens, and this is to be determined on case by case basis according to treatment guidelines set within the national strategy. .[27]

21- El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

22- Ministry of Health. 2014. Press Conference on 16 October 2014.

23- Doss, Wahid. 2014. Meeting with EIPR's Right to Health programme at the Liver Institute, 5 March 2014.

24- El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

25- MOH and WHO. 2014. Press Release: Ministry of Health launches action plan to prevent, care and treat viral hepatitis in Egypt. Press conference held at the Ministry of Health, Cairo, 16 October 2014.

26- Doss, Wahid. 2014. Interview in Assoura Alkamela TV programme. OnTV. 11 September 2014.

27- National Committee for the Control of Viral Hepatitis. 2014. New Guidelines for the Management of HCV. August 2014. Unpublished document.

New HCV treatment: expensive but efficacious

Towards the end of 2013, Gilead Sciences Inc. obtained the FDA approval of its new oral direct acting antiviral (DAA) called sofosbuvir (SOF), a nucleotide polymerase inhibitor. This new class of antivirals is a breakthrough in HCV treatment because they are administered orally, whereas INF is administered via subcutaneous injection.

The significance of Gilead's sofosbuvir lies in its role as a "backbone" of many oral HCV regimens in clinical trials, which apply to all HCV genotypes, including genotype-4, the one most prevalent in Egypt.[28]

Treatment using sofosbuvir-based combinations is usually shorter (6 to 24 weeks), more effective and requires less monitoring. Besides, compared to PEG-INF and RBV, it has fewer and milder side effects.

Sofosbuvir-based combinations have very high cure rates of over 90% in some groups[29]

New Treatment protocols

Treatment regimens and guidelines for enrollment with the national treatment programme were announced by the Ministry of Health. Two treatment regimens were announced:

1) Pegylated interferon (peg-INF) + ribavirin + sofosbuvir for 3 months
2) Sofosbuvir + ribavirin for 6 months (for patients who are intolerant to INF).[30]

28- Couzin, Odilon and Kaplan, Karyn. 2014. Pills cost pennies, greed costs lives: 1st Hepatitis C Virus World Community Advisory Board Report. Treatment Action Group. Available at: http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/1st%20HCV%20World%20CAB%20Report.pdf

29- Couzin, Odilon and Kaplan, Karyn. 2014. Pills cost pennies, greed costs lives: 1st Hepatitis C Virus World Community Advisory Board Report. Treatment Action Group. Available at: http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/1st%20HCV%20World%20CAB%20Report.pdf

30- Zayed, Hossam. 2014. "Minister of Health announces new treatment guidelines for HCV patients: Receiving hepatic fibrosis patients of 3rd and 4th stages in 26 centres." (in Arabic) Al-Ahram. 17 August 2014.

Interferon-based treatment has been the standard treatment of HCV in Egypt, where genotype 4 (GT-4) of HCV is the most prevalent. Now with the introduction of SOF, other treatment regimens are under consideration by the National Committee for the Control of Viral Hepatitis.

Patients who are eligible to receive INF will be treated with daily SOF + RBV + weekly peg-INF for 12 weeks, and patients who are eligible for INF-free treatment will receive SOF + RBV for 24 weeks.[31]

The deal with Egypt: the dilemma of pricing

The price of SOF in the USA was announced to be USD 84,000 per 12-week course, or USD1000 per tablet. This price caused outrageous reactions, not only in the USA but also across the world, being a clear obstacle to access to treatment in developing countries where HCV is most prevalent.

Gilead had Egypt as the first country on their list for priority registration, which is based on prevalence, disease awareness, and regulatory pathway and timelines.[32]

Negotiations between the company and the Egyptian government, represented by the National Committee for the Control of Viral Hepatitis, resulted in what was perceived to be a good deal: USD 300 per box of Sovaldi (per month). This is the price to be paid by the government for supply of Sovaldi to be provided for patients on government treatment registers. In other words, patients will not benefit from this price should they privately pay for their treatment.

International headlines celebrated this government price and portrayed it as a 99% discount of the original Sovaldi price in the USA, turning a blind eye to the other part of Gilead›s deal.[33] That same product was registered for the private market at EGP 14,900 per box (USD 2,130).[34] This is the retail price which patients will have to pay outside the national treatment programme, which is almost 7 times the government price. This means that purchasing one box of Sovaldi® privately outside the national treatment programme would cost a patient what the government pays for a 12-week treatment course.

31- National Committee for the Control of Viral Hepatitis. 2014. New Guidelines for the Management of HCV. August 2014. Unpublished document.

