

Department of Health
Guidance Notes for ADR Reporting

Introduction

The World Health Organization defines Adverse Drug Reaction (ADR) as “a reaction to drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” ADR reporting/monitoring is important for post-marketing drug safety surveillance.

Doctors, Chinese medicine practitioners, dentists and pharmacists are encouraged to report suspected ADR of their patients to the ADR Monitoring Unit voluntarily. ADR reports can be submitted for all western and Chinese medicines (including Chinese herbs, proprietary Chinese medicines and vaccines). For suspected Chinese medicine poisoning cases that require investigation, please use the form "DH 1B", which can be downloaded at <http://www.chp.gov.hk/files/pdf/hpf-form3-en-20070214.pdf>.

To facilitate the assessment process, please provide the following information when reporting ADR: (i) name of the suspected drug including the brand name (for vaccine, please also provide batch/lot number), (ii) description of the reaction, (iii) information of the patient and (iv) contact telephone number of the person who submits the report. All reports are reviewed by professional staff of the Unit and safety alerts will be issued when new hazards are found.

What to report

Please report any of the following types of adverse reactions:

1. Suspected serious *ADR, even if the reactions are well known;
2. Suspected drug interactions;
3. Non-serious ADR but the reactions are deemed medically significant by the healthcare professional;
4. Unexpected ADR, i.e. the reactions are not consistent with product information or labeling.

*Note: Serious ADR is defined as an adverse reaction which:

- is fatal;
- is life-threatening;
- results in or prolongs hospitalisation;
- causes persistent incapacity or disability;
- causes birth defects.

In addition, ADR related to vaccine can be classified under one of the following 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 generalised edema. Allergic reactions usually occur within 24 hours of immunisation.
Local reaction	Local reactions, usually occurs within 5 days of immunisation, 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 immunisation. 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 hospitalisation). 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 immunisation. Brachial neuritis or Guillain-Barré Syndrome, if occurred within 3 months of immunisation, may be related to the immunisation.

If in doubt, please report.

You do not need to be certain that the suspected drug is related to the ADR before making the report.

How to report

Download an ADR report form

(available at <http://www.psdh.gov.hk/eps/eng/html/adrform-20.jsp>) and return the completed report by:

1. mail using the self-addressed ADR report form or send to the ADR Monitoring Unit, Pharmaceutical Service, Department of Health at 3/F, Public Health Lab. Centre, 382 Nam Cheong Street, Kowloon; or
2. fax to 2572 4570; or
3. email (please refer to the following instructions).

Reporting by email

1. Access to the electronic ADR report form,
2. Complete the report form,
3. Save the completed report in the computer,
4. Email the file to adr@dh.gov.hk

What information should be included in a report

An ADR report should contain all the essential information to assist assessment.

Please try and provide the following information as far as possible:

1. patient information (no need for full name of the patient; initials/ref. no. will be sufficient);
2. adverse reaction description (including the date of onset of reaction and, if related to a vaccine, adverse reaction category);
3. drug therapy or vaccine including name of the suspected and concomitant drug(s), dosage, route, dates of starting and stopping drug therapy, reason for use;
4. treatment of ADR;
5. outcome of the reaction;
6. sequelae of the reaction;
7. comments (e.g. allergies, relevant information - hepatic and renal functions, alcohol use, smoking);
8. reporter details (daytime contact telephone number must be provided for necessary follow-up).

Follow up of a report

Acknowledgment with a unique reference number will be issued to each report received. Please quote this number when sending in follow up information of previously submitted ADR report.

What happens to the report

- All ADR reports are reviewed by professional staff;
- Serious ADR reports may be reviewed by expert advisors if indicated;
- Information of the report will be entered into the ADR database system for analysis.

What regulatory actions can be taken

The ADR reports may identify some unexpected ADR, or indicate that certain ADR occur more commonly than previously expected, or that some patients are more susceptible to certain problems than others. Such findings can lead to the following changes to the products, for example: restrictions in use, refinement of dose instructions or introduction of specific warnings in the product literature. Rarely when a hazard is considered as unacceptable, a medicine may have to be withdrawn from the market.

Contact for further information

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