Adverse Event (AE) Form – Marketed Products

1. Seriousness assessment
Serious Adverse Event (SAE): yes ☐ no ☐

2. Initial adverse event (AE) or a follow-up report? ☐ Initial ☐ Follow-up

3. Patient:

Sex:	☐ Male	☐ Female
Date of birth or age: (DD-MMM-YYYY e.g. 31-AUG-2008)		
Initials:		
Weight (kg):		
Height (cm):		

Study ID of applicable:

Pregnant:	☐ Yes	☐ No
If this is a pregnancy observation, please fill in a Pregnancy Form		

4. Suspected drug:

LEO Pharma Product	Lot / batch no.	Expiry date	Formulation and strength (e.g. ointment 20mg/g)	Total daily dose / dose+ frequency	Route (e.g. oral)	Duration of therapy		Indication for use of suspected drug
						Started DD-MMM-YYYY	Stopped DD-MMM-YYYY	

5. Adverse event:

Main diagnosis/syndrome:				Overall Outcome:	Causality:	Severity:
				☐ Recovered ☐ Recovering ☐ Not recovered ☐ Recovered w/sequelae ☐ Fatal ☐ Unknown	☐ Possible related ☐ Not related	☐ Mild ☐ Moderate ☐ Severe
Start date: DD-MMM-YYYY		Stop date: DD-MMM-YYYY				

If patient died, cause of death: _____ Autopsy report: ☐ Yes ☐ No

If patient recovered with sequelae, please specify: _____

If the patient experienced other events/experiences (OEs), please specify: _____

_____

6. If AE is serious, please tick all appropriate to AE(s):

☐ Fatal
☐ Life-threatening
☐ In-patient hospitalisation
☐ Prolongation of existing hospitalisation
☐ Persistent or significant disability/incapacity
☐ A congenital anomaly/birth defect
☐ Other medically important condition: _____

7. Date of hospitalisation: _____ **Date of discharge:** _____

8. Description of AE(s):
Diagnosis, signs, symptoms, course of event(s), drugs used for treatment and other examinations/treatments performed. Please detail the start/stop date and/or outcome of the Adverse Events if they are different. Please use date format as DD-MMM-YYYY.

9. Dechallenge and rechallenge for LEO Pharma suspected drug:

Was treatment with product stopped due to the event(s)?	☐ Yes	☐ No	☐ N/A
Did reaction(s) stop after discontinuing the drug?	☐ Yes	☐ No	☐ N/A
Did reaction(s) reappear after reintroduction of the drug?	☐ Yes	☐ No	☐ N/A

10. Has the patient previously been exposed to the suspected drug?
☐ Unknown ☐ No ☐ Yes, when? _____ Did any AE(s) occur then? ☐ No ☐ Yes If yes, which AE: _____

11. Concomitant medication:
Exclude medicines given to treat the AE – must be included in the description of AE (field no.8). ☐ **None**

Drug(s) (trade name/ generic name)	**Formulation and strength** (e.g. tab 5 mg)	**Total daily dose/dose+ frequency**	**Route** (e.g. oral)	**Duration of therapy**		**Indication for use of concomitant drug**
				Started (DD-MMM-YYYY)	Stopped (DD-MMM-YYYY)	

12. Are any of the concomitant medications suspected of being causally related to the AE?
☐ No ☐ Yes If yes, specify drug _____

Did the AE disappear after stop of drug?	☐ Yes	☐ No	☐ N/A
Did the AE reappear after restart of drug?	☐ Yes	☐ No	☐ N/A

13. Relevant medical history: (e.g. previous diagnoses, surgery, allergies) ☐ **None**

Disease, surgical procedure, etc.:	**Start date:** (DD-MMM-YYYY)	**Continuing: (Y/N/Unknown)**	**End date:** (DD-MMM-YYYY)	**Comments:**

14. Relevant clinical/laboratory assessments: ☐ None ☐ Attached ☐ See below

Test(s):	**Assessment date:** (DD-MMM-YYYY)	**Results:**	**Unit:**

15. Reporter:

Reporter's name:			Profession:	☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Health Care Professional ☐ Consumer
Institution:			Country:	
Address:			Phone No.:	
Date & signature:			Fax No.:	

16. May the reporter be contacted again if necessary: ☐ Yes ☐ No