**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: Naira Sargsyan | Name of Organisation: : "ARMENICUM" CJSC |
| Signature: | Date aware of Safety Information: |
| Telephone Number: | Country of Occurrence of Safety Information: ARMENIA |
| Fax No/Email: sknarina70@mail.ru | |

## Patient Details

| **DOB:** 1960 (or year of birth): | **Sex:** Male☑ Female ☐ | **Initials:** A. H. | **Age:** 57 |
|---|---|---|---|

## 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 |
|---|---|---|---|---|---|---|
| TZDPD | HEP C | On-going | 05/07/2017 | PO | 400MG | SOVALDI |
| | | On-going | 05/07/2017 | PO | 60MG | DACLATASVIR |
| | | | | | | |

## 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.

The patient began treatment with sovaldi and daclatasvir on 05.07.2017. During the treatment patient experienced weakness, anemia (to treat thet for the events folic acid and recormon were administered), itching, emotional lability, elevation of creatinine and urea, decrease in creatinine clearance.

The patient was hospitalized from 26.07.2017 to 03.08.2017, patient experienced ascites, diarrhea, anemia, prothrombin time 19.2, prothrombin index 56.1, International normalized ratio 1.97 (Hep C treatment was stopped from 27.07.2017 to 05.08.2017).

On 31.08.2017 patient developed encephalopathy, ascites, renal failure, anemia. The patient was hospitalized for the event on 01.09.2017 until 11.09.2017 (Hep C treatment was stopped from 28.08.2017 to12.09.2017).

| 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**<br>First Line:<br>Town/City:<br>County/State:<br>Postcode/Zip code: | HCP Name:<br>HCP Telephone No/FAX No:<br>HCP Email: |
|---|---|

*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.*