

GF-21045H.03

Please complete as many details as possible and forward within one business day to:									
Program Details									
Name of Program:	Form Completed By								
Name of Organisation: MA	Print Name: Giorgi Khatelishvilli Signature: J. 6001 co 3300 o				; ;				
Date aware of Safety Inform	Telephone Number: +995598708807								
Country of Occurrence of S	afety Informati	ion Geor	gia	Fax No/Email: Gkhatelishvili@moh.gov.ge					
Patient Details	The second secon								
Age: 60 Init	ials: (M	Sex:	Male ☑	Female 🗍	DOB: W) <i>/0</i> 9	(or year of birth	1): 1951	
Drug Details (Provide ad	ditional drugs on a	a separate pag				79131. Parament F8131. Parament			
Drug Name	Dose	Route	Start Date (DD/MONYYYY)		te (or On-going) MON/YYYY)	Reaso	on For Taking	Lot/Batch No	
Sovaldi	400mg	PO	24/08/15	5/17/0	29/15	Chro	nic hepc	PWMKD	
Ribavivin	Wong	Po	27/08/1	s 17/0	29/15	Chron	ic Nep C	FU E2791	
Interteron	180m	Inl	27/08/1	5/17/0	21/LS	Chron	ric Hep C	47-RB 70304	
Safety Information D	ietails: 🏳 is	provice a shor	summary of the adv	erse event(s) (AE) or other safety in	formation (e.g.	reports such as pregr	ancy deall	
exposure from pressiteeding). Plea given to treat the event(s), any rele	se include the star	t and stop dates	and the outcome of	the event(s) of co	nfirm it the events	i is/are still on o	ping. Please also pro	ide any treatment	
Advorse E	ient,	Caro	liac P);seas(2	,	et held held held held held held held held		
				•					
	•				•				
Does the Reporter consider t drug? Yes [V]	Has this safety information previously been reported to a Regulatory Authority? Yes No								
Reporter Details (i.e. who notified you of the above safely 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 = etails below) No									
HCP Name:				HCP Addre	ess				
HCP Telephone No/FAX N	o:			First Line: Town/City:	•				
HCB Email:	County/State:								
HCP Email:					Postcode/Zip code:				



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Please complete as many details as possible and forward within one business day to: Program Details Form Completed By Name of Program: **HCV** Elimination Project Giorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: 2. bousendzaen Affairs of Georgia Signature: Date aware of Safety Information: Telephone Number: Country of Occurrence of Safety Information Georgia Gkhatelishvili@moh.gov.ge Fax No/Émail: **Patient Details** (or year of birth) Male 🗵 Female Initials: Drug Details (Provide additional drugs on a separate page) Start Date Stop Date (or On-going) Lot/Batch No Drug Name Dose Route PO Sovaldi 400mg Safety Information Details: Please provide a short-summary of the adverse event(s) (AE) prouter salety information (e.g. reports seen as pregnancy, death. hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure. Also associated with product comparists or Alica in an infant following exposure from preastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) stare still engoing. Please also provide any treatment given to provide any treatment of the event(s), any relevant medical history and for reports of death notice the date of death — continue on and, or page if necessary Portal vein thrombosis Has this safety information previously boon reported to a Regulatory Authority? Yes ☐ No ☐ Does the Reporter consider that the event(s) were possibly related to the drug?

Yes

No □ Reporter Details (i.e. who notified you of the above safety information?) Non-healthcare professional (e.g. patient, relative)* □ Is the Reporter a: Doctor [Nurse 🗌 Pharmacist [1] 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) HCP Name: **HCP Address** First Line: HCP Telephone No/FAX No: Town/City: County/State: HCP Email: Postcode/Zip code:



