

## 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:

Name of Program: HCV Elimination Project    Form Completed By								Mar Carlo
Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia  Date aware of Safety Information: 28, 11. (\$\frac{1}{5}\$  Country of Occurrence of Safety Information: 28, 11. (\$\frac{1}{5}\$  Country of Occurrence of Safety Information: 28, 11. (\$\frac{1}{5}\$  Country of Occurrence of Safety Information: 28, 11. (\$\frac{1}{5}\$  Country of Occurrence of Safety Information: Ceergia  Fax No/Email: Ckhatelishvilli@moh.gov.ge  Patient Details  Age: \( \frac{1}{5} \) Initials: \( 2, \frac{1}{5} \) Sex: Male \( \frac{1}{5} \) Female \( \circ \) DOB: \( \frac{1}{3}.03, \frac{1}{9}\) #\( \frac{1}{6} \) (or year of birth):  Drug Details (Provide additional drupp on a separate page)  Drug Name	Program Details					and the second second	and Commission By	
Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia  Date aware of Safety Information: 28, 11.75  Country of Occurrence of Safety Information: 28, 11.75  Country of Occurrence of Safety Information: 28, 11.75  Telephone Number: +995598708807  Fax No/Email: Ckhatelishvili@moh.gov.ge  Patient Details  Age: 45 Initials: 2, 7. Sex: Male Female DOB: 18.03, 1976 (or year of birth):  Drug Details (Provide additional drugs on a separate page)  Drug Name Dose Route Sunt Date (Congoling) Reason For Taking LotBatch No Sovaldi 400mg PO 01/10/2015 On going HCV \$2000  PEG. Jat. 120 Janks SC 01/10/2015 On going HCV \$2000  Ai Bourin 1200ms PO 01/10/2015 On going HCV YESPAY.  Safety Information Details: Please provide a short summary of the adverse evently (AP) or other safety Information (e.g. reports such a preprince) hospitalization, overdose, insue, abuse, medication error, lack of elect. offseed use coupsing one apostus. As associated with product complaints or APS in an institutional perposure from beastfeeding. Please abuse for search of the evently or confirm if the overalls since all organity. Please abuse provide any teament plants to teach the control of the evently or confirm if the overalls since all organity. Please abuse provide any teament plants to teach the control of the evently or confirm if the overalls since all organity. Please abuse provide any teament plants to teach the control of the evently or confirm if the overalls since all organity. Please abuse provide any teament plants to teach the control of the evently or confirm if the overalls since and the provide complaints or APS in an institutional plants to the control of the evently or confirm if the overalls since and the provide to a Regulatory No 20 (1900).  Book the Reporter consider that the event(s) were possibly related to the label of the another organity or confirm if they are willing to provide contact information, please record below if the Reporter is a Healthcare Professional (HCP) and they are willing to provi	Name of Program: HCV Elimination Project							
Telephone Number: *995998708807  Country of Occurrence of Safety Information Georgia  Patient Details  Age: \( \frac{1}{2} \)					· init italia			
Patient Details  Age:	Date aware of Safety Infor	mation: 28	11.15		Telephone I	Number: +99	5598708807	
Age: \$\frac{\frac{1}{5}}{\text{ Initials: \$\mathcal{Z}\$, \$\mathcal{T}\$. Sex: Male \$\mathcal{L}\$ Female \$\mathcal{L}\$ DOB: \$\frac{1}{5}.0.3 \frac{1}{9}\frac{1}{9}(0\) (or year of birth):  \[ \text{Drug Details} \text{ (Provide additional drugs on a separate page)} \]  \[ \text{Drug Name}  \text{Dose}  \text{Route}  \text{Start Date}  \text{DDADQWYYYY}  \text{DDADQWYYYY}  \text{DDADQWYYYY}  \text{DDADQWYYYY}  \text{DDADQWYYYY}   \text{DDADQWYYYY}  \text{DDADQWYYYY}   \text{DDADQWYYYY}   \text{DDADQWYYYY}   \qquad   \qquad  \qq \qq \qq\qq\qq\qq\qq\qq\qq\qq\qq\qq\qq\qq\qq	Country of Occurrence of Safety Information Georgia				Fax No/Email: Gkhatelishvili@moh.gov.ge			
