

**Contract of Donation**  
**Between the Ministry of Labour, Health and Social Affairs of Georgia and the Ministry of Health of the Republic of Armenia**

The Ministry of Labour, Health and Social Affairs of Georgia and the Ministry of Health of the Republic of Armenia, hereinafter referred to as "Parties", based on Point 2.1 of this contract between the Ministry of Health of the Republic of Armenia and the Ministry of Labour, Health and Social Affairs of Georgia, have agreed as follows:

**Article 1**

This Contract is not an International Agreement.

**Article 2**

2.1. Within the framework of this Contract the Ministry of Labour, Health and Social Affairs of Georgia will transfer through donation to the Ministry of Health of the Republic of Armenia 3,000 units of pharmaceutical product "Sovaldi" (Sofosbuvir tablets of 400 mg N28), which will be implemented by the procedure set forth in this Contract.

2.2 The Parties agree that pharmaceutical product "Sovaldi" are not being provided as an inducement or reward for the purchase, use or recommendation of any pharmaceutical product manufactured and/or marketed by Gilead Sciences Ireland UC and/or its affiliates, and/or to promote such products.

**Article 3**

3.1 The Ministry of Labour, Health and Social Affairs of Georgia.

Ensures donation of 3,000 unit of pharmaceutical product "Sovaldi" (hereinafter referred to as "drug") with an unexpired shelf life;

Will support the representatives of the Ministry of Health of the Republic of Armenia to settle formalities in the territory of Georgia regarding transportation and acceptance of drugs;

Is authorized to demand from contracting party to ensure traceability of drugs, also upon request of drug manufacturer will demand to ensure drug recall procedures from the market.

Will actively cooperate with competent government agencies of the Ministry of Health of the Republic of Armenia in order to achieve objectives set forth in this Contract.

### 3.2. The Ministry of Health of the Republic of Armenia:

Will ensure acceptance of drugs and its safe transportation to the Republic of Armenia within 10 working days, but no later than May 20, 2017, after signing the Agreement by both Parties;

Is responsible for maintaining conditions of the Product as per instructions set out in the Product labelling while storage and distribution of the product in the destination country;

Takes responsibility that received drugs will be distributed to only patients infected with HCV that reside in the Republic of Armenia;

Takes responsibility to ensure that HCV patients will receive the drugs, donated within this Contract, free of charge;

Shall not have any claim to the Government of Georgia and manufacturer of drugs (Gilead Sciences Ireland UC) and/or its affiliates that is or might be connected to drugs, its' use and quality, including any consequential, incidental, special, punitive or indirect damages in connection with drugs whether foreseeable or not, and whether tort or negligence.

Will ensure safe transportation and storage of drugs to "the Destination" in the Republic of Belarus in accordance with the instructions and conditions displayed on the package of the product including protection of temperature regime; will bear the expenses for delivery of the product to the destination, including transportation and insurance costs. Also, is responsible for all other expenses and issues associated with import and distribution of product within the Republic of Belarus, including all taxes, duties, customs and clearances. Also, is responsible for any other expenses and on the issues related to import and distribution of the product within the Republic of Belarus, including taxes, duties and clearance. Also, is responsible for maintaining conditions of the product as per instructions set out in the product labeling while storage and distribution of the drug in the destination country

Is responsible to ensure drug traceability.

Is responsible upon request of drug producer and/or contracting party to ensure drug recall from the market of the Republic of Armenia, in accordance with recall procedures.

Is responsible for any damages that may arise to the Ministry of Labour, Health and Social Affairs of Georgia from Gilead Sciences Ireland UC) and/or its affiliates due to the violation of the provisions of this Contract.

Takes responsibility to provide Georgian party with drug safety reports in the following manner:

1. The Ministry of Labour, Health and Social Affairs of Georgia should receive submitted monthly drug safety report in English in accordance with provided special reporting form which includes all adverse events ("AE"), serious adverse events ("SAE"), or Special Situation Reports. (According to the Attachment 1)

2. All employees involved in the program must complete the training on safety of drugs. Training certificates should be sent to Gilead by e-mail to: [standards.&collaborationsDSPH@gilead.com](mailto:standards.&collaborationsDSPH@gilead.com).

3. The representative of the Ministry of Health of the Republic of Armenia is responsible for submission of drug safety reports. The representative should be appointed promptly within 10 days following the effective date of the Contract.

4. Upon request of the Ministry of Labour, Health and Social Affairs of Georgia the Ministry of Health of the Republic of Armenia will provide with all reasonable assistance in obtaining any further information regarding clinically approved adverse events in order to identify its reasons. In addition, will provide the Ministry of Labour, Health and Social Affairs of Georgia with the contact information of the relevant healthcare representative in order to determine medical confirmation and causes.

5. The Parties agree that the Ministry of Health of the Republic of Armenia will be responsible for accuracy of any submitted information to Ministry of Labour, Health and Social Affairs of Georgia

6. Ministry of Labour, Health and Social Affairs of Georgia upon expiry or termination of this Agreement will provide a summary of all safety information that will be received from the Republic of Belarus to Gilead Sciences Ireland UC and/or its affiliates, according to the confirmed report form.

#### Article 4

Any disagreement that may arise from the interpretation and/or application of this Agreement shall be solved by negotiations and/or consultations between the Parties.

#### Article 5

Amendments and (or) additions may be done to this Contract upon mutual consent of the Parties, which shall be an integral part of this Contract.

If the Parties fail to achieve an agreement on the Contract, the dispute will be settled in accordance with Georgian legislation, by the relevant court of Georgia.

#### Article 6

6.1. This Contract shall come into effect on the date of its signature by both Parties and shall remain into force until fulfilment of obligations undertaken by the Contract, apart from exceptions set forth in the paragraph 6.2 of the Contract.

6.2 In case of breach of terms defined by the paragraph 3.2 of the Contract, Georgian party is authorized to terminate this Contract unilaterally.

Signed in two originals in English language.

On behalf of Ministry of Labour, Health  
and Social Affairs of Georgia

Minister David Sergeenko



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08 May 2017

On behalf of Ministry of Health of  
the Republic of Armenia

Minister Levon Altunyan



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