

**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

Signature:

Date aware of Safety Information:

Telephone Number: +995598708807

Country of Occurrence of Safety Information Georgia

Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age: 50

Initials: Z.S.

Sex: Male ☒Female ☐

DOB: 11.09.1965 (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	14.01.16	24.03.16	HCV	TZDND
Aibavirin	1200mg	PO	14.01.16	24.03.16	HCV	FLE4355
Peg-IFN α2a	180mcg/w	S.C.	14.01.16	24.03.16	HCV	1908-2

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.

From 6 week of treatment patient suffered with severely exacerbated Cluster Headache, uncontrolled by all appropriated medications. From 8 week of tx - he suffered with severe weakness and skin allergy.

Treatment was stopped at the 10th week of treatment.

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:

Town/City:

HCP Email:

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.