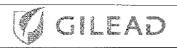
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Please complete as many details as possible and forward within one business day to.										
Program Details		11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		21/21/20						
Name of Program: HCV Elimination Project							orm Completed By			
Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia					Print Name: Giorgi Khatelishvili					
Date aware of Safety I	nformation:			Signa	iture:	-	one Buse ned.	0		
	7	9.10.	·	Telephone Number: +995598708807						
Country of Occurrence of Safety Information Georgia					Fax No/Email: Gkhatelishvili@moh.gov.ge					
Patient Details		60 / Graga		dover 3		1000		Control of Market Control of the Con		
Age: 10	Initials: MG	Sex:	Male ☑	Female	DOB:	ß	/ 02 (or year of birth): 19W		
Drug Details (Provi	te additional drugs on	a separate pag	12000000000000000000000000000000000000					100 mm		
Drug Name	Dose	Route	Start Date (DDMONYYYY)		Stop Date (or On-g (CD/MON/YYYY)		Reason For Taking	Lot/Batch No		
Sovaldi	400mg	РО	31/0715	$\int \langle $	3/09/	5	Unronic Hepc	PWMSD		
Bibavinin	200 mg	PO	31/07/1	50	3/09/15	, \	Chronic Mep C	NO 338BC		
	O									
Safety Information Details: Please provide a short summary of the adverse event(s) (AE) product safety information (e.g. reports such as pregnancy, death hospitalization, overdose, misuse, abuse, medication error, tack of effect, of label use, occupational exposure, AEs associated with product combinats or AEs in an intent following exposure, from breastfeeding), Please include the start and stop dates and the outcome of the overtis) or confirm if the event(s) finde 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 or death — combine on another page (finecessary).										
Adverse Event, wealeness										
There is a second of the secon										
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 \(\text{Doctor} \) Nurse \(\text{Nurse} \) Pharmacist \(\text{Non-healthcare professional (e.g. patient, relative)}^* \(\text{Doctor} \)										
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HCP Name:					HCP Address					
HCP Telephone No/FAX No:				First Line:						
				Town/City: County/State:						
HCP Email:					Postcode/Zip code:					



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Program Details					0.0000000000000000000000000000000000000					
Name of Program:	HCV Eliminat	tion Project			F	orm Completed	Ву			
					Print Name: Giorgi Khatelishvil					
Name of Organisation: Ministry of Labour, Health and Social Affairs of Georgia					Signature: 3. 63 By Ch					
Date aware of Safety Information: 29, LO 15					Telephone Number: +995598708807					
Country of Occurrence of S.	Fax No/Email: Gkhatelishvili@moh.gov.ge									
Patient Details					190 00 00 10 10 10 10 10 10 10 10 10 10 10			Transport of the Park of the P		
Age: 🎚 🎗 💮 Initi	als: くつ	Sex:	Male ☑	Female 🔲	DOB: 2 /	/O / (or	year of birth): 1 <u>9</u> 39		
Drug Details (Provide add	itional drugs on	a separate pag	90 (154 × 17 ± 17 4 4 4 1	Arrestal To America			HE ATTACHE			
Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Da	te (or On-going)	Reason Fo	r Taking	Lot/Batch No		
Sovaldi	400mg	PO	03/08/1	S 07 /	09/15	Chamir	Henc	PWMKD		
Ribavirin	200 mg	Po	03/02/1	507/	09/15	Chronic.	<i>Henl</i>	FGF 2861		
11190011111	3	.10	03/08//	<u> </u>	-077-	7,0110	7-7	, , ,		
Safety Information D hospitalization, overdose, misuse, a exposure from breastfeeding), Pleas given to boat the event(s), any relev	buse, medication is se include the star	error, läck of effe Land stop Cates	ct, off-label use, occurrent to	upational exposu he event(s) or co	re, AEs associated rifirm if the event;	with product compla , is/are still engoing	ints or AEs in an	rinfant following		
Serious Adverse Event, Mospitalization due to extrakepation										
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 🗌					
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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HCP Address										
				First Line:						
HCP Telephone No/FAX No:				Town/City:						
HCP Email:				County/State:						
TIOT Email.	Postcode/Zip code:									



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Please complete as many details as possible and forward within one business day to: Program Details Name of Program: Form Completed By **HCV** Elimination Project Giorgi Khatelishvili Print Name: Name of Organisation: Ministry of Labour, Health and Social a. 60810, Jaco Affairs of Georgia Signature: Date aware of Safety Information: 26, LO, 2015 Telephone Number: Country of Occurrence of Safety Information Georgia Fax No/Email: Gkhatelishvili@moh.gov.ge **Patient Details** Male [4 Initials: M 6 1965 Age: 50 Female (or year of birth): Drug Details (Provide additional drugs on a separate page) Start Date Stop Date (or On-going) **Drug Name** Dose Route Reason For Taking Lot/Batch No PO Sovaldi 400mg Safety Information Details: Please provide a short summary of the adverse even(s; (AE) or other safety information (e.g. reports such as pregnancy, neath, hospitalization, overdane, misuse, abuse, medication error; lack of effect, off-label use, occupational exposure. Also associated with product complaints or Also in an infant following exposure from breastfeeding). Please include the start and stop cates and the outcome of the event(s) or confirm if the event(s) is are still organized lease also provide any treatment given to treat the event(s), any relevant medical history and for reports of geath, include the date of death — confinue on another page if necessary. Howerse event. Hnemia Does the Reporter consider that the event(s) were possibly related to the drug?