32- Alton, G. Pang, P; Samuel, C. Gilead Sciences: Expanding Access to HCV Treatment. A presentation at the World Community Advisory Board (CAB) on HCV Treatment, Bangkok, Thailand. 25 February 2014.

33- Fick, Maggie and Hirschler, Ben. 2014. Gilead offers Egypt new hepatitis C drug at 99 percent discount. 21 March 2014. Available at: http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321

34- The MOH gave Gilead fast-track registration for Sovaldi®, a process which normally takes about two years, and its registration was completed on 10 July 2014. Source: Sorour, Asmaa. 2014. "Today registration completed for Sovaldi for the treatment of hepatitis C virus". Al-Shorouk News. 10 July 2014.

Unfortunately, the deal between the Egyptian government and Gilead was not disclosed to the public in great detail. According to the National Committee for the Control of Viral Hepatitis, the deal, as signed, will not be exclusive to Gilead and will not be restrictive. If this is the case, the MOH would still be able to contract other companies and even re-negotiate prices, particularly that several other DAA's are in the pipelines of pharmaceutical companies.[35] These include simeprevir (produced by Janssen and Medivir), which has been approved for treating genotype-4 in combination with SOF +/- ribavirin.[36]

Learning from the past: the PEG-INF story and how generic competition brought prices down

Until 2004, the pegylated interferon (peg-INF) market was monopolised by the two multinational pharmaceutical companies Roche and Schering-Plough with their products PegasysÒ and Peg-IntronÒ respectively. The two products were priced at around EGP 1400 per ampoule upon registration in 2002 and 2003.

In 2004, a local private company, Mina Pharm, introduced a biosimilar version of peg-INF with the name Reinferon RetardÒ, priced at EGP 370 per ampoule, which is nearly 26% of the price of imported peg-INF by Roche and Schering-Plough. This locally produced product gave bargaining power to the National Committee which succeeded in reducing the prices of the imported peg-INF of Roche and Schering-Plough.

In 2011, the two companies agreed to sell peg-INF at EGP 250 to National Treatment Centres, that is, at 17% of its original price. Ultimately, a 48-week treatment course with peg-INF + RBV from Roche and Schering-Plough cost the government approximately EGP 25,000 (USD 3,580). Following this, Mina Pharm agreed to provide its product at EGP 220 for Health Insurance Organisation, which is about 40% reduction in price.[37]

Unsubsidised treatment outside the national programme would cost a patient approximately EGP75,000 (USD10,700) for a full course.[38]

35- Doss, Wahid. 2014. Meeting with EIPR's Right to Health programme at the Liver Institute, 5 March 2014.El-Sayed, Manal. 2014. The New National Strategy on Viral Hepatitis. Presentation in a seminar hosted by Al-Ahram Science Clubs, 1 June 2014.

36- Simeprevir approved in the European Union for the treatment of adults with hepatitis C genotype 1 and 4 infection. Available at: http://www.natap.org/2014/HCV/051614_03.htm

37- Iskander, Dina. 2013. The Right to Health: a case study on Hepatitis C in Egypt. MA thesis submitted to the American University in Cairo. Available at: https://dar.aucegypt.edu/bitstream/handle/10526/3748/Thesis%20IHRL%20%20Dina%20Iskander%20Dec2013.pdf?sequence=3

38- Egyptian National Control Strategy for Viral Hepatitis 2008-2012. Available at: http://www.pasteur.fr/ip/resource/filecenter/document/01s-00002i-03t/nsp-10-april-2008-final.pdf

The drop down of the peg-INF prices is considered a success story which other countries continue to use as a reference on the importance of generic competition.

Policy makers in Egypt should keep this experience in mind when examining the SOF case. Generic production should be encouraged, rather than resisted, because this is a guaranteed strategy of bringing down prices especially in the absence of a tent.

Low production cost of SOF: deal could have been better?

At the industrial level, sofosbuvir is inexpensive to produce. Cost calculations were conducted by researchers in response to the exaggerated price tags by pharmaceutical companies. The total cost of producing the SOF active pharmaceutical ingredient (API) and all the necessary additives is significantly lower than the announced price by Gilead. Price per pill was calculated to be less than USD 2.00.[39] For combination therapy, the predicted unit cost of SOF+RBV is USD 304 for a 6-month course.[40]

Developed from a known class of compounds, SOF did not require very high research and development (R&D) expenditure compared to more innovative medicines. Usually, it is the R&D cost that determines how expensive a pharmaceutical product would be. However, Gilead defends the high price tag of SOF based on the cost of long-term hepatitis C treatment prior to SOF development, which was mostly INF-based.[41]

Given the low cost of SOF production, and the size of its guaranteed global markets, Gilead could have equally secured high return on investment with a much lower price.

