SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
(FOR DRUGS USED IN PROPHYLAXIS/TREATMENT OF COVID-19)

For VOLUNTARY reporting of ADRs by Healthcare Professionals

NDIAN 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:

a. Lab confirmed COVID-19 case □
b. Asymptomatic healthcare worker involved in the care of suspected or confirmed COVID-19 cases □
c. Asymptomatic household contacts of laboratory confirmed cases □
d. Others (Please specify)

Reg. No. /IPD No. /OPD No. /CR No. :

AMC Report No. :

Worldwide Unique No. : To be generated by PvPI

1. **Patient/Subject Initials**

2. Age /Date of Birth

3.Weight (in Kg)

4.Gender: Male □ Female □ Transgender □

5. If female - pregnant Yes □ No □

6. Lactating Yes □ No □

9. Relevant tests/ laboratory data with dates

Test for COVID-19 :

RT PCR Test ☐ Rapid Antibody test ☐

Positive □ Negative □ Not done □

B. SUSPECTED ADVERSE REACTION

S.No	Reaction	Start Date	End Date	Outcome*

***Outcome may be indicated as (✓) one of the following**

(a) Recovered **(d)** Recovering
(b) Not recovered **(e)** Fatal
(c) Recovered with sequelae **(f)** Unknown

10. Any other tests performed:

1. Chest X-Ray Yes □ No □
2. ECG Findings If any Yes □ No □
3. Biochemical Examination such as Serum Electrolytes (Na, K, Mg, Ca etc) Yes □ No □
4. Ophthalmology Exam findings, if any
5. Radiological examination
6. Other Relevant information, if any

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

11. Recent Travel Information:

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

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 ☐

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)*

S.No.	Drug Name (Brand/Generic)	Manufacturer/ MAH# (if known)	BatchNo. / LotNo.	Exp. Date (if known)	Dosage Form	Dose used	Route of Admn.	Frequency (Once a day, Twice a day etc.)	Therapy dates		Indication	Causality Assessment (Prefer WHO-UMC Scale)
									Date started	Date stopped		
i.												
ii.												
iii.												
iv.												

S.No.	Drug Name	Reaction abated on (please tick)				Reaction if reappeared after drug reintroduction			
		Drug withdrawal	Dose reduction	Without modification of dose	Any other	Yes	No	Effect unknown	Dose (if reintroduced)
i.									
ii.									
iii.									

14. Concomitant medication including drug used for co-morbidities, and complementary medicines with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand/Generic)	Dose used	Route used	Frequency (Once a day, twice a day etc.)	Therapy dates		Indication
					Date started	Date stopped	
i.							
ii							
iii							
iv							

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. Submissionof 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 inSuspected 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:

http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

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 ofmedicines.

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.netorpvpi.ipcindia@gmail.com**
- ***PvPI Helpline (Toll Free):1800 180 3024****(9:00 AM to 5:30 PM,Monday-Friday)*
- ***ADR Mobile App: "ADRPvPI"***