Yes M

No Has this safety information previously been reported to a Regulatory Authority? Yes 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) № П HCP Name: **HCP Address** First Line: HCP Telephone No/FAX No: Town/City: County/State: HCP Email: Postcode/Zip code:



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Program Details								
Name of Program:	ition Project		Form Completed By					
Name of Organisation: Ministry of Labour, Health and Social				Print Name:		Giorgi Khatelishvili		
Name of Organisation:	gia	ana saciái	Signature:		2 1222 722			
Date aware of Safety In	9 W.	15]		J. 6-2012 - F30cm			
0 1 10			relephone Nur					
Country of Occurrence	of Safety Informa	tion Get	orgia	Fax No/Email:	G	Gkhatelishvili@moh.gov.ge		
Patient Details								
Age: 49	Initials: BS	Sex:	Male 🔯		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	7.0 (or year of birth): 1967	
Drug Details (Provide	e additional drugs or	a separate pag	E)					
Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (c		Reason For Taking	Lot/Batch No	
Sovaldi	400mg	PO	10/08/1	5 03/0	9//5	Chnouic Mep C	PWMKD	
Therteron	180 mg	Pnd	20108/5	5 03/09	1/15	Chronic Kenc	1966-05	
Bibarinia	200 mg	PÕ	20/02/19	5 03/09	1/15	Chronic Kepc	FGE-2561	
Safety Information Details; Pease provide a short summary of the adverse events (TAE) or other safety information (e.g. reports such as pregnancy, death, nospitalization, 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 breastieeding).	Please include the sta	rt and stop dates	and the outcome of t	ne eventis) or confirm	if the event/s	is/ere still ongoing. Please also prov		
Adverse event, Cardiae problems								
Does the Reporter consider that the event(s) were possibly related to the drug? Yes W No Were possibly related to the Authority? Yes W No W								
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:			700	HCP Address				
HCP Telephone No/FAX			First Line: Town/City:					
HCP Email:			County/State:					
HOF LIBRIE			Postcode/Zip code:					



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Please complete as many details as possible and forward within one business day to: Program Details Form Completed By Name of Program: **HCV** Elimination Project Ciorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: Affairs of Georgia J. portungsrum Signature: Date aware of Safety Information: 29.10.15 Telephone Number: Country of Occurrence of Safety Information Fax No/Email: Gkhatelishvili@moh.gov.ge **Patient Details** Sex: Male ☑ DOB: 15 (or year of birth): Age: 61 Initials: Female Drug Details (Provide additional drugs on a separate page) Stop Date (or On-going) Start Date Lot/Batch No Drug Name Reason For Taking Dose Route PO Sovaldi 400mgSafety Information Details: Plase provide a short summary of the poverse event(s) (AE) or other safety information (e.g. reports such as prognancy, death, hospitalization, overdose, reisuse, abuse, medication error, lack of effect, off-label use, occupational exposure. Alsa associated with product complaints of Alsa in an infant following exposure from preasfleeding. Please include the start and stop dates and the outcome of the event(s) of confirm if the event(s) start still engoing. Please also provide any treatment given to hear the event(s), any relevant medical history and for reports of doath include the date of death — confinue on another page if necessary. Stoped testing drug with his own will Does the Reporter consider that the event(s) were possibly related to the 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?) Non-healthcare professional (e.g. patient, relative)* Is the Reporter a: Doctor [Nurse Pharmacist [1] 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) HCP Name: **HCP Address** First Line: HCP Telephone No/FAX No: Town/City: County/State: HCP Email: Postcode/Zip code:



