SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
(For Drugs used in Prophylaxis/Treatment of COVID-19)

For VOLUNTARY reporting of ADRs by Healthcare Professionals

Indian Pharmacopoeia Commission (National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free): 1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

A. PATIENT/SUBJECT INFORMATION

**Patient/Subject Category:**
- Lab confirmed COVID-19 case □
- Asymptomatic healthcare worker involved in the care of suspected or confirmed COVID-19 cases □
- Asymptomatic household contacts of laboratory confirmed cases □
- Others (Please specify) □

**Reg. No. /IPD No. /OPD No. /CR No. :**
**AMC Report No. :**
**Worldwide Unique No. :** To be generated by PvPI

**Initials**
**Age /Date of Birth**
**Gender:** Male □ Female □ Transgender □
**Weight (in Kg)**

5. If female - pregnant Yes □ No □
6. Lactating Yes □ No □

B. SUSPECTED ADVERSE REACTION

<table>
<thead>
<tr>
<th>S.No</th>
<th>Reaction</th>
<th>Start Date</th>
<th>End Date</th>
<th>Outcome*</th>
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*Outcome may be indicated as (√) one of the following
(a) Recovered        (d) Recovering
(b) Not recovered    (e) Fatal
(c) Recovered with sequelae (f) Unknown

**Any other tests performed:**
- Chest X-Ray
- ECG Findings if any
- Biochemical Examination such as Serum Electrolytes (Na, K, Mg, Ca etc)
- Ophthalmology Exam findings, if any
- Radiological examination

7. Describe Event(s)/Reaction(s) with treatment details, if any in chronological order

8. Seriousness of the reaction: No □ if Yes □ (please tick appropriate box)
- Death (dd/mm/yyyy) □
- Life threatening □
- Hospitalization/Prolongation of hospitalization □
- Other Medically important events □

11. Recent Travel Information:
- Recent History of International Travel:
  - Yes □ No □
- Country Visited:
- Date of Return to India:
  - Inter-state travel/domestic travel

12. Relevant medical/medication history:
- Allergy/Hypersensitivity Reaction □
- Chronic Alcoholism □
- Smoking □
- Obesity □
- Renal Dysfunction □
- Hepatic Dysfunction □
- Diabetes □
- Epilepsy/Seizures □
- Bronchial Asthma □
- Cardiovascular Disease □
- Chronic Lung Disease □
- Immunodeficiency Disorder □
- Immunosuppressant Drug □
- Anaemia □
- Neurological disorder □
- G-6-PD Deficiency □
- Dermatological findings if any □
- Others □

13. Drug Interaction: Mention name of any interacting (with Suspected Drug) drug taken:
### C. SUSPECTED MEDICINE(S)*

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Drug Name (Brand/Generic)</th>
<th>Manufacturer/MAH*</th>
<th>BatchNo/ LotNo.</th>
<th>Exp. Date (if known)</th>
<th>Dosage Form</th>
<th>Dose used</th>
<th>Route of Admin.</th>
<th>Frequence (Once a day, Twice a day etc.)</th>
<th>Therapy dates</th>
<th>Indication</th>
<th>Causality Assment (Prefer WHO-UMC Scale)</th>
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<tr>
<th>S.No.</th>
<th>Drug Name</th>
<th>Reaction abated on (please tick)</th>
<th>Reaction if reappeared after drug reintroduction</th>
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<td>Drug withdrawal</td>
<td>Dose reduction</td>
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<td>Without modification of dose</td>
<td>Any other</td>
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<td>Yes</td>
<td>No</td>
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<td>Effect unknown</td>
<td>Dose (if reintroduced)</td>
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### D. REPORTER DETAILS

15. Name of the Healthcare Professional with Address: ____________________________

__________________________________________

Pin: ______________________________________ E-mail ____________________________ Tel. No. (with STD code) ____________________________ Occupation: ____________________________

__________________________ Signature: ____________________________

16. Date of this report (dd/mm/yyyy): ____________________________

Sign. and Name of Receiver: ____________________________

Confidentiality: The patient’s identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

*Use separate page for more information, *MAH- Marketing Authorization Holder
ADVICE ABOUT REPORTING

A. What to report?
All adverse events should be reported.
Report every serious adverse drug reactions. A reaction is serious when the patient outcome is:
- Death
- Life-threatening
- Hospitalization (initial or prolonged)

Report all non-serious, known or unknown, frequent or rare adverse drug reactions.
Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?
All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses etc) can report adverse drug reactions.

C. Where to report?
Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.
Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
A list of nationwide AMCs is available at:

D. What happens to the submitted information?
Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC- PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR reporting form
Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For Adverse Drug Reaction Reporting Tools
- E-mail: pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- PvPI Helpline (Toll Free): 1800 180 3024 (9:00 AM to 5:30 PM, Monday-Friday)
- ADR Mobile App: “ADRPvPI”