SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Case ID (For office use only):

A. Patient Information:

1. Patient initials:_____ 2. Age (yr) at the time of event or date of birth (DD/MM/YYYY):_____ 3. Sex:_____ 4. Weight(kg) : _____

B. Suspected adverse reaction:

			OUTCOME OF THE EVENT				
Sr.No.	**Event Description**	**Event Start Date (DD/MM/YYYY)**	**1. Recovered 2. With sequel (Mention date)**	**Recovering**	**Not Recovered**	**Unknown**	**Fatal (Mention date)**
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

C. Suspected medication(s):

Drug Information											
Sr. No.	**Name** (brand/ generic name)	**Manufacturer** (if known)	**Batch No. / Lot No.**	**Exp. Date** (If known)	**Dose used**	**Route used**	**Frequency** (OD, BD, etc.)	**Therapy dates (if known give duration)**		**Indication**	**Causality Assessment (Annexure 1)**
								Date Started	**Date Stop**		

Sr. No.	**Action Taken (Please tick)**						**Reaction reappeared after reintroduction**			
	Drug withdrawn	**Dose increased**	**Dose reduced**	**Dose not changed**	**Not Applicable**	**Unknown**	**Yes**	**No**	**Effect Unknown**	**Dose (if reintroduced)**

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

Sr. No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	

E. Relevant tests / laboratory data with dates:

_____

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

_____

G. Seriousness of the reaction: No ☐ if Yes ☐ (Tick the relevant option):

☐ Death (dd/mm/yy)_____ ☐ Life threatening ☐ Hospitalization-initial/prolonged ☐ Disability anomaly

☐ Required intervention to prevent permanent damage ☐ Others (specify)_____

H. Additional Information:

_____

_____

_____

_____

I. Reporter Details:

Name:_____ **Occupation:**_____

Address:_____ **Pincode:**_____

Telephone (with STD code):_____ **Email:**_____

Signature:_____ **17. Date of report:**_____**(dd/mm/yy)**

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ADVICE ABOUT REPORTING:

What to report:

Serious, non-serious, expected or unexpected suspected adverse drug reactions with medications

Instructions for filling the form:

1. Whenever there is any suspected adverse event reported with the use of Troikaa Pharmaceuticals Ltd. Products, this form should be filled and forwarded to head office of Troikaa Pharmaceuticals Ltd.
2. The minimum data elements for suspected reporting of ADR: Identifiable reporter, an identifiable patient, an adverse reaction and suspect product (Brand name, Batch no. and Route of administration).
3. This form should be filled by any health care professional (Doctors, nurses and pharmacists) with the causality assessment.
4. In case the space given in this form is not sufficient, please attach extra pages with an appropriate heading.

How to report:

Duly filled Adverse Drug Reaction form can be send to

A. Medical Services Department , Troikaa Pharmaceuticals Ltd. Commerce House-1, Satya Marg Bodakdev, Ahmedabad – 380054, Gujarat, India, or

B. Can directly mail this filled form to : pv@troikaapharma.com and medicalservices@troikaapharma.com

Helpline number:

Call: 1800-120-782-222

Confidentiality: *The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.* ***Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.***

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Annexure 1: WHO-UMC Causality Assessment criteria

Causality term	Assessment criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenological (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon) • Re-challenge satisfactory, if necessary
Probable	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Re-challenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified