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

Program Details

Form Completed By	Name of Program: TREATMENT OF HCV PATIENTS WITH DONATED "SOVALDI" MEDICINE IN THE REPUBLIC OF ARMENIA
Print Name: ELENA SILKA	Name of Organisation: NATIONAL CENTRE FOR AIDS PREVENTION
Signature:	Date aware of Safety Information: 22/06/2017
Telephone Number:	Country of Occurrence of Safety Information ARMENIA
Fax No/Email:	

Patient Details

DOB: 30/01/1967 (or year of birth):	**Sex:** Male ☑ Female ☐	**Initials:** V.A.	**Age:** 50

Drug Details (Provide additional drugs on a separate page)

Lot/Batch No	Reason For Taking	Stop Date (or On-going) (DD/MON/YYYY)	Start Date (DD/MON/YYYY)	Route	Dose	Drug Name
L000726 TZDPD	HEP C	On-going	20/06/2017	PO	400MG	SOVALDI
	HEP C	On-going	20/06/2017	PO	60MG	DAKLATASVIR
	HEP C	On-going	20/06/2017	PO	1200MG	COPEGUS

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.

Patient started treatment with sovaldi, daklatasvir and copegus on 20/06/2017. On the next day experienced weakness, dizziness, labile blood pressure, heart rate decreased (63 beat /min) for about 4 hours. The AEs expired without any medical intervention. Medicines were not stopped .

Patient also is on the HIV treatment from 2006. Apart of HCV medicines he was administered also the following HIV medicine:

1. Emtricitabine / Tenofovir Disoproxil Fumarate 300/200mg
2. Aluvia 800/200
3. Methadon 20mg

Has this safety information previously been 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?)

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:	HCP Name: HCP Telephone No/FAX No: HCP Email:

Postcode/Zip code:	

Please be aware that information provided to the Ministry of Labour, Health and Social Affairs of Georgia(MoLHSA) 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 MoLHSA in accordance with applicable data protection laws and the MoLHSA privacy policy.