

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: Hasmik Ghazinyan      | Name of Organisation: "NORK" REPUBLICAN INFECTIOUS CLINICAL HOSPITAL                                  |
| Signature:                        | Date aware of Safety Information: 18/10/2017                                                          |
| Telephone Number:                 | Country of Occurrence of Safety Information: ARMENIA                                                  |
| Fax No/Email: ghazinian@gmail.com |                                                                                                       |

### Patient Details

|                          |                                                                               |               |         |
|--------------------------|-------------------------------------------------------------------------------|---------------|---------|
| DOB: (or year of birth): | Sex: Male <input checked="" type="checkbox"/> Female <input type="checkbox"/> | Initials: E.Y | Age: 52 |
|--------------------------|-------------------------------------------------------------------------------|---------------|---------|

### Drug Details (Provide additional drugs on a separate page)

| Lot/Batch No | Reason For Taking | Stop Date (or On-going)<br>(DD/MON/YYYY) | Start Date<br>(DD/MON/YYYY) | Route | Dose  | Drug Name   |
|--------------|-------------------|------------------------------------------|-----------------------------|-------|-------|-------------|
| TZDPD        | HEP C             | On-going                                 |                             | PO    | 400MG | SOVALDI     |
|              |                   | On-going                                 |                             |       | 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.

Patient started treatment with Sovaldi and Daclatasvir on unknown date. On the 3rd month of treatment patient experienced muscle tension and anxiety.

|                                                                                                                                                     |                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Has this safety information previously been reported to a Regulatory Authority? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> | Does the Reporter consider that the event(s) were possibly related to the drug? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|

### Reporter Details (i.e. who notified you of the above safety information?)

Is the Reporter a: Doctor ☒ Nurse ☐ 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        | 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.

