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
Name of Organisation:	Ministry of Labour, Health and Social Affairs of Georgia
Date aware of Safety Information:	
Country of Occurrence of Safety Information	Georgia

Form Completed By

Print Name:	Giorgi Khatelishvili
Signature:	
Telephone Number:	+995598708807
Fax No/Email:	Gkhatelishvili@moh.gov.ge

Patient Details

Age: 40 | Initials: D. I | Sex: Male ☑ Female ☐ | DOB: 21.05.1975 (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	01/06/2015	21/03/2016	HCV	TZDND
Ribavirin	1200mg	PO	01/06/2015	21/03/2016	HCV	FLE4355

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.

Patient with decompensated liver cirrhosis, started treatment with Sof/Rib, planed duration was 48 weeks. At the 42 weeks, of treatment was stopped due to varicaal bleeding, band ligation of esofageal varices was performed.

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.