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: 25.01.16

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: 67 | Initials: M.R. | Sex: Male ☐ Female ☑ | DOB: 12/11/1948 (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	21/01/2016	25/01/2016	HCV	SZDXD
Ribavirin	1000mg	PO	21/01/2016	25/01/2016	HCV	4RCJA43A07

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.

Antiviral treatment (SOF/RIBA) started on 21.01.16. After first intake of ribavirin, patient suffered from periorbital swelling, head and neck erithematous rash and severe itching. Ribavirin stopped imediately, antihystamins started and treatment discontinued, after 3 days 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 Telephone No/FAX No:

HCP Email

HCP Address

First Line

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 collection and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and as detailed in our Privacy Statement available to you either on www.gilead.com/privacy or upon request.