# 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)* Male ☐ Female ☐ | Wt (kg) | *Ethnic Group | *Please tick (if applicable):* ☐ 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 :

*revision-01*

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:**<br>**(i) Time to onset of reaction**: time interval between first dose (initiation) of the drug until first sign of the ADR.<br>**(ii) Initial report:** First submission of report to NPRA of a particular patient involving a particular ADR.<br>**(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)*<br>• Date started and stopped for each medication<br>• Please state 'cont' for any medication still continued after the ADR |
| 4 | Please state the specific **indication** of the suspected drug<br>(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).*<br>• If possible, follow-up the patient periodically until the final outcome is known.<br>• 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.<br>*(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

Lipat di sini

***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**

- Sila lipat dua, lekat, dan hantar. Tekan beberapa saat dan pastikan pelekatan adalah memuaskan -

**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

   _____

   _____

| **Questions** | **Yes** | **No** | **Don't know** | **Score** |
|---|---|---|---|---|
| 1. Are there previous conclusive reports on this reaction? | +1 | 0 | 0 | |
| 2. Did the adverse event appear after the suspected drug was administered? | +2 | -1 | 0 | |
| 3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered? | +1 | 0 | 0 | |
| 4. Did the adverse reaction reappear when the drug was re-administered? | +2 | -1 | 0 | |
| 5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | -1 | +2 | 0 | |
| 6. Did the reaction reappear when a placebo was given? | -1 | +1 | 0 | |
| 7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic? | +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 adverse event confirmed by any objective evidence? | +1 | 0 | 0 | |
| | | | **TOTAL** | |

(Naranjo CA et al. "A method for estimating the probability of adverse drug reactions". Clin. Pharmacol. Ther. August 1981)

The Adverse Dug Reaction is assigned to a probability category from the total score as follows:

**Definite** > 8
**Probable** 5 to 8
**Possible** 1 to 4
**Doubtful** < 1