Medicinal Side Effects Reporting Form (by all) **East India Pharma** **P-Vig ICSR Form 2550 F1** (*version 1.2*)

(based on ADR Reporting Form, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt of India; CDSCO, CIOMS & ICH E2B Formats)

REPORT DATE d d - M M M - 20 y y **Company REF No.** *For internal use only*

A. PATIENT : 1. **Initials** 2. **Sex** 3. **Body Wt** kg 4. **Residing at** *Locality / City / District / Country*

5. **Date of Birth** d d - M M M - y y y y 6. **Age at time of event** yrs mths days

B. SUSPECTED MEDICINE : (Tick >1 box wherever applicable. Write NA if not applicable, NK if not known. Use additional sheets if required.)

1. **Brand**		2. **Strength**	
3. **Dosage Form**	**Oral** ❑ Susp ❑ Syr ❑ Gel ❑ Tab ❑ Cap **Drops** ❑ Oral ❑ Eye ❑ Ear ❑ Nasal **Skin** ❑ Cream ❑ Gel ❑ Ointment **Injection** ❑ SC ❑ IM ❑ IV ❑ Infusion	4. **Composition** (Chemical / Compound / Molecular / Generic)	
5. **Dose Amount / Quantity**	❑ 1 ❑ 2 ❑ 3 ❑ 4 **Tab / Cap / TSF** (5 mL) or _____ drops / puffs / mL / mg	6. **Dose Frequency & Duration**	❑ 1x ❑ 2x ❑ 3x ❑ 4x ❑ 5x ❑ 6x **daily** ❑ Stat ❑ SOS ❑ Wkly **FOR :** _____ days
7. **START DATE** (& Time)	*dd-MMM-yyyy*	8. **STOP DATE ~** (last taken on)	*dd-MMM-yyyy*
9. **Reason for starting** (Indication / Disease / Symptoms)		10. **Reason for stopping**	❑ Course / treatment complete ❑ Symptoms relieved / cured : by _____ % ❑ Oversight / negligence by patient / provider ❑ Appearance of side effects
11. **Suggested * by** (details)		12. **Prescriber / Doctor Name**	
13. **Batch No.**		14. **Expiry Date**	*dd-MMM-yyyy*

~ Write CONT if continuing * Doctor, Pharmacist, Self (from past experience / no such), Friend / Relative, Advertisement (media / online), etc.

C. SIDE EFFECT(s) / ADVERSE EXPERIENCE : (Tick >1 box wherever applicable. Write NA, NK as applicable. Use additional sheets if required.)

1. **Detailed description**		2. **START DATE** (& Time)	*dd-MMM-yyyy*
		3. **STOP DATE ~** (last noted on)	*dd-MMM-yyyy*
		4. **Severity / Intensity**	❑ Barely noticeable ❑ Tolerable ❑ Intolerable **Daily activity** ❑ Disrupted ❑ Somewhat ❑ Not **Based on these, state if :** ❑ Mild 1-3 ❑ Moderate 4-7 ❑ Severe 8-10
5. **Action taken**	❑ Continued drug without much discomfort ❑ Continued drug despite discomfort ❑ Reduced drug amount / dose quantity ❑ Reduced dose frequency ❑ Had to stop medicine altogether ❑ Required treatment / antidote (specify) : _____	6. **Seriousness**	❑ Death (*dd-MMM-yyyy*) _____ ❑ Life threatening ❑ Hospitalised / Prolonged ❑ Temporary impairment _____ ❑ Permanent diasability _____ ❑ Birth defect / cancer _____ ❑ Needed specific treatment _____ ❑ **NIL** ❑ Others _____
7. **Outcome of action**	❑ Recovered ❑ Recovering ❑ Ongoing ❑ Fatal ❑ Unknown ❑ Others _____	8. **Past reaction to same drug**	❑ None ❑ Same ❑ Other _____ _____ times _____ yrs ago ❑ **NO prior use**
9. **When drug reduced**	❑ Reaction also reduced ❑ Continued unabated ❑ Unknown ❑ Not applicable	10. **If / when re-introduced**	❑ Reaction reappeared ❑ Did not reappear ❑ Unknown ❑ Not applicable
11. **Lab tests with date** (if any)		12. **History of pre-existing / ongoing conditions / diseases**	❑ Pregnancy ❑ Allergy ❑ Smoking ❑ Alcohol ❑ Diabetes ❑ High BP **Diseases of :** ❑ Liver ❑ Lungs ❑ Heart ❑ Kidney ❑ Nerve ❑ Eyes ❑ Bones ❑ Skin ❑ Others _____ ❑ **NIL**