This should have been used as a bargaining tool to bring the price of the deal with Egypt further down, cheaper than USD 300 per box. Unfortunately, this was not the case.

The significance of the deal with Egypt lies in the fact that it was globally benchmarking SOF prices. It is unlikely that any other country will be able to get a cheaper price. Gilead follows a tiered pricing system, where-

39- Hill A et al. What is the minimum cost per person to cure HCV? 7th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Kuala Lumpur, abstract TuLBPe16, 2013. (Poster presentation available at: http://pag.ias2013.org/EPosterHandler.axd?aid=3142)

40- Hill, A et al. 2014. Minimum Target Prices for Production of Direct Acting Antivirals and Associated Diagnostics to Combat Hepatitis C in Developing Countries. Presentation at the 20th International AIDS Conference, Melbourne, Australia. 21 July 2014.

41- Gokhale, Ketaki and Langreth, Robert. 2014. Gilead Close to Sending $84,000 Drug to Poor Countries. Bloomsburg News. 5 September 2014. Available at: http://www.bloomberg.com/news/2014-09-04/gilead-close-to-sending-84-000-drug-to-poor-countries.html

by it categorises countries in sets of low-income, lower-middle income, and upper-middle income countries. These pre-set price tiers follow the World Bank per capita gross national income (GNI), although Gilead claims they are more "wide-raging" to accommodate more countries.[42]

42- Alton, G. Pang, P; Samuel, C. Gilead Sciences: Expanding Access to HCV Treatment. A presentation at the World Community Advisory Board (CAB) on HCV Treatment, Bangkok, Thailand. 25 February 2014.

Intellectual property: no SOF patent in Egypt

Seeking to obtain a patent protection over its product in Egypt, Gilead filed a patent application at the Egyptian Patent Office (EGYPO) at the Ministry of Scientific Research. Patent protection of pharmaceutical products, when granted, give their holders exclusive production and marketing rights within the country. In other words, a patent holder can prevent third parties from producing and marketing the product without prior permission or a licence.

Examination of the patent application of sofosbuvir at EGYPO showed that it does not qualify for a patent since it does not fulfill the patentability criteria of novelty and inventiveness, in accordance with the Egyptian law on intellectual property rights.[43] This means that Gilead is unlikely to obtain patent protection over SOF in Egypt. It will be then possible for other companies to produce generic versions of SOF locally, without having to obtain a license from Gilead as originally planned.

The patent application should not be confused with the MOH registration process, which takes place at the Central Administration for Pharmaceutical Affairs (CAPA). The CAPA/MOH registration is about ensuring the quality, safely and efficacy of the product before giving the company an authorization to market its product. On the other hand, the patent application is a legal procedure by which the company seeks to protect its intellectual property rights over SOF, via a patent, to prevent other companies from producing it and marketing it within Egypt. The two processes are separate and independent of one another.

Locally produced generic SOF: available but unaffordable?

Egyptian companies expressed their interest in locally producing SOF at a low cost at an early stage, while negotiations were taking place between Gilead and the government. Yet, at the time, generic companies were faced with reluctance from the MOH to support their endeavours in fear of violating the intellectual property

43- Egypt, Arab Republic of. 2002. Law 82/2002 on the Protection of Intellectual Property Rights. Official Gazette (22), 2 June 2002

rights of Gilead.[44] In fact, supporting local production would have been a strong point at the Egyptian negotiators' side to help bring the price of SOF lower than what they agreed However, there is now strong support from the government to local pharmaceutical companies. "Fast track registration" of generic versions of sofosbuvir has been granted to interested companies, and the MOH is increasingly vocal about the importance of facilitating local production of HCV treatment in order not to allow for market monpolisation by multinational companies.[45]

The patent application of SOF is still pending at the Egyptian Patent Office (EGYPO), with very high chances that it will be rejected. After receiving the result of examination at EGYPO, Gilead filed a grievance before the EGYPO Ombudsman Committee. This is a lengthy process, which is unlikely to change the outcome of the patent application.[46] That said, there will be no intellectual property barriers before local pharmaceutical manufacturers, and they will be free to produce and market SOF.

Recently, the situation has changed, and local pharmaceutical companies were given fast track registration to produce cheaper generic versions of SOF. The first of these is Pharco Pharmaceuticals, which announced its product at: EGP 9,700 (USD 1,380) per box/month (28 tablets) for the private sector. This retail price was set at 65% of that of Gilead's Sovaldi®, according to Egyptian medicine pricing decision or policy currently in force.[47] Looking at it in light of the level of income in Egypt, and high private out-of-pocket expenditure on pharmaceuticals, this is still a very high price. Generic sofosbuvir will remain unaffordable and beyond the reach of an average HCV patient who was not lucky enough to find a place on the national treatment programme.

