GILEAD	Post Market Query Template	GT-21043B (2.0)

Date: 01 JUNE 2018

MCN: 2018-0341157

Dear Reporter,

To comply with our global regulatory reporting obligations and as part of our pharmacovigilance process, we are required to report adverse events that may be associated with our product. Patient confidentiality will be maintained in accordance with applicable laws/policies.*

We received the following report on **25-MAY-2018** for your patient who was treated with **LEDIPASVIR/SOFOSBUVIR**.

Patient: **VV** DOB: **20-NOV-1938** Age: **79** Gender: **Male**

Adverse Event(s): **Deterioration of kidney function**

Patient Information:

Initials: V.V. ***Date of Birth:*** 20 NOV 1938 (DD/MMM/YYYY) ***Age Group:*** ☐ Child (<18 yrs.) ☐ Adult (≥ 18 yrs. < 65 yrs.) ☒ Elderly (≥ 65 yrs.)

Sex: ☒ Male ☐ Female

Race: ☐ Caucasian ☐ Hispanic ☐ Of African Descent ☐ Asian ☐ Other (specify) _____

Age at onset of event: _____(yrs.) ***Height:*** _____ ☐ in ☐ cm ***Weight:*** _____ ☐ lb ☐ kg

Adverse Event(s): Adverse Event Description (provide diagnosis, if known) **Append separate sheet, if necessary**	***Causality*** Was the event considered related to Gilead drug? (Yes/No)	***Resulted in*** (Check any that apply) [1](A) Hospitalization (B) Disability (C) Life-threatening (D) Congenital Anomaly [2](E) Death	***Outcome*** (A) Resolved (B) Not Resolved (C) Unknown (D) Fatal (died due to event)	***Event Start Date*** (DD/MMM/YYYY)	***Event Stop Date*** (DD/MMM/YYYY)
1. deterioration of kidney function		A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	18 MAY 2018	27 MAY 2018
2.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
3.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
4.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
5.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
6.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
7.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
8.		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		

[1] **If Adverse event resulted in hospitalization, please provide dates:** 29 Apr 2018 (DD/MMM/YYYY) **to** 5 May 2018 (DD/MMM/YYYY)

rehospitalization: 18 May 2018 – 27 May 2018

[2] **For Fatal events please provide autopsy report and date of death:** _____ (DD/MMM/YYYY)

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Summary of Event(s) / Other Relevant Information:

Please provide a short summary of the event(s) and include any treatment given, **relevant medical history**, **risk factors**, and the results of any supportive laboratory data or other investigations (append results separately, if necessary). Before HCV treatment, Patient was diagosed with: decompensated cirrhosis (F4), ascities. In the first month of HCV treatment patient's health condition improved. After 1st month of treatment RVR was 0. In the end of April patient was hospitalized due to the acute respiratory failure. On May 7th, patient was rehospitalized and died on 27th of May. The cause of rehospitalization was deterioration of kidney function and acute respiratory failure.

If medical intervention was required to prevent the reported event becoming serious, please check here ☐ and briefly describe the clinical course.

Medication Details - including Gilead drug(s):

*List **all** medications (including non-prescription and herbal preparations) the patient was receiving at the time of the event(s). **Append separate sheet, if necessary.***

	Name	Dose	Route	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Indication	Lot/Batch No.	Suspect Drug* Yes/No
1.	Harvoni	400/90mg	PO	21 Mar 2018	29 Apr 2018	Chronic HCV		
2.	Ribavirin	1200mg	PO	21 Mar 2018	29 Apr 2018	Chronic HCV		
3.								
4.								
5.								
6.								
7.								
8.								

** Yes = Considered to be causally associated with the reported event(s) No = Considered to NOT be causally associated with the reported event(s)*

Action taken with Gilead Drug(s):

Due to the event, was the dosage of the Gilead drug(s):

☐ Continued unchanged ☐ Discontinued ☐ Reduced (new dosage _____) ☐ Unknown

If the dose was reduced or drug discontinued, did the symptoms:

☐ Resolve ☐ Improve ☐ Remain the same

If the Gilead drug was restarted, did the event reappear? ☐ No ☐ Yes (please provide details)

If the requested information is not available, please provide a response to this query indicating that the requested information is not available.

Please respond via E-mail: Safety_FC@gilead.com or Fax: 1-650-522-5477

If you need to speak with someone, please call **650-522-5114** and leave a voice message **including the MCN number** noted on the form, the **Gilead product** involved, **your name**, and **your phone number**. Thank you for your assistance with this case.

Kind regards,
Alexandra Chevalier

HISTORY OF REVISIONS

Effective Date	Version	Author	Description of Changes
Refer to EDMS	2.0	Peregrin Angeles	Administrative Change: Changed from ".dotx" to ".docx" file type.
07-Jun-2017	1.0	Grace Liu	New Template.