

**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:	29.10.15	Signature:	<i>G. Khatelishvili</i>
Country of Occurrence of Safety Information	Georgia	Telephone Number:	+995598708807
		Fax No/Email:	Gkhatelishvili@moh.gov.ge

Patient DetailsAge: 60 Initials: CM Sex: Male ☒ Female ☐ DOB: 20/09 (or year of birth): 1955**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	24/08/15	17/09/15	Chronic Hep C	PWMKD
Ribavirin	600mg	PO	27/08/15	17/09/15	Chronic Hep C	FN E2791
Interferon	180mg	Inj	27/08/15	17/09/15	Chronic Hep C	47RB70304

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, or 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.

Adverse Event, Cardiac Disease

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 ☐
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Reporter Details (i.e. who notified you of the above safety information?)

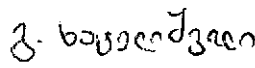
Is the Reporter a: Doctor ☐ Nurse ☐ Pharmacist ☐ Non-healthcare professional (e.g. patient, relative)* ☐
If the Reporter is a Healthcare Professional (HCP) and they are willing to provide us with their contact information, please record below
*If the Reporter is a Non-healthcare professional, please confirm if they are willing to provide contact information for their HCP:
Yes ☐ (Please record 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.

 GILEAD	Solicited Program Adverse Event/Special Situation Report Form	GF-21045H.03
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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: 29.10.15	Signature: 
Country of Occurrence of Safety Information: Georgia	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details					
Age: 62	Initials: SA	Sex: Male ☒ Female ☐	DOB: 01/02	(or year of birth): 1953	

Drug Details (Provide additional drugs on a separate page)						
Drug Name	Dose	Route	Start Date (DD/MM/YYYY)	Stop Date (or On-going) (DD/MM/YYYY)	Reason For Taking	Lot/Batch No
Sovaldi	400mg	PO	24/08/15	15/10/15	Chronic Hep C	PWM13D
Rebetol	200mg	PO	24/08/15	15/10/15	Chronic Hep C	5RCJA87 A01

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/or reports of death include the date of death – continue on another page if necessary.

Adverse event, Portal vein thrombosis

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 ☐
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HCP Email:	County/State:
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Program Details

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Name of Organisation:	Ministry of Labour, Health and Social Affairs of Georgia	Print Name:	Giorgi Khattelishvili
Date aware of Safety Information:	29.10.15	Signature:	<i>Giorgi Khattelishvili</i>
Country of Occurrence of Safety Information	Georgia	Telephone Number:	+995598708807
		Fax No/Email:	Gkhattelishvili@moh.gov.ge

Patient DetailsAge: 70 Initials: MG Sex: Male ☒ Female ☐ DOB: 13/02 (or year of birth): 1940**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	31/07/15	03/09/15	Chronic HepC	PWMKD
Bilbavirin	200mg	PO	31/07/15	03/09/15	Chronic HepC	NO338B08

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.

Adverse Event, weakness

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 ☐
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Yes ☐ (Please record HCP details below) No ☐

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**Solicited Program Adverse Event/Special
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GF-21045H.03

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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: 29.10.15	Signature:
Country of Occurrence of Safety Information: Georgia	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age: 48	Initials: KS	Sex: Male ☒ Female ☐	DOB: 21/01 (or year of birth): 1939
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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	03/08/15	07/09/15	Chronic HepC	PWUKD
Ribavirin	200mg	PO	03/08/15	07/09/15	Chronic HepC	FGE 2861

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.

Serious Adverse Event, Hospitalization due to extrahepatic manifestation

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 ☐
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Reporter Details (i.e. who notified you of the above safety information?)

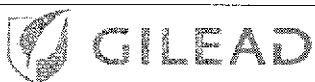
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Program Details

Name of Program: HCV Elimination Project

Form Completed By

Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia

Print Name: Giorgi Khatchelishvili

Signature:

Date aware of Safety Information: 26.10.2015

Telephone Number: +995598708807

Country of Occurrence of Safety Information Georgia

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

Patient Details

Age: 50

Initials: MG

Sex: Male ☒Female ☐

DOB: 15/01

(or year of birth): 1965

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	29/05/15	24/08/15	Chronic Hep C	PL54BH
Bilavacin	200mg	PO	29/05/15	24/08/15	Chronic Hep C	ND338BC8

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.

Adverse event, Anemia

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)* ☐

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Yes ☐ (Please record HCP details below)No ☐

HCP Name:

HCP Address

HCP Telephone No/FAX No:

First Line:

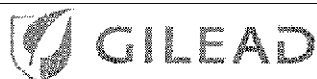
Town/City:

HCP Email:

County/State:

Postcode/Zip code:

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Name of Organisation:	Ministry of Labour, Health and Social Affairs of Georgia	Print Name:	Giorgi Khatchelishvili
Date aware of Safety Information:	29.10.15	Signature:	<i>Giorgi Khatchelishvili</i>
Country of Occurrence of Safety Information	Georgia	Telephone Number:	+995598708807
		Fax No/Email:	Gkhatelishvili@moh.gov.ge

Patient Details

Age:	49	Initials:	BS	Sex:	Male ☒ Female ☐	DOB:	27.01	(or year of birth):	1967
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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	20/08/15	03/09/15	Chronic HepC	PWMKD
Interferon	180mg	Ind	20/08/15	03/09/15	Chronic HepC	1906-05
Bilavirin	200mg	PO	20/08/15	03/09/15	Chronic HepC	FGE-2561

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.

