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

Date:13 April 2018

MCN: 2018-0331123

Dear Maia Nikoleishvili,

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 **01-Apr-2018** for your patient who was treated with **Harvoni**.

Patient: **R.K.** DOB: **03-Feb-1970** Age: **Not Reported** Gender: **Female**

Adverse Event(s): **Anemia**

1. **Please complete the fields below.**

Patient Information:

Initials: R.K ***Date of Birth:*** 03 FEB 1970 (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: 48 (with units) ***Height:*** 161 ☐ in ☑ cm ***Weight:*** 63 ☐ 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. Anemia	No	A☐ B☐ C☐ D☐ E☐	A☑ B☐ C☐ D☐	05 Mar 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:** _____ (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). Due to Anemia, which was revealed in March 2018 (hemoglobin level 10.5) physician prescribed iron drug (Fernicsil) to the patient. Repeated blood test was conducted on March 19, 2018 and hemoglobin level was 10.8. Patients general condition is normal. By physician's recommendation patient continues taking iron drug next 2 weeks.

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	16 Nov 2017	ongoing	Chronic HCV		
2. Ribavirin	1000mg	PO	16 Nov 2017	ongoing	Chronic HCV		
3. Iron drug-Fernicsil		PO	06 Mar 2018	Ongoing	Anemia		
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,
Adeeb Khan