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

Date: 29 May 2018

MCN: 2018-0341152

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 **25-MAY-2018** for your patient who was treated with **Harvoni.**

Patient: **RJ** DOB: **19-APR-1958** Age: Gender: Male

Adverse Event(s): Bleeding of peptic ulcer

> 1.**Would you be able to provide us with information about event outcome? Was the patient also hospitalized?**

Patient Information:

Initials: RJ   *Date of Birth:* 19-APR-1958   *Age Group:*
DD/MMM/YYYY

Sex: ☒ Male ☐ Female

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

☐ Child (<18 yrs.)
☒ Adult (≥ 18 yrs. < 65 yrs.)
☐ Elderly (≥ 65 yrs.)

Age at onset of event: _____ (yrs.)   *Height:* 170 ☐ in ☒ cm   *Weight:* 60 ☐ 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. Acute bleeding of	No	A☒ B☐ C☐ D☐ E☐	A☒ B☐ C☐ D☐	3 May 2018	9 May 2018
2. peptic ulcer		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:** 3 MAY 2018 to 9 MAY 2018
DD/MMM/YYYY   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 8th week of treatment patient had Acute bleeding of peptic ulcer. Due to this problem, patient was hospitalized. After five days of relevant treatment he was recovered. Despite patient's physician's

If medical intervention was required to prevent the reported event becoming serious, please check here ☐ and briefly describe the clinical course. recommendation to continue treatment, patient decided to stop taking Harvoni.

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	07 Mar 2018	2 MAY 2018	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,
Katerina Koeva

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.