Adverse event, Cardiac problems

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 ☐
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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

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Yes ☐ (Please record HCP details below) No ☐

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HCP Telephone No/FAX No:	First Line:
HCP Email:	Town/City:
	County/State:
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Name of Organisation:	Ministry of Labour, Health and Social Affairs of Georgia	Print Name:	Giorgi Khatelishvili
Date aware of Safety Information:	29.10.15	Signature:	
Country of Occurrence of Safety Information	Georgia	Telephone Number:	+995598708807
		Fax No/Email:	Gkhatelishvili@moh.gov.ge

Patient Details

Age:	67	Initials:	TT	Sex:	Male ☒ Female ☐	DOB:	15/01	(or year of birth):	1948
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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	30/07/15	07/09/15	Chronic HepC	PWMKD
Interferon	180mg	Inj	30/07/15	07/09/15	Chronic HepC	1907-1
Ribavirin	200mg	PO	30/07/15	07/09/15	Chronic HepC	CFGE2560

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.

Adverse event, stopped taking drug with his own will

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 ☐
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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)* ☐
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Please complete as many details as possible and forward within one business day to:

Program DetailsName 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: *G. Khatelishvili*Date aware of Safety Information: *29.10.15*Telephone Number: *+995598708807*Country of Occurrence of Safety Information *Georgia*Fax No/Email: *Gkhatelishvili@moh.gov.ge***Patient Details**Age: *39*Initials: *PG*Sex: Male ☒Female ☐DOB: *13/07*(or year of birth): *1976***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	13/07/15	21/09/15	Chronic Hep C	PWMKD
Ribavirin	200mg	PO	13/07/15	21/09/15	Chronic Hep C	FHE2791

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.

*Adverse Event, Pulmonary Tuberculosis*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)* ☐

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Yes ☐ (Please record HCP details below)No ☐

HCP Name:

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Date aware of Safety Information: <i>29.10.15</i>	Signature: <i>[Signature]</i>
Country of Occurrence of Safety Information: <i>Georgia</i>	Telephone Number: <i>+995598708807</i>
	Fax No/Email: <i>Gkhatelishvili@moh.gov.ge</i>

Patient Details

Age:	Initials:	Sex: Male ☐ Female ☐	DOB: (or year of birth):
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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	03/06/15	30/06/15	Chronic HepC	SFMTD
Ribavirin	200mg	PO	03/06/15	30/06/15	Chronic HepC	N0337B02

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.

Liver transplantation

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 ☐
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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
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Date aware of Safety Information: <i>29.10.2015</i>	Signature: <i>G. Khatelishvili</i>
Country of Occurrence of Safety Information: <i>Georgia</i>	Telephone Number: <i>+995598708807</i>
	Fax No/Email: <i>Gkhatelishvili@moh.gov.ge</i>

Patient Details

Age: <i>68</i>	Initials: <i>QT</i>	Sex: Male ☒ Female ☐	DOB: <i>27.03</i> (or year of birth): <i>1947</i>
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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	13/07/15	25/09/15	Chronic HepC	PWMKD
Ribavirin	200mg	PO	13/07/15	25/09/15	Chronic HepC	FGF 2860
			1			

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.

Adverse Event, Cardiac disease

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 ☐
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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.

**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 DetailsName of Program: *HCV Elimination Project*Name of Organisation: *Ministry of Labour, Health and Social
Affairs of Georgia*Date aware of Safety Information: *29.10.15*Country of Occurrence of Safety Information: *Georgia*

Form Completed By

Print Name: *Giorgi Khatelishvili*Signature: *G. Khatelishvili*Telephone Number: *+995598708807*Fax No/Email: *Gkhatelishvili@moh.gov.ge***Patient Details**Age: Initials: *SL* Sex: Male ☒ Female ☐ DOB: *14/01* (or year of birth): *1961***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
<i>Sovaldi</i>	<i>400mg</i>	<i>PO</i>	<i>17/06/15</i>	<i>Ongoing</i>	<i>Chronic Hep C</i>	<i>SEMTD</i>
<i>Interferon</i>	<i>180mg</i>	<i>Inj</i>	<i>17/06/15</i>	<i>Ongoing</i>	<i>Chronic Hep C</i>	<i>4RCVA 32 A01</i>
<i>Pibavirin</i>	<i>200 mg</i>	<i>PO</i>	<i>17/06/15</i>	<i>Ongoing</i>	<i>Chronic Hep C</i>	<i>1906-3</i>

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*Adverse Event, Anemia*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:

County/State:

HCP Email:

Postcode/Zip code:

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**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 DetailsName of Program: *HCV Elimination Project*Name of Organisation: *Ministry of Labour, Health and Social
Affairs of Georgia*Date aware of Safety Information: *29.10*Country of Occurrence of Safety Information *Georgia*

Form Completed By

Print Name: *Giorgi Khatalishvili*Signature: *G. Khatalishvili*Telephone Number: *+995598708807*Fax No/Email: *Gkhatalishvili@moh.gov.ge***Patient Details**Age: *50* Initials: *X M* Sex: Male ☒ Female ☐ DOB: *29/06* (or year of birth): *1965***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
<i>Sovaldi</i>	<i>400mg</i>	<i>PO</i>	<i>22/06/15</i>	<i>14/07/15</i>	<i>Chronic HepC</i>	<i>PK4BD</i>
<i>Ribavirin</i>	<i>200mg</i>	<i>PO</i>	<i>22/06/15</i>	<i>14/07/15</i>	<i>Chronic HepC</i>	<i>4RCJA56A07</i>
<i>Interferon</i>	<i>180mg</i>	<i>IM</i>	<i>22/06/15</i>	<i>14/07/15</i>	<i>Chronic HepC</i>	<i>1906-3</i>

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*Adverse Event, subarachnoid haemorrhage*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)* ☐

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