

Guidance for Healthcare Professionals – Adverse Drug Reaction Reporting

Drug Office
Department of Health
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1. INTRODUCTION

Adverse drug reaction reporting is an integral element in drug safety surveillance and pharmacovigilance.

To enhance the post-market drug surveillance activities, the Drug Office of the Department of Health (DH DO) collects adverse drug reaction reports of pharmaceutical products for use in Hong Kong from healthcare professionals and conducts causality assessment to assist subsequent formulation of risk management strategies when necessary.

Healthcare professionals including doctors, Chinese medicine practitioners, dentists, pharmacists and nurses are encouraged to report suspected adverse drug reaction of their patients voluntarily.

This document serves as a guidance for reporting adverse drug reaction by healthcare professionals. It covers the types of adverse drug reactions which are encouraged to be reported, the information to be included in the report, and the manner of reporting.

2. WHAT IS ADVERSE DRUG REACTION?

2.1 Adverse Drug Reaction

An adverse drug reaction is a response, which is noxious and unintended, to a pharmaceutical product.

2.2 Serious Adverse Drug Reaction

A serious adverse drug reaction is any untoward medical occurrence that at any dose:

- results in death;
- is life threatening;
- requires inpatient hospitalization or results in prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

2.3 Unexpected Adverse Drug Reaction

An unexpected adverse drug reaction is an adverse drug reaction whose nature, severity, specificity, or outcome is not consistent with the term or description used in the local product labelling.

3. WHERE TO GET THE REPORT FORM?

Adverse drug reaction report can be made by completing the online report form at <http://www.drugoffice.gov.hk/adr.html>.

Alternatively, adverse drug reaction report can be made on DH DO Adverse Drug Reaction Report Form (APPENDIX 1). The form is also available at <http://www.drugoffice.gov.hk/adr.html>.

4. WHAT TO REPORT?

Healthcare professionals are encouraged to report the following adverse drug reaction cases:

- All suspected serious adverse drug reaction, even if the reaction is well known;
- Suspected drug interactions including drug-drug and drug-herb interactions;
- Non-serious adverse drug reactions but the reactions are deemed medically significant by the healthcare professional (e.g. increased frequency or unusual presentation of a known adverse drug reaction);
- Unexpected adverse drug reactions, i.e. the reactions are not found in the product information or labeling (e.g. an unknown side effect in a new drug).

If in doubt, please report.

You do not need to be certain that the adverse drug reaction is related to the suspected drug.

5. WHAT SHOULD BE INCLUDED IN THE REPORT

Use a separate form for each patient. Please try to complete the form to the best of your knowledge and provide as much information as possible. The following items are considered essential for causality assessment and should be provided whenever possible:

- patient information (initials or reference number will be sufficient; **full name and other kinds of personal identifier of the patient**, such as identity card number and hospital admission number, should **NOT** be provided on the report form);
- adverse reaction description (including the date of onset of reaction and, if related to a vaccine, adverse reaction category*);
- drug therapy or vaccine including product name (particularly biological product and vaccine; or manufacturer's information) of the suspected and concomitant drug(s), batch number (particularly biological product and vaccine), dosage, route, dates of starting and stopping drug therapy, reason for use, etc.;
- the interacting agent(s) (i.e. drugs, herbs or food) if suspected drug interaction is involved;
- treatment of adverse drug reaction;
- outcome of the reaction;
- sequelae of the reaction;
- comments (e.g. allergies, relevant information - hepatic and renal functions,

- alcohol use, smoking);
- reporter details (contact information should be provided for necessary follow-up; please read the Statement of Purposes (APPENDIX II) in respect of the collection of personal data).

* Note: Adverse drug reaction related to vaccine can be classified under one of the following Adverse Reaction Categories

Adverse Reaction Categories	Descriptions
Allergic reactions	Anaphylaxis is the severe reaction that characteristically evolves rapidly towards cardiovascular collapse requiring resuscitative therapy. Other examples of severe allergic reactions are wheezing or shortness of breath due to bronchospasm, swelling of mouth or throat, skin manifestation (e.g. hives, eczema, pruritus); or facial or generalized edema. Allergic reactions usually occur within 24 hours of immunization.
Local reaction	Local reactions, usually occurs within 5 days of immunization, of concern may include abscess (sterile or infected), or other severe local reactions, such as redness and swelling that extend beyond the nearest joint or last 4 days or more.
Systemic reaction	Systemic reactions usually occur within 5 days but may occur up to 3 months after immunization. Early onset ones of concern include toxic shock syndrome, hypotonic-hyporesponsive episode, persistent crying or screaming episodes, high fever (greater than 39 °C or 102.2 °F), sepsis, or rash (especially those lasts for 4 days or more or requires hospitalization). Thrombocytopenia (with platelet < 50,000/mm ³) may have a delayed onset.
Neurological disorders	Some neurological adverse reactions may be related to vaccination. Seizures (usually generalized convulsion), encephalopathy, meningitis or encephalitis, if occurred, may have an onset within 15 days of immunization. Brachial neuritis or Guillain-Barré Syndrome, if occurred within 3 months of immunization, may be related to the immunization.

5.1 FOLLOW-UP REPORTS

Acknowledgement with a unique reference number will be issued to each report received. Any follow-up information of an adverse drug reaction that has been reported to DH DO previously can be made on a new report form. Please indicate that it is a follow-up report and quote the unique reference number from the previous report.

6. HOW TO REPORT?

1. Report online by completing the online report form at <http://www.drugoffice.gov.hk/adr.html>; or
2. Download the report form (available at <http://www.drugoffice.gov.hk/adr.html>) and return the completed report by:
 - (i) email to adr@dh.gov.hk;
 - (ii) fax to 2319 6319; or
 - (iii) mail or delivery to the Pharmacovigilance Unit, Drug Office, Department of Health at Room 1856, Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong.

7. WHAT HAPPEN TO THE REPORT?

Any information related to the identities of the reporter and the patient will be kept in strict confidence.

All adverse drug reaction reports are reviewed by a team of professional staff. Serious adverse drug reaction reports may be reviewed by expert advisors if indicated.

Information of the report will be entered into the adverse drug reaction database system for analysis.

Through monitoring and analysis of adverse drug reaction reports, signals related to safety profile of medicines such as unexpected adverse drug reactions, unusual presentation of a known adverse drug reaction, or a susceptible patient group may be identified. These findings will initiate further evaluation to establish the possible role of a medicine in causing the reaction and provide important information for the DH DO to conduct necessary actions such as changes in marketing authorization or providing early warnings to healthcare professionals.

8. CONTACT FOR FURTHER INFORMATION

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

Phone: 2319 2920
Fax: 2319 6319
Email: adr@dh.gov.hk

APPENDIX 1. DH DO ADVERSE DRUG REACTION REPORT FORM



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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APPENDIX 2. STATEMENT OF PURPOSES

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