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: 60 | Initials: A. G. | Sex: Male ☑ Female ☐ | DOB: 21.02. (or year of birth): 1956

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	19.06.15	11.03.16	HCV	TZDND
Ribavirin	1200mg	PO	19.06.15	11.03.16	HCV	FLE4354

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.

Decompersated cirrhosis, planed duration of tx - 48 weeks. After 7 month of treatment patient developed severe ascitis, prolonged fever (SPB?), stopped treatment at 38 weeks.

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: