

## Brazil is excluded from license authorizing production of generic medicine for hepatitis C

The pharmaceutical company Gilead Sciences announced last Monday (September, 15th) a license that allows the production of generic versions of sofosbuvir, a medicine used in the treatment of hepatitis C. The license authorizes seven generic manufacturers in India to produce the drug<sup>1</sup>, which will be sold at lower prices than those charged by Gilead. However, these prices will be offered only to a limited number of countries, defined by Gilead. Brazil, like most middle-income countries in Latin America and other regions, is out of the list of countries for which the generic version can be sold.

Sofosbuvir is the new hope for many people infected with the hepatitis C virus, including in co-infection with HIV. The new treatment can provide increased cure rate up to 90% of cases. The most commonly used treatment in Brazil, currently consists of pegylated interferon and ribavirin, cures around 45% of cases, generates many adverse effects and is difficult to use because it is injectable. In Brazil, the commercialization of the new drug is still pending approval from ANVISA - National Agency for Sanitary Vigilance, which should be announced soon. The registration of the drug in Brazil must be followed by the publication of guidelines for their distribution in the public health system, but the astonishing high price charged by Gilead (US\$ 84,000 for 12 weeks of treatment) and which has generated debates about sustainability even in the USA and Europe, can become a barrier to expanded access, especially with the recent exclusion of many developing countries from the list of those who can access the generic version. So it becomes increasingly pertinent the question: how many people will have access to sofosbuvir?

Gilead, once again, proves much more interested in segmented countries and ensure their astronomical profits than to allow millions of people who need the medicine to have access to it. In the United States and Europe there are already a large public outcry around the price of sofosbuvir. The drug became known as the 1,000 dollars pill, because of the price Gilead, producer of the drug, charges in the United States. That price is not accessible to the people and not for even for governments of any country. This finding triggered a major campaign to reduce the price of the drug and increased access.

Currently, Gilead is the sole producer of the drug because of the rules of intellectual property protection. Gilead filed patent applications for sofosbuvir in countries around the world. In Brazil, the application has not yet been granted by INPI - National Institute of Industrial Property, the body responsible for granting or not granting a patent in the country. If the patent is granted, Gilead will be the only company that can produce and market the drug sofosbuvir in Brazil. While the patent application is still pending analysis, the patent is not valid, but in practice no other producer venture to produce and market the

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<sup>1</sup> The Indian companies entering the license are: Cipla, Hetero, Ranbaxy, Strides, Mylan, Sequent and Cadila Healthcare. More information about the license and the countries that were included can be found at: <http://www.gilead.com/~media/Files/pdfs/other/HCVGenericAgreementFactSheet.pdf>



drug in this period. This is because if the patent is granted, the validity of the patent is retroactive to the date of filing, and the patent holder could sue other producers.

Because of this pending patent application in Brazil, the Brazilian government opted for negotiating prices exclusively with Gilead. There is no official information about the price that sofosbuvir will be sold in Brazil, but there are rumors that it would be somewhere around US\$ 7,000 for each 12-week treatment. The estimated production price of the generics is between US\$ 135-400 for the same treatment, which already includes the company's profit, according to the NGO I-MAK - Initiative for Medicines, Access and Knowledge<sup>2</sup>. The price being negotiated with Gilead in Brazil could be **52 times more expensive** than the generic version. This would represent an **additional cost of at least US\$ 1 billion** to treat all people with hepatitis C in Brazil<sup>3</sup>.

Although there is no patent granted in Brazil, the government cannot buy the generic version that will be produced in India, because of unfair and abusive restrictions imposed by Gilead voluntary license of the patent for the Indian generic manufacturers.

### **But, should the sofosbuvir patent be granted?**

Although this new treatment can increase the quality of life of people infected with HCV, there is however doubt that SOF meets patentability criteria to justify the grant of a patent. In Egypt, the patent application for the molecule was denied. In India, an opposition to the patent application was submitted, presenting technical arguments showing that the application does not meet the requirements for the granting of a patent. A similar opposition is being prepared by civil society organizations in Brazil, with arguments that the patent application should be denied here.

In addition to toughening negotiation with Gilead, since US\$ 7,000 per treatment is absolutely unacceptable, the Brazilian government must also take other initiatives. Investment in domestic production of sofosbuvir by public laboratories is urgent. We cannot forget that it was the public production of generic drugs for the treatment of HIV/AIDS that enabled universal access to treatment in Brazil at the beginning of the epidemic. In addition to producing various ARVs, public laboratories were important to estimate production costs of patented drugs, which allowed the government to negotiate better prices with suppliers of these drugs. The rules of intellectual property protection allow other producers to have generic versions of the drug ready for use immediately after the patent expires, or in case of granting a compulsory license, for example.

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<sup>2</sup> Available at: [http://i-mak.squarespace.com/storage/FINAL\\_I-MAK%20Press%20Backgrounder\\_SOF%20Cost.pdf](http://i-mak.squarespace.com/storage/FINAL_I-MAK%20Press%20Backgrounder_SOF%20Cost.pdf).

<sup>3</sup> The calculation considered the estimate that 1.5 million people are infected with hepatitis C in Brazil, used by the Ministry of Health. We used the estimated value of the generic medicines (US\$ 400) and the probable price being negotiated between the Brazilian government and Gilead (US\$ 7,000). The treatment time period of 12 weeks was considered in the calculation.



Thus, GTPI/Rebrip - Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples:

- Vehemently repudiates the license from Gilead and any other agreements exclusively commercial based, treating medicines as commodities and preventing millions of people to have access to medicines;
- Requires that the Brazilian government negotiate a fair price for the incorporation of sofosbuvir, taking into account mainly the cost of production of the drug;
- Asks the Brazilian government to create treatment protocols to ensure that all people who need sofosbuvir, including in coinfection with HIV, have access to the medicine;
- Demands that the Brazilian government immediately begin efforts to enable the production of sofosbuvir by the public sector;
- Asks INPI to speed the analysis of the patent application;
- Claims that the INPI denies the application because it does not meet minimum requirements of patentability for the grant of a patent;
- Requires that if the patent is granted, the Brazilian government to immediately issue a compulsory license, allowing local production of the drug or importation of generic versions.

#### **Who we are:**

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/Rebrip) is a group formed by civil society organizations, researchers and activists, which works from a public interest perspective. Since 2003, GTPI develops activities aimed at reducing the negative impacts of pharmaceutical patents on public policies of access to health in Brazil and in the Global South. Learn more about GTPI and our actions: [www.deolhonaspateentes.org.br](http://www.deolhonaspateentes.org.br).