REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@npra.gov.my Website: www.npra.gov.my

(Please report **all** suspected adverse drug reactions including those for vaccines, health supplements and traditional products. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential.**)

REPORT No. (*for official use only*): .....

PATIENT INFORMATION

I.C. No. / R/N / Initials	*Age	*Gender *(please tick)*	Wt (kg)	*Ethnic Group	*Please tick (if applicable):*
		Male ☐ Female ☐			☐ Initial Report ☐ Follow-up Report

***ADVERSE REACTION DESCRIPTION** (inc. sequence of adverse events, details of rechallenge, interactions)

Time to onset of reaction : ☐ mins/ hours/ days/ months/ years *(please circle)* Date start of reaction : ☐ Date end of reaction : ☐

Reaction subsided after stopping drug / reducing dose : Yes ☐ No ☐ Unknown ☐ *N/A (drug continued) ☐

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Unknown ☐ *N/A (not reintroduced) ☐

Extent of reaction : Mild ☐ Moderate ☐ Severe ☐

Seriousness of reaction : Life threatening ☐ Caused or prolonged hospitalisation ☐ Caused disability or incapacity ☐ Caused birth defect ☐ *N/A (not serious) ☐

Treatment of adverse reaction & action taken : ☐

Outcome : Recovered fully ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal: ☐ Date & Cause of death:.....

Drug-reaction relationship : Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

***Suspected Drug(s) :** **N/A: Not applicable*

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

For Vaccines Only: Vaccine dose (*please circle*) : 1st/ 2nd/ 3rd/ booster/ others _____ Diluent Batch / Lot No. ☐

Concomitant Drug(s) / Other Vaccine(s) given just prior to AEFI [adverse events following immunisation] *(please state 'NIL' if none)* :

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

(Please attach additional sheets if necessary)

Relevant Investigations / Laboratory Data	Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc)

Reporter Details

*Name : *Institution Name & Address :

Designation : *Tel No :

ADR Reporting Guide

Before submitting your ADR report, do check if you have inserted the following information.
Please try to fill every section in the ADR form overleaf, stating **'none / nil' if applicable. A complete report is a useful report.*

NO.	IMPORTANT POINTS TO NOTE
1	**Definitions:** **(i) Time to onset of reaction:** time interval between first dose (initiation) of the drug until first sign of the ADR. **(ii) Initial report:** First submission of report to NPRA of a particular patient involving a particular ADR. **(iii) Follow-up report:** Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report. Please mention the date of initial report for reference.
2	Please specify any previous history of **allergy** (including drugs, food, etc.).
3	Include information on any **concomitant medications** or **underlying illnesses**? *(Please state 'nil' if none)* • Date started and stopped for each medication • Please state 'cont' for any medication still continued after the ADR
4	Please state the specific **indication** of the suspected drug (e.g.: '*pneumonia due to S. Pneumoniae*' - not 'infection' or 'antibiotic').
5	If the ADR reappeared after reintroducing drug (**rechallenge**), please describe the rechallenge fully (dose given, timing, brand used, etc.) under section 'Adverse Reaction Description'.
6	Please specify if any **treatment** was given for the ADR, or if the suspected drug was stopped, what **alternative drug** was started and how the patient responded.
7	Please include the latest / current **outcome** of the patient *(e.g. recovered fully, not recovered)*. • If possible, follow-up the patient periodically until the final outcome is known. • A follow-up report may be sent in to update on the final outcome of the patient.
8	**Skin reactions:** Please describe the specific type and location of the skin reaction. *(Use the Cutaneous ADR form and guide available on **www.npra.gov.my**)*
9	Do keep your own record of details enabling you to **contact** the patient or trace the case notes later on if necessary *(e.g. IC number, patient name and phone number)*.

*Please refer to our website for additional guidance on ADR Reporting, or contact us at **fv@npra.gov.my** if you have any queries.*

Lipat di sini

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Laporan Kesan Advers Ubat
Bahagian Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN

BAHAGIAN REGULATORI FARMASI NEGARA

LOT 36, JALAN UNIVERSITI

46200 PETALING JAYA

SELANGOR