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 enquiries, please contact the Clinical Trials and 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 circle the suspected drug.)	**Daily Dosage** (dose number for vaccines e.g. 1st 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 fold inside along the dotted line and seal the edge

Please Affix Stamp

To: Clinical Trials and Pharmacovigilance Unit
Drug Office
Department of Health
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon, Hong Kong

Please seal the edge

Please seal the edge

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
Clinical Trials and Pharmacovigilance Unit
Drug Office
Department of Health
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon, Hong Kong
Tel: 2319 2920