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

Program Details

Form Completed By	Name of Program:
Print Name: ANGELA MURADYAN	TREATMENT OF HCV PATIENTS WITH DONATED "SOVALDI" MEDICINE IN THE REPUBLIC OF ARMENIA
Signature:	Name of Organisation:
Telephone Number:	"NORK" REPUBLICAN INFECTIOUS CLINICAL HOSPITAL
Fax No/Email:	Date aware of Safety Information: 20/06/2017
	Country of Occurrence of Safety Information; ARMENIA

Patient Details

DOB: (or year of birth):	**Sex:** Male ☐ Female ☑	**Initials:** AA	**Age:** 49

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
N/A	HEP C	21/06/2017	15/06/2017	PO	400MG	SOVALDI
N/A	HEP C	21/06/2017	15/06/2017	PO	60MG	DAKLATASVIR

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.

On 15.06.2017 patient started treatment with Sovaldi and daklatasvir and on the 5th day of medicine intake patient experienced facial oedema, suffocation feeling and angioedema.

Patient was immediately administered dimedrol 1g/ml for AE correction. The symptoms of AE expired the same day.

Patient mentioned that in past he was experiencing allergic reactions with other drugs as well.

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 ☐ 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	HCP Name:
First Line:	HCP Telephone No/FAX No:
Town/City:	HCP Email:
County/State:	
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.