September 15th, 2014

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Press Backgrounder on Sofosbuvir

Gilead is excluding 51 middle-income countries (MICs) from its license for sofosbuvir, an oral hepatitis C drug.[1] Across these MICs[2], where nearly 50 million people are infected with hepatitis C virus (HCV), lack of access to generic sofosbuvir will increase the total cost of curing hepatitis C by an estimated **$60 billion dollars,** according to I-MAK's analysis. [3,4]

I-MAK's team based this estimate on generic price projections for sofosbuvir (~$135-400 per 12-week course of treatment), and the assumption that Gilead's MIC price would be ~75% more than the $900 price they are expected to charge to low-income countries (LICs).[5] Even if Gilead were to extend its $900 access price to all MICs – which is unlikely – these countries would still need to spend ~$30 billion more to treat their HCV patients than if generic versions of sofosbuvir were available. This underscores the need to address patent barriers for sofosbuvir to make HCV treatment affordable for these MICs.

Explanatory note about impact calculation

Opening up generic access to sofosbuvir in all MICs would save an estimated $30-60 billion in treatment costs versus Gilead's branded pricing.

These estimates were calculated using the following methodology and assumptions:

1. **Branded sofosbuvir price** – As Gilead has not advertised a price for MICs, a range was calculated using the following assumptions:
    a. The low end of the range uses Gilead's expected access price of $900.[6] Gilead has set this price expectation for LICs and has reportedly only offered it to MICs in very select circumstances, typically restricting it to specific programs or subpopulations. Therefore, the low-end estimate of $30 billion should be considered a lower bound for the impact analysis rather than a realistic estimate.

[1] While the license covers sofosbuvir and ledipasvir, this analysis is restricted to sofosbuvir alone.
[2] HCV prevalence data is publicly available for only 48 of the 51 excluded MICs (no data is available for American Samoa, Kosovo, or the West Bank & Gaza). We confine our analysis to these 48 MICs.
[3] I-MAK is a team of lawyers, pharmaceutical scientists and public health cost analysts that work in the public interest.
[4] This figure does not account for the fact that sofosbuvir must be co-prescribed with another drug, raising treatment costs even more.
[5] "Diagnosis and Treatment of Hepatitis C: A technical landscape." MSF Access Campaign, April 2014.
[6] Ibid.

b. The high end of the range, which is far more realistic, was calculated by looking at the analogous market for HIV/AIDS medication, where Gilead offers two different pricing tiers for developing countries.[7,8] The lowest tier includes most LICs and Sub-Saharan African (SSA) countries, and the second tier includes most MICs outside of SSA, with a price differential of ~75% between the two tiers. We applied this price differential to the $900 LIC price for sofosbuvir to calculate an indicative price for MICs ($1,567). Using this price, the impact calculation is $60 billion.

2. **Generic sofosbuvir price** – A recent paper on HCV treatment costs[9] indicates that over the long-term, generic sofosbuvir prices could drop to approximately $102. However, this figure assumes high volume production, an optimized production process, and competition from multiple suppliers. Given that these conditions will take time to realize, I-MAK's team has estimated the generic launch price and medium-term price for a 12 week course of sofosbuvir ($400 and $135, respectively). The analysis uses an average of these prices, then applies two adjustments:
   a. A royalty rate of 7%, based on the royalty requirements of Gilead's voluntary license (however, actual royalties could be lower if a country accesses generic sofosbuvir through a compulsory license rather than a voluntary license.)
   b. A "price premium" of 6%, based on the average premium that these same MICs typically pay for HIV/AIDS medication versus the advertised lowest prices from generic suppliers.[10] This adjustment accounts for the fact that countries are not always able to access the lowest price from generics.

3. **Patient demand for sofosbuvir** – The above price assumptions were used to calculate a per-patient cost savings figure, which is then applied to country-level HCV prevalence data.[11] Here we look at current HCV prevalence in the MICs excluded from Gilead's voluntary license. This is the relevant patient population that may require hepatitis C treatment, even though the timeframe under which they will receive treatment is not clear. Therefore, the $30-60 billion

[7] The HIV price differential is the only indicator HCV advocates have to understand how Gilead may price sofosbuvir in MICs. This price differential is conservative, given that HIV drugs are taken over time whereas sofosbuvir is a one-course treatment. As such it is possible that Gilead will attempt to maximize profits in the short term by applying a higher price differential than the one we use here.
[8] "Untangling the Web of Antiretroviral Price Reductions, 17th Edition." MSF, July 2014. Price differentials for TDF and TDF/FTC were averaged.
[9] Hill, Andrew, Saye Khoo, Joe Fortunak, Bryony Simmons and Nathan Ford. "Minimum costs for producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries." Clinical Infectious Diseases (2014) 58 (7):928-936, 6 January 2014.
[10] Actual ARV purchase data for these MICs in 2012-13 was taken from the WHO's Global Price Reporting Mechanism (GPRM). The lowest advertised generic prices were taken from the MSF "Untangling the Web" pricing guide cited above.
[11] "Evolving Epidemiology of Hepatitis C." Lavanchy, 2010.

figure represents the total estimated cost of treating all patients in these countries regardless of the timeframe. *(Note: Because HCV incidence data is not available, this analysis does not account for new infections, globally estimated to be 2-3 million per year.*[12] *If incidence data were incorporated, the cost for MICs to treat their HCV-infected populations would be even higher. Leaving large populations untreated instead of curing them will allow the epidemic to keep spreading.)*

[12] Certain other variables, such as the longer treatment duration required for certain HCV genotypes, were not included in this analysis.