Drug Details (Provide additional drugs on a separate page)  Drug Name  Dose Route CDANDONTYY)  Sovaldi  400mg PO OI/IO/2015 On going WCV SCDXD  PEG. Int. 216 120mkg SC OI/IO/2015 On going WCV SCDXD  PEG. Int. 216 120mkg SC OI/IO/2015 On going WCV SCDXD  PEG. Int. 216 120mkg SC OI/IO/2015 On going WCV SCDXD  PEG. Int. 216 120mkg PO OI/IO/2015 On going WCV SCDXD  Safety Information Details: Please provide a short summay of the adverse event(s) Aproximation (e.g. reports such as pregnancy, Jean), hospitalization, overdose, misuse, abuse, medication error, lack of effett, Off-abel use, occupational exposure, AEs associated with product complaints or AEs in an infall following exposure from breastleeding). Please include the start and stop dates and the outcome of the event(s) or ordiffirm the event(s) share 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.  Pue to anemia Air Barrier Air Barri	Patient Details							
Drug Name  Dose Route Start Date (DOMONITY) Sovaldi  A00mg PO O!/!0/20!5 On going WCV SCDXD PEG. Int. 226 Int.	Age: 45 Ini	tials: Z. T.	Sex:	Male 🗹 F	emale	DOB: 18.6	73. 1970 (or year of b	irth):
Sovaldi 400mg PO 01/10/20/5 On going WCV SEDXD  PEG. Int. J26 120mkg SC 01/10/20/5 On going WCV SEDXD  A 160 winin 1200mg PO 01/10/20/5 On going WCV SEDXD  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 or effect, off-abel use, occupational exposure. AEs associated with product companies or AEs in an infant following recopour from the sevent(s), any relevant medical history and for reports of death include the date of death - continue on another page if necessary.  Pue to anemia Airban Ai	Drug Details (Provide a	dditional drugs on a	separate pag	ge)		4.03		
PEG. Int. 126   120 m/s   SC   011/01/2015   On yoing   HCV   YEQ1407    Ribarin   120 mg   PO   01/10/2015   On yoing   HCV   YEQ1407    Ribarin   120 mg   PO   01/10/2015   On yoing   HCV   YEQ1407    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.  Pue to anemia Ailon Vicin dose decreased with Pipelos and Pipelos Vicin dose decreased with Pipelos Vicin Reporter as Policials (i.e., who notified you of the above safety information?)  Reporter Details (i.e., who notified you of the above safety information?)  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 Address   First Line:   Town/City:   County/State:	Drug Name	Dose	Route				Reason For Taking	Lot/Batch No
PEG. Jet. 126   120 m/kg   5C   01/10/2015   0n going   WCV   YR03497    Riboroin   1200mg   PO   01/10/2015   0n going   WCV   YR03497    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 breastleeding). Please include the start and stop dates and the outcome of the event(s) exposure from the event(s) sizere still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event(s) is large still ongoing. Please also provide any treatment given to text the event	Sovaldi	400mg	PO	01/10/201	115 On going		WCV	SZDXD
Aifdurin   100 mg   P0   01/10/2015   On going   HCV   YRCJAYI.  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 ascidiated with product complaints or AEs in an infant following exposure from breastleeding). Please include the start and stop dates and the outcome of the event(s) confirm if the event(s) islare still opping. 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.  Pue fo anemia Ribon and Ribon and Ribon and for reports of death include the date of death – continue on another page if necessary.  Pue fo anemia Ribon and Ribon and Ribon and for reports of death include the date of death – continue on another page if necessary.  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 Address   First Line:  Town/City:  County/State:	PEG. Int. 128	120 mkg	SC	01/10/201	15 On	going	HCV	41014070
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 as accided with product complaints or AEs in an infant following exposure from the event(s) share 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.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter consider that the event(s) were possibly related to the date of death – continue on another page if necessary.    Does the Reporter co	Ribarian	4	PO			•	HCV	YRCJAYIA
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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 Address  First Line:  Town/City:  County/State:								
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HCP Name:  HCP Address  First Line:  Town/City:  County/State:	*If the Reporter is a Non-h	nealthcare profe	ssional, ple	ease confirm if the			Esser in the second sec	
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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.