The high price of the generic product, which should be easily affordable under normal circumstances, flags the importance of revisiting the medicine pricing system in Egypt. Medicine pricing has been subject to a lot of discussion over the last few years since the issuing of Pricing Decree 377/2009 which first introduced external reference pricing as a replacement to the long-standing system of cost-plus and mark-up regulation.

44- رئيس-http://www.alborsanews.com/2014/01/27رئيس قطاع التطوير بـ« فاركو »: 5 شركات محلية تقدمت بملفات تسجيل دواء فيروس سى لـ«الصحة» بينها فاركو قطاع-التطوير-بـ-فاركو5--شركات-مح/ The owner of national pharmaceutical company reiterated this in a meeting hosted by EIPR, 4 February 2014.

45- Dr. Adel Adawy, Minister of Health. 2014. Press conference held at the Ministry of Health on the occasion of launching the Plan of Action for the Prevention, Care and Treatment of Viral Hepatitis 2014-2018, Cairo, 16 October 2014.

46- A phone call with Mr. Adel Eweida, Acting Director of the Egyptian Patent Office on 14 September 2014.

47- Ministry of Health and Population. 2012. Decree 499/2012 on pricing of human pharmaceutical preparations. Official Gazette (153), 3 July 2012.

In 2009, the Egyptian Initiative for Personal Rights filed a case before the Administrative Court against the Minister of Health for issuing Pricing Deree 377/2009. The EIPR claimed that external referencing of prices, the concept introduced by that Decree, would threaten the right to health of Egyptian citizens by eventually depriving them of affordable medicines. Besides, the MOH had not consulted patient groups issuing the Decree, whereas it had consulted pharmaceutical companies.[48]

The Administrative Court ruled with the suspension of Decree 373/2009; however, the MOH appealed and the Decree came back to force based on procedural grounds. There was no court ruling regarding the substance of Decree 373/2009, until decree 499/2012 replaced it three years later.[49]

Securing access to HCV treatment: available options50

In September 2014, Gilead signed a licensing agreement with seven Indian generic companies

. The licensees will be able to manufacture the active pharmaceutical ingredients sofosbuvir and ledipasvir, also a DAA, and sell them to a list of 91 low and middle-income countries. The list includes Egypt and India; however, excludes a lot of countries which suffer from HCV infection such as China. There is 51 excluded countries with estimated 49 million patients who will not be able to access generic treatment according to this licensing agreement.[51]

Accordingly, there is an opportunity for Egyptian companies to import API from licensed Indian manufacturers and produce sofosbuvir as a finished product for sale to Egyptian patients. It should be noted, however, that this is not a sustainable solution, because importing API from India would leave us at the mercy of Gilead›s licence terms.

Egyptian pharmaceutical industry should aim at producing API locally. This is a long-term objective which requires transfer of technology and a lot of investment by manufacturers.

48- Egyptian Initiative for Personal Rights. 2009. Facts about the New Drug-Pricing Decree: The Decree Threatens Citizens› Right to Health. Available at: http://eipr.org/en/report/2009/12/15/671

49- Egyptian Initiative for Personal Rights. April 2013. Pricing Decree 499/2012: Where is it from the right to medicine? Available at: http://eipr.org/sites/default/files/reports/pdf/right_to_medicine.pdf

50- Recommendations by experts in a round-table discussion hosted by EIPR on 21st of September 2014. Invited experts included: Dr. Alaa Awad: Professor, Gastroenterology & Liver Diseases at Teodorblhars Institute, Dr. Emad El-Azazi: Professor, Pharmacoeconomics at the German University in Cairo, Ms. Dina Iskander: Researcher at Oxfam, and Dr. Mohamed Salem: Researcher at the American University in Cairo.

51- Baker, B. 2014. Gilead›s Hepatitis C Medicines License: Troubling Territorial Exclusions, Illusory Exceptions, and Tiered Pricing Policy Fracture Global Access. Available at: http://www.healthgap.org/hep_c

The Egyptian government should make use of all policy options in order to secure access to affordable treatment. HCV is a major public health challenge facing Egypt at the moment. Now that there is no patent protection for sofosbuvir, the first DAA for which a patent application is filed, Egyptian companies can produce it locally without IP-related restrictions. In case a patent is granted in Egypt, which is very unlikely, the government can utilise flexibilities in the TRIPS Agreement, namely compulsory licensing and government use, to make the medicine available.

There is a need for more collaborative efforts between policy makers, national pharmaceutical industry, media, and civil society organisations and patient groups.