



Report can be returned by fax to 2319 6319

For Follow-up report (see Guidance),

Please provide previous case Ref. No.: _____

Department of Health

Adverse Drug Reactions (ADR) Report Form

Please read the following instructions:

1. Please read the Guidance for Healthcare Professionals (<http://www.drugoffice.gov.hk/adr.html>); and Guidance for Pharmaceutical Industry (http://www.drugoffice.gov.hk/adr_industry.html) before completing the ADR report form.
2. ADR can be briefly described as a noxious and unintended response to a pharmaceutical product (i.e. drug or vaccine).
3. If the ADR of a newborn/child may be related to the mother, please submit a separate report for the mother.
4. Please provide information to every section.
5. **Full name and any kind of personal identifier of the patient**, such as identity card number and hospital admission number, **should not be provided** on the report form.
6. Information of individual reporter will be treated in strict confidence. Please read the Statement of Purposes overleaf in respect of the collection of your personal data.
7. As limited space is provided, please use another page for additional information if necessary.
8. For further enquires, please contact the Pharmacovigilance Unit of Drug Office of the DH at 2319 2920.

Section (A): Patient Information

Patient initials or ref. no.: _____ (Please read instruction 5 above)

Sex: ☐ M ☐ F ☐ Unknown For woman, is she pregnant? ☐ No ☐ Yes ☐ Unknown

Weight (if known): _____ kg Date of birth: (dd/mm/yyyy) ____/____/____ or age (at last birthday): _____

Ethnic group: ☐ Chinese ☐ Asian (Not Chinese) ☐ African ☐ Caucasian ☐ Eurasian ☐ Unknown ☐ Others _____

Section (B): About the Adverse Drug Reaction

Date of onset of ADR: (dd/mm/yyyy) ____/____/____

Description of event: _____

ADR category (for vaccine related ADR only):

☐ Allergic reaction ☐ Local reaction ☐ Systemic reaction ☐ Neurological disorders

Severity (can tick more than 1 box if appropriate):

☐ Life threatening ☐ Prolonged Hospitalization ☐ Hospitalized on: (dd/mm/yyyy) ____/____/____

☐ Hospitalization NOT required

Laboratory result (if applicable): _____

All Drug Therapies/Vaccines Prior to ADR (Please use trade names and, for vaccine, indicate batch number. Please <u>circle</u> the suspected drug.)	Daily Dosage (dose number for vaccines e.g. 1 st DTP)	Route	Date Begun	Date Stopped	Reason for Use

Section (C): Treatment & Outcome

Treatment for ADR: ☐ No ☐ Yes. Details (including dosage, frequency, route, duration) _____

Laboratory result (if applicable): _____

Outcome: ☐ Recovered on: (dd/mm/yyyy) ____/____/____ ☐ Not yet recovered ☐ Unknown ☐ Died on: (dd/mm/yyyy) ____/____/____

Sequelae: ☐ No ☐ Yes: ☐ Persistent disability ☐ Birth defect ☐ Medically significant events Details: _____

Allergies or other relevant history (including medical history, liver/kidney problems, smoking, alcohol use etc) _____

Section (D): Reporter Details (Please read instruction 6 above)

Name of Reporter and Organization: _____ Sector of service: ☐ Private ☐ Public

Occupation: ☐ Doctor ☐ Chinese medicine practitioner ☐ Dentist ☐ Pharmacist ☐ Nurse ☐ Others _____

Correspondence Address: _____

Tel. no.: _____ Fax. no.: _____ Email: _____

Also report to: ☐ Manufacturer ☐ Distributor/Importer ☐ Others _____ Date of this report: _____

Please
Affix
Stamp

**To: Pharmacovigilance Unit
Drug Office
Department of Health
Room 1856, Wu Chung House,
213 Queen's Road East, Wanchai,
Hong Kong**

Statement of Purposes

Purpose of Collection

This personal data are provided by reporter for the purposes of reporting adverse drug reaction of the patient to the Department of Health (DH). The personal data provided will be used by DH for the following purposes:

- (a) follow-up of the case report; and
- (b) surveillance of drug-related events.

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to assess the report properly.

Classes of Transferees

3. The personal data you provide are mainly for use within DH. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making access and corrections, should be addressed to:

Senior Pharmacist (PV&RM)1
Pharmacovigilance Unit
Pharmacovigilance and Risk Management Division
Drug Office
Department of Health
Room 1856, 18/F, Wu Chung House
213 Queen's Road East, Wan Chai, Hong Kong
Tel: 2319 2920

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