GILEAD	Solicited Program Adverse Event/Special Situation Report Form	GF-21045H.03

Please complete as many details as possible and forward within one business day to:

Program Details

Name of Program: HCV Elimination Project	Form Completed By
Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia	Print Name: Giorgi Khatelishvili
Date aware of Safety Information:	Signature:
Country of Occurrence of Safety Information: Georgia	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age: 66 | Initials: E.T. | Sex: Male ☑ Female ☐ | DOB: 28.08.1950 (or year of birth):

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No
~~Sovaldi~~	~~400mg~~	~~PO~~				
Harvoni	90/400mg	PO	12.04.2016		HCV	VCKSD
Ribavirin	600mg	PO	12.04.2016	16.08.2016	HCV	N0433B01

Safety Information Details: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g. reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

Hepatitis C, Liver Cirrhosis (Child-Pugh-B), HCC (TACE in 2015)
Treated with PegINF + Riba in 2009, HCV genotype 1b.
In 12.04.16 started treatment with SOF/LED + Rib600.
From 12th week of treatment he suffered with severe weakness, fatigue and insomnia. from 16th week of tx (16.08.16) stopped Riba. He feels much better now (30.08.16)

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☑ No ☐

Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☑

Reporter Details (i.e. who notified you of the above safety information?)

Is the Reporter a: Doctor ☐ Nurse ☐ Pharmacist ☐ Non-healthcare professional (e.g. patient, relative)* ☐

If the Reporter is a Healthcare Professional (HCP) and they are willing to provide us with their contact information, please record below

**If the Reporter is a Non-healthcare professional, please confirm if they are willing to provide contact information for their HCP:*

Yes ☐ (Please record HCP details below) No ☐

HCP Name:	**HCP Address**
HCP Telephone No/FAX No:	First Line:
HCP Email:	Town/City:
	County/State:
	Postcode/Zip code:

Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.