# Yellow Card

## SUSPECTED ADVERSE EVENT REPORTING FORM

*Identities of reporter, patient, institution, and product trade name(s) will remain confidential*

* Mandatory Information

**FOR OFFICE USE ONLY**

AE report number _____ Data received _____

## A. PATIENT INFORMATION

Name/Initial:
Address:

* Contact number

*Age--------- Weight(Kg)------- *Gender ☐ Male ☐ Female ☐ Other

Pregnant : ☐ Yes ☐ No ☐ Unknown ☐ Not applicable

## B. SUSPECTED ADVERSE EVENT INFORMATION

**Type of event:**

- ☐ Adverse drug reaction/AEFI
- ☐ Product quality problem
- ☐ Medication error
- ☐ Others (Please specify)

***Describe event including relevant tests and laboratory results:**

***Event start Date** _____

***Event stopped Date** _____

**Was the adverse event treated?** ☐ **Yes** ☐ **No**

**If yes, please specify:**

**Action taken after reaction:**

- ☐ Dose stopped
- ☐ Dose reduced
- ☐ No action taken

**Did reaction subside after stopping / reducing the dose of the suspected product?** ☐ Yes ☐ No ☐ Not applicable

**Did reaction appear after reintroducing the suspected product?** ☐ Yes ☐ No ☐ Not applicable

**Seriousness of the adverse event:**

- ☐ Non serious
- ☐ Serious
  - ☐ Hospitalization or prolongation of hospitalization
  - ☐ Disability or permanent damage
  - ☐ Congenital anomaly/birth defect
  - ☐ Life threatening
  - ☐ Death

***Outcomes attributed to the adverse event:**

- ☐ Recovered
- ☐ Recovered/resolved with sequela
- ☐ Not recovered
- ☐ Unknown
- ☐ Fatal (date of death: _____ )

**Other relevant history: (pre-existing medical history)**

☐ Hypersensitivity ☐ Allergies ☐ Hypertension ☐ Liver or kidney problems ☐ Smoking ☐ Alcohol ☐ Diabetes

☐ Others (Please specify):

## C. SUSPECTED DRUG/VACCINE INFORMATION

Brand/Trade name _____ *Generic name with strength _____

*Indication _____

*Medication Start Date/Vaccination Date _____ End Date/Vaccination Time _____

Dosage Form _____ *Frequency (Daily Dose) _____ Batch/Lot number _____

Manufacturer _____ Diluent Information for vaccine _____

**CONCOMITANT MEDICINE/VACCINE INFORMATION**

| Brand/Trade name | Generic name | Indication | Dosage form | Strength & Frequency |
|---|---|---|---|---|
| | | | | |
| | | | | |



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## D. REPORTER INFORMATION

*Name & Address _____

_____

Email address _____ *Mobile phone _____

Occupation _____ *Signature

*Date of this report submission _____

**Evaluation/Review Committee Comments:**

| ADRM Cell | TSC | ADRAC |
|---|---|---|
| | | |

**General instructions for completing the form:**

- Detailed information about each field can be found in the instructions available in the DGDA website. (www.dgda.gov.bd).
- Fill in as much information as possible. Do not leave anything blank. If unknown, write "unknown" or "n/a" if not applicable.

**What to report:**

- Adverse drug reactions/AEFI
- Unknown or unexpected ADRs/AEFI
- All suspected reactions to new drugs/vaccines
- Unexpected therapeutic effects
- All suspected drug/vaccine interactions
- Product quality problems
- Medication/vaccination errors

**How to fill and submit the report :**

ADE/AEFI reports can be submitted through online in the DGDA website (www.dgda.gov.bd)

Hard copy of Yellow Card can also be filled and sent to the ADRM Cell by (i) email (adrmcell.dgda@gmail.com or (ii) post. In emergency cases or when forms are not readily available, it can be notified to the ADRM cell by phone.

**N.B:** Additional Page can be used for detailed information if needed

**ঔষধ ব্যবহারকারীদের নির্দেশনাঃ**

১। নিবন্ধনকৃত চিকিৎসকের ব্যবস্থাপত্র অনুযায়ী সঠিক মাত্রায়, সঠিক পদ্ধতিতে পূর্ণকোর্স এন্টিবায়োটিক ব্যবহার করুন।

২। কোন ঔষধ ব্যবহারে বিরূপ প্রতিক্রিয়া দেখা দিলে ঔষধ প্রশাসন অধিদপ্তরকে অবহিত করুন।


**Postal Address:**

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