D. ANY OTHER SIMULTANEOUS MEDICATION(s) : (including herbal & self-medications, except those used to treat side-effects)

		(i)	(ii)	(iii)	(iv)
1.	**Indication**				
2.	**Brand, Route & Form, Strength**				
3.	**Composition**				
4.	**Dose Amount & Frequency**				
5.	**START DATE** *(dd-MMM-yyyy)*				
6.	**STOP DATE** ~ *(dd-MMM-yyyy)*				
7.	**Expiry Date** *(dd-MMM-yyyy)*				

E. REPORTER : 1. **Relation to patient** _____ 2. **Date** d d - M M M - **20** y y

3. **Initials** _____ 4. **Age** _____ yrs 5. **Sex** _____ 6. **Edu Qualification** _____

7. **Cell : +** _____ - _____ 8. **wApp : +** _____ - _____

9. **FULL NAME** (Block Capitals)

10. **e-mail**(s)

11. **Professional ADDRESS** (Designation, Dept, Unit, Bldg, Institution, Seal, Signature, Regn No, etc,)

12. **Residential ADDRESS** (Locality, Village, City / Town, PO, PS, Block, District, State, PIN code, Landmark, etc.)

• ***If filled up*** *(on behalf of reporter)* ***by company representative / anybody else*** **:**

13. **FULL NAME** (Block Capitals) _____ 14. **Age** _____ yrs 15. **Sex** _____

16. **Cell +** _____ - _____ 17. **wApp : +** _____ - _____

18. **Professional ADDRESS** (Designation, Dept, Branch, Headquarters, Unit, Seal, etc.)

19. **Residential ADDRESS** (Locality, Village / Town, PO, District, State, PIN code, Landmark, etc.)

REPORT ADRs (adverse drug reactions / side effects of medicines) – **Just a Few Min could Save Many :**

WHY : ADRs are the **4th-6th major cause of deaths** worldwide. Filling out this form could help us ensure safer medicines, as the data generated will help in continual risk-benefit analysis of medicinal drugs.

WHO : Anybody can report : • Laymen / General Public : Patients (consumer), their friends / relatives, etc. Specially • Health care professionals : Doctors, Dentists, Nurses, Paramedics, Pharmacists, etc. whose participation is vital.

WHEN : Even if you • don't have all details • are not certain that reactions have been caused by that product only

WHAT : Any adverse experience : • Adverse Drug Reactions • Adverse Events • Product Problems

WHERE & HOW : Please download, fill-up offline & submit hard / soft / scanned copy of this form, to any of :

- Our company's Medical Representatives
- email to reportsideeffects@eastindiapharma.org
- East India Pharmaceutical Works Ltd., 119 Biren Roy Road (West), Kolkata 700061, India.
- Online version of this form available at dedicated Medicinal Safety webpage of our website www. eastindiapharma.org

Disclaimer : Patient's identity will be kept **Strictly Confidential** & protected to the fullest extent, at all times & circumstances. Reporter's identity too is not for public disclosure. Reporting is **purely voluntary** & aimed at patient safety only. Merely its compilation / submission **DOES NOT** amount to an admission of causality / contribution by the physician, manufacturer or product, towards the reported untoward incident or adverse outcome. Neither does it have any legal binding / implications.