# ADVERSE DRUG REACTION REPORTING FORM

## 1. PARTICULARS OF PATIENT*

Patient Initials: …… Country: …… Date of Birth: …… *Age (At the time of event): ……..…...

Weight (kg): …… Height (cm): …… Patient address: …… *Sex: ☐Male ☐Female

*Pregnant:☐ Yes ☐ No Not applicable…… Pregnancy week: ……

## 2. ADVERSE EVENT*

Date of reaction started*: …… Date of recovery (If applicable): ……

Describe the Reaction(s) or problem*:

## 3. SERIOUSNESS OF THE REACTION

Tick appropriate box with reference to the adverse drug reaction:

- ☐ Life threatening
- ☐ Death (date): ……
- ☐ Congenital anomaly
- ☐ Requires or prolongs hospitalization
- ☐ Permanently disabling or incapacitating
- ☐ Other medically important condition (Please Specify): ……

## 4. OUTCOME OF THE REACTION

- ☐ Fatal (Death)
- ☐ Recovering
- ☐ Recovered
- ☐ Continuing
- ☐ Unknown
- ☐ Other (Please Specify): ……

## 5. SUSPECTED MEDICATIONS or DRUGS*

| Brand Name* | Generic Name* | Manufact-urer | Batch No. | Strength | Dose* (Amount of medicine taken) | Route* (Oral, Parental, Ophthalmic, etc.) | Dosage form* (Tablet, Capsule, Cream, etc.) | Purpose of use (Indication) | Duration of treatment (days/month etc.) | Drug discontinued or dose reduced (De-challenge) | Reaction stopped after drug discontinuation (Yes/No/NA) | Reaction reappeared after re-administration (Yes/No/NA) |
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## 6. *CONCOMITANT MEDICATIONS (Other than suspect drugs) *

Concomitant medical product including self-medication and herbal remedies with therapy dates (exclude those used to treat the reaction):

## 7. MEDICAL HISTORY

Other relevant history including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc.)

Have you experienced the same side effect before with the same medicine? ○ Yes ○ No

## 8. RELEVANT TESTS / LABORATORY DATA WITH DATES

## 9. PRIMARY REPORTER DETAILS (Patient/Physician/Pharmacist/Nurse/Dentist/ Other healthcare professional) *

Name*: …… Qualification*: …… Reporter organization: ……..

Address: …… Town: ……State or province: …… *Country: ……

Phone No.*: …… Email: ……

## 10. SECONDARY REPORTER DETAILS (Med. Rep. / Distributer/ etc.)

Name: …… Qualification: …… Reporter organization: ……

Address: …… Town: …… State or province: …… Country: ……

Phone No.: …… Email: ……

## 11. CAUSALITY ASSESSMENT – DRUG REACTION CORELATION (By Primary reporter only)

☐ Certain ☐ Possible ☐ Probable ☐ Not related ☐ Unassesable ☐Unknown

## 12. DATE OF THIS REPORT (dd/mm/yy):

**Confidentiality & Data Privacy**: The patient's identity is held in strict confidence and fully protected. Jamjoom staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

- By providing your data, you consent to the collection, processing, and submission of your information to regulatory authority, when required.
- You acknowledge that your data will be handled in accordance with applicable data protection and privacy laws and may be shared with the authorized entities.
- This data will be retained for a period of 10 years for regulatory compliance and related purposes
- Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

**ADVICE ABOUT REPORTING**

Report on adverse experiences with medications: A reaction is serious when the patient outcome is: 1) Death 2) Life threatening 3) Requires or prolongs hospitalization 4) Permanently disabling or incapacitating 5) Congenital anomaly

Report even if:

- You're not certain the product caused adverse reaction
- You don't have all the details, however, point nos. 1, 2, 5, 6, 9, and Points with (*) marks are essentially required.