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:	16.08.16
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: 48 **Initials:** G.K. **Sex:** Male ☑ Female ☐ **DOB:** 04/05/1968 (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~~ Harvoni	400mg	PO	29/03/2016	On-going	HCV	WBGT(2242.3)
Peg.INT α2-B	120 mkg	SC	29/03/2016	16/08/2016	HCV	4IQC40412(90133)
Ribavirin	1200 mg	PO	29/03/2016	On-going	HCV	FLE 4359

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 started treatment on 29.03.16 with SOF/PEG/RIBA, 12w. After 4 weeks of treatment, HCV RNA PCR - 3200 IU/ml. It was decided to change regimen with SOF/LED/PEG/RIBA, 24w. Patient suffered from anxiety, depression, common weakness. Simptoms worsened and were not menegable. In ~~29/03/2016~~ 16/08/2016 we have decided to stop Interferon injections. Treatment with SOF/LED/RIBA continues till today. Patients common health condition improved

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

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