Exeltis

PVEX-F02.03 - ADVERSE EVENT REPORT FORM

Signature for entry into effect:
Effective date: 30/09/2019
Approval date: 30/09/2019

I. REPORT INFORMATION

1. LOCAL CASE ID	3. REPORTER SOURCE	4. OTHER CASE IDs
	☐ Health professional ☐ Study ☐ Literature ☐ Regulatory Authorities ☐ Patient/Consumer	*(Health Authorities ID, partners IDs, Quality Complaint ID, Medical Query ID…etc)*
2. CASE VERSION ☐ Initial report ☐ Follow-up report		

5. INITIAL RECEIPT DATE	6. FU1 RECEIPT DATE	7. FU2 RECEIPT DATE *Please add subsequent follow-up dates, if needed*

II. REPORTER INFORMATION

8. REPORTER QUALIFICATION	9. REPORTER'S NAME, QUALIFICATION AND CONTACT DETAILS
☐ Physician ☐ Pharmacist ☐ Other Healthcare Provider ☐ Regulatory Authorities ☐ Patient/Consumer	*(Reporter's region mandatory for Spanish cases)* *(Anonymize consumer/patient's details)*

III & IV. PATIENT DETAILS & REACTION INFORMATION

10. COUNTRY OF OCCURRENCE	11. DATE OF BIRTH			12. AGE (*Years*)	13. SEX	14. REACTION ONSET DATE			15. CHECK ALL APPROPIATE
	Day	Month	Year			Day	Month	Year	☐ Fatal ☐ Life-threatening ☐ Involved or prolonged patient hospitalization ☐ Involved persistent or significant disability or incapacity ☐ Other-significant medical event ☐ Congenital anomaly/birth defect
16. DESCRIBE THE EVENT(S) (*Please include signs and symptoms, final diagnosis, relevant tests and lab data*)									

17. ADVERSE EVENT OUTCOME		18. DATE OF OUTCOME		
☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Unknown	☐ Recovering/Resolving ☐ Not recovered / Not resolved ☐ Death	Day	Month	Year

19. FOR FATAL OUTCOMES (*Relevant autopsy report or post-mortem findings*) **Cause of death:** **Autopsy Report available:** ☐ **Yes (if yes, please provide a copy)** ☐ **No** **Post-mortem findings:**

V. SUSPECT DRUG INFORMATION *(if more than one, please repeat section)*

20. SUSPECT DRUG (*Include product name, active substance/s and strength*)			
21. DAILY DOSE(S)	22. ROUTE OF ADMINISTRATION	23. BATCH NUMBER (*mandatory for biologics / biotechnological products*)	24. EXPIRY DATE
25. INDICATION(S) FOR USE			
26. THERAPY START DATE	27. THERAPY END DATE	28. THERAPY DURATION	
29. ACTION TAKEN WITH SUSPECT DRUG ☐ Unchanged ☐ Dose reduced ☐ Dose Increased ☐ Discontinued ☐ Interrupted – Date when restarted: ☐ Unknown			
30. Did reaction abate after stopping the drug? ☐ YES ☐ NO ☐ NA		31. Did reaction reappear after reintroduction of the drug? ☐ YES ☐ NO ☐ NA	

VI. CONCOMITANT MEDICATION & MEDICAL HISTORY

32. CONCOMITANT DRUG(S), HERBAL MEDICINES, FOOD SUPPLEMENTS *(Please include indications, doses and dates of administration, if available)*
33. RELEVANT MEDICAL HISTORY (*E.g. risk factors, allergies, family history…etc*)

VII. ADDITIONAL INFORMATION

34. CAUSALITY ASSESMENT *(Reporter's causal relationship with the suspect drug)* ☐ Related ☐ Probably related ☐ Possibly related ☐ Unlikely related ☐ Not related ☐ Unknown ☐ Non-assessable	35. OTHER RELEVANT INFORMATION