VIGICARIB REPORTING FORM – CONFIDENTIAL

***Report Type:** ☐ Adverse Drug/Medicine Reaction (ADR/AMR) – *Complete all sections*
☐ Substandard/Falsified (SF) product – *Complete sections A, B, and D*

A. MEDICINAL PRODUCT DETAILS			
***Generic name, strength, formulation** *(Brand, if available)*	Manufacturer ***(mandatory for SF reports)***	Batch / Lot No. ***(mandatory for SF reports)***	Expiry Date *(dd/mm/yy)*

B. DESCRIPTION OF PRODUCT ANOMALY (SF) OR ADVERSE REACTION

C. PATIENT INFORMATION AND ADVERSE REACTION DETAILS

***Patient's Initials:** Record #	***Sex:** ☐ Female ☐ Male ☐ Not given	
***Date of Birth** *(dd/mm/yyyy):* **Or *Age** *(include units):*	Weight (kg):	Height: (cm)
For the suspected medicine, please describe Dosage / Frequency / Route: Indication:	Start date *(dd/mm/yy)*: Stop date *(dd/mm/yy):* Or Duration of use:	
Other Medicines (including complementary medicines used at the same time and/or 3 months before):		
Additional Details of Adverse Reaction Onset Date: _____ *(dd/mm/yy)* End Date: _____ *(dd/mm/yy)*		
Treatment given: ☐ No ☐ Yes *(please specify):* _____		
Seriousness: ☐ Death. Date of death: _____ ☐ Life-threatening ☐ Prolonged hospitalization *Tick all that apply* ☐ Congenital anomaly ☐ Persistent / significant disability or incapacity ☐ Other		
Outcome: ☐ Fatal ☐ Not Recovered ☐ Recovering ☐ Recovered on *(dd/mm/yy)* _____ ☐ Unknown		
Event subsided after stopping drug / reducing dosage? ☐ No ☐ Yes ☐ Unknown ☐ N/A (drug continued)		
Event reappeared after reintroducing drug/ dosage? ☐ No ☐ Yes ☐ Unknown ☐ N/A (not reintroduced)		
Other relevant information *(e.g. medical history, pregnancy, lab results, allergies):*		

D. REPORTER INFORMATION

***Initials:**	***Institution:**
Role/Profession: ☐ Physician ☐ Nurse ☐ Pharmacist ☐ Other Health professional ☐ Patient / caregiver ☐ Focal Point ☐ Other (describe):_____	***Country:** National PV Ref. #: **Report Date *(dd/mm/yy)*:** _____
If we need additional information, please provide a contact (name, email / phone#):	

FOR OFFICIAL USE:
Reference # _____ *Date received: _____*

INSTRUCTIONS:

Word: Type directly into this form. To select checkboxes, hover the cursor over and left-click using your mouse.
PDF: Use the Fill&Sign Tools to enter text or select checkboxes.

Use this form to report the following:

i. Suspected adverse medicine (drug) reactions (AMR/ADR) to pharmaceuticals, biologics, and natural health products, or
ii. Quality issues arising from suspected substandard or falsified or unregistered (SF) medicinal products to the Caribbean Network for Pharmacovigilance and Post-Market Surveillance. Patient details are not required. Manufacturer name, location and batch number are required.

Note: Submission of a report does NOT constitute an admission that the health personnel caused or contributed to the adverse reaction or problem.

To Health Professionals or Patient Representatives:
Complete the sections with *bold titles, and any additional information you can provide. Reports and contact information will not be shared with unauthorized persons or organizations. This information will be sent to the national pharmacovigilance / post-market surveillance centre in your country for follow-up if needed, and archiving. You may include photos of SF products as attachments.

To Focal Points:
Ensure that the form is complete and that sections with *bold titles have been completed. You may follow-up with the reporter if needed. DO NOT include the patient's or the reporter's name. You may include patient and reporter identifiers for your national database to facilitate tracking. Assign a local identifier to the report that you will use in your local database for follow-up if needed. You may include photos of SF products as attachments.

How to Submit this Form:
Completed forms may be submitted using any of the following methods:

- Email to: vigicarib@carpha.org or
- Complete this form Online at: https://form.jotform.co/72934157245864

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS FORM

For further information on AMR/SF reporting to the regional network, contact us at: vigicarib@carpha.org.
Follow us on: (CARPHA Facebook page, CARPHA Twitter)