



BARRIERS TO ACCESS AND SCALE UP OF HEPATITIS C (HCV) TREATMENT: GILEAD'S ANTI-DIVERSION PROGRAM

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The international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF) began introducing hepatitis C (HCV) treatment to several patients in India in 2013, and is in the process of scaling up treatment for HCV in several additional countries. MSF plans to use direct acting anti-viral medicines that have recently come to market that have the potential to revolutionize treatment for people living with HCV. One critical drug that MSF will procure for use in its treatment programmes is sofosbuvir, which was launched by Gilead Sciences in 2013, and is marketed as *Sovaldi*.

Until recently, Gilead was the sole producer of sofosbuvir. Governments, MSF and other treatment providers have therefore been dependent on the willingness of the company to make this urgently-needed drug available and accessible. Generic versions of sofosbuvir have recently been launched by a number of generics companies in India, Bangladesh, Nepal and Egypt. However, these generic versions are not yet widely registered, and some of the companies that have launched generic versions are also required to introduce anti-diversion measures because of the voluntary licence they signed with Gilead. Furthermore, since these generic versions are not yet approved by a stringent regulatory authority, nor have completed WHO quality review ('prequalification'), some governments and treatment providers will not yet use these products in their treatment programmes.

In the course of discussions with Gilead to purchase the drug, MSF has learned that the company will institute an 'anti-diversion' programme in developing countries through its distributors and licensees (generics companies that have signed a voluntary license with Gilead) to prevent what they characterize as the possible 'bulk diversion' or re-sale of such medicines from low- or middle-income countries to high-income countries.

With this programme, Gilead is demanding that patients and treatment providers in developing countries comply with a web of onerous and potentially harmful procedures that aim to preserve Gilead's ability to charge exorbitant prices in developed countries (up to US\$1,000 per pill, or \$84,000 per treatment course).

Gilead's programme violates patient privacy and autonomy, undermines confidentiality of patient data, introduces coercion and policing upon medical providers and may result in treatment interruptions for patients, leading to treatment resistance and failure. As far as is known to MSF, such a programme, motivated solely by commercial interests, is unprecedented.

Registration of the drug is already being fast-tracked in a number of high-burden countries—for example registration is complete in Egypt, nearing completion in Pakistan, and India is considering it—so Gilead's programme could impact patients in a number of countries in very short order.

MSF has learned the following information about the anti-diversion programme:

Overview of the Gilead anti-diversion programme

1. Access from a Gilead distributor or a treatment provider is on a named-patient basis, with proof of identification, citizenship and residence as pre-requisites.
2. Each pill bottle, before being dispensed to the patient, will have a QR code printed/engraved on it that has embedded information, including the patient's name and address. Information in the QR code can be read with a smartphone, enabling Gilead or its representatives to track patient information. Gilead will be able to demand tracking information and status regarding the use of the medicine from treatment providers at any time and will have the unrestricted right to use such information for any purpose.

3. The patient will have to sign an agreement agreeing to return the empty bottle/s before the next dispensation or sale of the drug is approved or allowed.
4. The medicine will be given to the patient bottle by bottle after their personal information is entered into the QR code on the bottle. In addition to the prescription, proof of identification will be required for the distributor to supply the drug to the patient. Patients are prohibited from obtaining multiple bottles, for example three bottles or six bottles at once, which would ease the burden on patients and treatment providers. Before a patient can get the next bottle of sofosbuvir from the local distributor, the patient must bring back or courier the empty bottle of sofosbuvir to the distributor. In Pakistan, where there are to be no retail sales across the different provinces, Gilead's distributor will courier the medicine to patients bottle by bottle.
5. The drug is starting to be registered by drug regulatory authorities in developing countries, and Gilead could introduce this program with all local distributors. Gilead included an anti-diversion clause in the voluntary license agreements it signed with Indian generic manufacturers in September 2014, and is attempting to get generic suppliers to implement a similar programme.

Key concerns with Gilead's anti-diversion programme

There are serious ethical concerns with the proposed programme:

1. The programme includes burdensome and ethically unacceptable pre-conditions, for example the provision of sensitive information for each patient needing the drug, including name, citizenship and proof of address, to a third party (i.e. Gilead) not involved in patient care.
2. The programme raises serious concerns with respect to the confidentiality of patients and may open the door for Gilead or its distributors to collect sensitive data on patients and their clinical outcomes without their consent. One of the key questions is likely to be how confidentiality of patient records will be protected given that under the programme, Gilead may have access to prescriptions and other medical documents, which could include mental health diagnosis, HIV status, history of drug use and other sensitive information.
3. The programme interferes with the traditional doctor-patient relationship by placing a third party distributor in the middle of decisions taken by doctor and patient with respect to administration of the drug. An industry representative (which Gilead has said will be called a 'patient support executive') could interfere with the treatment decision process, including drug allocation and the decision to extend the treatment from three months to six months, or even the decision to stop the supply of medicine if the medicine bottle is misplaced or lost.
4. Making access to treatment dependent on proof of identification, citizenship and residence could create conditions that lead to the exclusion of vulnerable and marginalized communities such as refugees, injecting drug users, poor economic migrants, homeless persons or those with unstable living arrangements.
5. Sale or dispensation bottle by bottle, with the potential to withhold from the patient the next month's quota, has a coercive and policing element. Any requirement imposed by a commercial entity, such as Gilead, that restricts the approach a patient adopts to take medicines is a violation of the patient's autonomy and privacy, and also places an undue burden on the patient vis-à-vis a third party that has enormous power over the patient's health and well-being. This also undermines the ethical principles of non-maleficence and beneficence that health care providers must observe.
6. The requirement on dispensation of the medicine should not exceed what drug regulatory authorities require for medicines to be sold or provided under prescription.

7. The programme imposes a heavily controlled system that will affect accessibility of the drug in both the public and private sectors, potentially restricting task-shifting by treatment providers, and requiring families of patients and clinicians to spend considerable amounts of time meeting conditions to ensure they can obtain the next bottle of medicine on time.
8. The program interferes with the free movement and trade in patented medicines allowed between developing countries – and in particular from low-price to high-price jurisdictions. Such a mechanism, known as *parallel importation*, is enshrined in legal flexibilities in domestic laws of many countries and is an important measure to improve access to supply and price reduction of medicines.
9. This system will interfere with a customs rule called the *traveler's exemption*. Usually customs rules allow travel to another country with personal use quantities; a rule of thumb is about a 90-day supply. The person must have a prescription, or written authorisation, showing that the medicine or medical device is for personal treatment. But if dispensation is bottle by bottle, Gilead's programme will interfere with this flexibility.

Conclusion

This programme has been expanded beyond Gilead and its distributors to now include the 11 Indian generics manufacturers that have signed a voluntary license, allowing them to produce and sell generic versions of Gilead's new antivirals in at least 91 low- and middle-income countries. Gilead has not yet completed negotiations on how generic company licensees will implement the anti-diversion programme, pursuant to Article 6.1 A of the voluntary license¹.

Generic pharmaceutical companies such as Cadila, Cipla, Hetero, Mylan, Ranbaxy, Natco, Aurobindo and others who are licensees of Gilead's are gearing up to launch more affordable generic versions. These companies can distinguish their product from Sovaldi with their own trade names, packaging and colouring of the pill, and should clearly reject any anti-diversion plan that hinders patient access to generic versions of the drug.

In the case of MSF's access to the drug in Pakistan, in discussions with the local supplier and Gilead, there has been an agreement in principle on conditions that do not require provision of patient names. However, the full range of conditions of the programme will apply to the millions of other patients affected by HCV in Pakistan. This programme has the potential to be very detrimental to patient care. It will be applied to individual patients who may be extremely disempowered and will be forced to agree to problematic conditions before they can access treatment. If unopposed, Gilead's anti-diversion measures will restrict access and impede scale-up of treatment for HCV in high-burden countries.

Gilead must provide greater transparency and information about this controversial programme. MSF has called upon Gilead to eliminate the programme where it has been established, terminate on-going negotiations with other governments to introduce such programmes, and amend any signed voluntary license agreements so that generics companies do not have to implement anti-diversion measures.

¹ Anti-Diversion Program. Licensee shall provide Gilead with written notice 6 months prior to its anticipated first sale of Product in each country within the Territory. Following Gilead's receipt of such notice, the parties shall discuss in good faith programs that Licensee may implement to minimize diversion of Product outside of such country, including by using commercially reasonable efforts in ensuring Product is sold direct to patients within such country, as may be determined by the parties. On a country by country basis, if requested by Gilead at any time either prior to Licensee's sale of any Product in such country or at any time thereafter, the parties shall discuss and agree upon a written anti-diversion plan that Licensee shall implement to ensure Product is not diverted out of such country (for each such country, the "Anti-Diversion Plan"). Gilead shall have the right to prohibit Licensee's sale of Product to any country (the "Subject Country") within Territory if it reasonably believes that material quantities of Product are being sold, transferred or otherwise diverted from such Subject Country outside the Territory by providing written notice thereof to Licensee (each such notice, a "Diversion Notice"). Except as may be necessary for patients within any Subject Country who have previously initiated their treatment with Product to complete such treatment, upon Licensee's receipt of a Diversion Notice, Licensee shall immediately cease all sales of Product in, and imports of Product to, the Subject Country (ies) that is covered by such Diversion Notice until such time that Gilead and Licensee have developed an Anti-Diversion Plan for such Subject Country (ies). Licensee shall not enter into any contractual arrangements or commitments that would prevent it from fulfilling its obligations under this Section 6.1(a).