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

Date: 22 May 2018

MCN: 2018-0336126

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 **26 Apr 2018** for your patient who was treated with **LEDIPASVIR/SOFOSBUVIR**.

Patient: **VA** DOB: **11-SEP-2018** Age: **Not Reported** Gender: **Male**

Adverse Event(s): **Leukocytosis**

Patient Information:

Initials: V.A. ***Date of Birth:*** 11 SEP 1979 (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: 39 (yrs.) ***Height:*** 197 ☐ in ☒ cm ***Weight:*** 82 ☐ 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 Relapse Harvoni		A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
2. Leukocytosis	No	A☐ B☐ C☐ D☐ E☐	A ☒ B ☐ C ☐ D ☐	19 Apr 2018	23 May 2018
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:** _____ (DD/MMM/YYYY) **to** _____ (DD/MMM/YYYY)

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

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). On 4th week of treatment, according to the blood test, the level of leukocytes was 16000, on 8th week of treatment – 8000. The increase of leukocytes was due to cystitis.

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	23 Mar 2018	ongoing	Chronic HCV		
2.								
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,
Shawn'ta Smith

Please be aware that information provided to Gilead 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 Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.

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.