FULL NAME:
WARD/CLINIC:
ALLEGRY CARD (IF APPLICABLE): DAC-11-08070022-

HTPG/FAR/RSADR/2013

REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@npra.gov.my Website: www.npra.gov.my Fax: 03-7956 7151

(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. / Passport	*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 : DD / MM / YYYY

Date end of reaction : DD / MM / YYYY

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 :

*Email Address :

Date of Report :

Signature :

rev01/2019

Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

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 NPCB 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 **portal.bpfk.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@bpfk.gov.my** if you have any queries.*

Additional information of Diluent Batch/Lot No. is important for vaccines in which the vaccine is not supply together with diluent (eg. COVID vaccine Corminarty). AEFI with unknown diluent batch/Lot No. please put dash(-).

Concomitant Drug:

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

CLINICAL MANIFESTATION OF ADVERSE DRUG REACTION

1. Type of cutaneous adverse drug reaction (please √)
   - You are allowed to choose more than one of the following.

1. Acneiform Eruption		9. Pruritus only	
2. Alopecia		10. Purpura	
3. Erythema multiforme		11. Toxic Epidermal Necrolysis	
4. Erythema nodosum		12. Stevens-Johnson Syndrome	
5. Fixed drug eruption		13. Urticaria / Angioedema	
6. Maculo-papular rash (exanthem)		14. Vasculitis	
7. Photosensitivity		15. Vesiculobullous reaction	
8. Pigmentary changes		16. Others : ……	

2. Please specify part of the body affected

_____

_____

Please use either WHO methodology or Naranjo Probability scale to assess for drug-reaction relationship:

WHO Methodology

- **Certain**
  - Good timing, no other cause, withdrawal response plausible, re-challenge. 'definitive'
- **Probable**
  - Good timing, other cause unlikely, withdrawal
- **Possible**
  - Good timing, other cause possible
- **Unlikely**
  - Poor timing, other causes more likely
- **Unclassifiable**
  - Insufficient or contradictory information

Naranjo Probability scale

Questions	Yes	No	Do Not Know
1. Are there conclusive reports on this reaction?	+1	0	0
2. Did the ADR appear after the suspected drug was administered?	+2	-1	0
3. Did the ADR improve when the drug was discontinued?	+1	0	0
4. Did the ADR appear with re-challenge?	+2	-1	0
5. Are there alternative causes for the ADR?	-1	+2	0
6. Did the reaction appear when placebo was given?	-1	+1	0
7. Was the drug detected in blood at toxic level?	+1	0	0
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
10. Was the ADR confirmed by any objective evidence?	+1	0	0

The score:
> 8 : Highly probable
5 – 8 : Probable
1 – 4 : Possible
0 : doubtful