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Please complete as many details as possible and forward within one business day to: Program Details Form Completed By Name of Program: HCV Elimination Project Giorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: Affairs of Georgia Signature: S. posto of stem Date aware of Safety Information: 29.10.1S Telephone Number: Country of Occurrence of Safety Information Georgia Gkhatelishvili@moh.gov.ge Fax No/Email: Patient Details Male 🗹 Initials: D (-(or year of birth): 1976 Age: 39 Drug Details (Provide additional drugs on a separate page) Stop Date (or On-going)
(DD/MON/YYYY) Start Date Lot/Batch No Route Reason For Taking **Drug Name** Dose PO Sovaldi 400mg Ribavirin 00 100ma 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. Alse associated with product complaints or Alse in an infent 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—confinue on another page if necessary. Stiduerse Event, Pulmonary Tuberculosis Does the Reporter consider that the event(s) were possibly related to the Has this safety information previously been reported to a Regulatory drug? Authority? Reporter Details (i.e. who notified you of the above safety information?) Non-healthcare professional (e.g. patient, relative)* 🗌 Is the Reporter a: Doctor Nurse 🔲 Pharmacist 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: County/State: HCP Email:

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Postcode/Zip code:

gase sandan



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Please complete as many details as possible and forward within one business day to: **Program Details** Form Completed By Name of Program: HCV Elimination Project Giorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: Affairs of Georgia る. しいいるかつ Signature: Date aware of Safety Information: 29.10.15 Telephone Number: Country of Occurrence of Safety Information Georgia Gkhatelishvili@moh.gov.ge Fax No/Email: Patient Details Initials: Male Female DOB: (or year of birth): Sex: Drug Details (Provide additional drugs on a separate page) **Start Date** Stop Date (or On-going) Reason For Taking Lot/Batch No Route Dose Drug Name (DD/MON/YYYY) (DD/MON/YYYY) PO 400mg Sovaldi Ribaviria 100 mg 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, tack of effect off-label use, occupational exposure. AEs associated with product complaints or AEs in an intent 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 mansplantation

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	on?)						
Is the Reporter a: Doctor ☐ Nurse ☐ Pharmacist ☐ If the Reporter is a Healthcare Professional (HCP) and they are willing	•						
*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: County/State:						
HCP Email:	Postcode/Zip code:						

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1 Sign and the control



HCP Email:

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 Form Completed By Name of Program: HCV Elimination Project Giorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: Affairs of Georgia Signature: 3. psallwagzulv Date aware of Safety Information: 2910,2015 Telephone Number: Country of Occurrence of Safety Information Gkhatelishvili@moh.gov.ge Fax No/Email: Patient Details (or year of birth): Initials: 🕜 Sex: Male 🔯 Female 27*0*3 68 Drug Details (Provide additional drugs on a separate page): Stop Date (or On-going)
(DD/MONYYYY) Start Date Lot/Batch No Reason For Taking Dose Route Drug Name (DD/MON/YYYY) PO 400mg Sovaldi 13107K Ribavirin Safety Information Details: Please provide a short-summary of the adverse event(s) (AE) or other safety information (e.g.: reports such as pregnancy, dealing 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 2 No ... Has this safety information previously been reported to a Regulatory Yes 🔼 Authority? Reporter Details (i.e. who notified you of the above safety informallon?) Non-healthcare professional (e.g. patient, relative)* Pharmacist [Nurse 🔲 Is the Reporter a: Doctor 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:

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.

County/State:

Postcode/Zip code:



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Postcode/Zip code:



HCP Email:

Solicited Program Adverse Event/Special Situation Report Form

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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 Giorgi Khatelishvili Print Name: Ministry of Labour, Health and Social Name of Organisation: Affairs of Georgia 2. borganding Signature: Date aware of Safety Information: +995598708807 Telephone Number: Country of Occurrence of Safety Information Georgia Fax No/Email: Gkhatelishvili@moh.gov.ge Patient Details Initials: X M Age: CO Male [☑ Female [7] 29/06 (or year of birth): Drug Details (Provide additional drugs on a separate page) Start Date Stop Date (or On-going)
(DD/MONYYYY) **Drug Name** Dose Route Reason For Taking Lot/Batch No (DD/MON/YYYY Sovaldi 400mg PO 106/15 22/06/15 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, tack of effect, oif-abel 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) occonfirm 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 haemontage Does the Reporter consider that the event(s) were possibly related to the Has this safety information previously been reported to a Regulatory drug? Yes ⊠ Authority? Yes 17 No 🔲 Reporter Details (i.e. who notified you of the above safety information?) Is the Reporter a: Doctor Nurse 🔲 Pharmacist [7] 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:

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County/State:

Postcode/Zip code: