



## **Official Statement Regarding Counterfeit Harvoni® Obtained Through Direct Import**

**São Paulo, June 2020** – On March 11, 2020, Gilead Sciences Farmacêutica do Brasil Ltda. was informed about a possible counterfeit of the drug Harvoni®, a combination of ledipasvir and sofosbuvir, indicated for the treatment of genotype 1 chronic hepatitis C (CHC), based on a report made by a patient beneficiary of the CASSI health plan to their physician.

According to the document delivered to Gilead, a patient in Brazil received 6 vials of Harvoni®, presented in German, with batch number 16UCKT35D5 and pink or white tablets. Gilead does not recognize this batch number as legitimate. Furthermore, the original packaging of Harvoni® for the Brazilian market is labeled in Portuguese, containing one vial with 28 white, diamond-shaped coated tablets with the engravings “GSI” on one side and “7985” on the other.

The 6 vials of counterfeit Harvoni® were imported into Brazil through the Brazilian company Medic Pharma, specifically for this patient, via direct import.

For Gilead, patient safety is the primary concern. Thus, we are committed to ensuring that patients receive legitimate products. Gilead is working together with the National Health Surveillance Agency (ANVISA) to assist in the investigation regarding this matter.

On May 21, 2020, ANVISA published in the Official Gazette of the Union information about Harvoni® identified by batch number 16UCKT35D5, which Gilead does not recognize as legitimate, in order to warn about the possible circulation of a counterfeit drug in the country.

Harvoni® was approved by ANVISA under registration number 109290002 and, like other drugs for HCV, is regularly available through the Unified Health System (SUS). All patients, regardless of their liver condition resulting from the disease, can have access to HCV medications (including Harvoni®) through the SUS, making direct imports of the product unnecessary. In any case, Gilead maintains an authorized local distributor (United Medical Ltda.) to ensure the availability of the product to patients through private channels.

In any case, as Gilead has only received this report of the counterfeit Harvoni® batch number 16UCKT35D5, obtained through direct import, there is no reason to believe that this counterfeit drug has reached Brazilian consumers on a large scale.

### **About Gilead Sciences**

*Gilead Sciences is a biopharmaceutical company dedicated to the research, development, and commercialization of therapies for the prevention, treatment, and cure of life-threatening diseases, such as HIV/AIDS, viral hepatitis, among others. Present in Brazil since 2013 with headquarters in São Paulo, Gilead*



*operates in more than 35 countries, with headquarters in Foster City, California, in the United States.*