Guidance Notes for Adverse Drug Reaction (ADR) Reporting

Introduction

Adverse drug reaction (ADR) 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) collects ADR 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.

What is Adverse Drug Reaction?

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.”

Who and What to report?

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

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.

Healthcare professionals are encouraged to report the following ADR cases:

- All suspected serious ADR, even if the reaction is well known, which is
  - life-threatening or fatal (e.g. Stevens-Johnson Syndrome / Toxic Epidermal Necrosis, Torsades de pointes, fatal hepatotoxicity.);
  - results in or prolongs hospitalization (e.g. renal toxicity, hepatotoxicity)
  - causes persistent incapacity or disability (e.g. hearing loss);
  - causes birth defect
- Suspected drug interactions including drug-drug and drug-herb interactions;
- Non-serious ADRs but the reactions are deemed medically significant by the healthcare professional (e.g. increased frequency or unusual presentation of a known ADR);
- Unexpected ADRs, 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 ADR is related to the suspected drug.

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 (It is not necessary to provide the full name of the patient; initials/reference number of the patient for identification purpose will be sufficient);
- Adverse reaction description (including the date of the onset of the ADR; and if the ADR is related to a vaccine, please refer to the *Adverse Reaction Category);
- Drug therapy or vaccine (including the name of the suspected and concomitant drug(s), dosage, route of administration, dates of starting and stopping drug therapy, reason for use, batch number if it is related to a vaccine);
- Treatment of ADR;
- Outcome of the reaction;
- Sequelae of the reaction (e.g. fully recover, persistent disability, birth defect, medically significant event);
- Comments (e.g. allergies, relevant information such as hepatic and renal functions, alcohol use, smoking habit, etc.)
- Reporter details (please provide your daytime contact telephone number for necessary follow-up).

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

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<tr>
<th>Adverse Reaction Categories</th>
<th>Descriptions</th>
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<tr>
<td>Allergic reactions</td>
<td>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.</td>
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<tr>
<td>Local reaction</td>
<td>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.</td>
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<tr>
<td>Systemic reaction</td>
<td>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). Thrombocytopaenia (with platelet &lt; 50,000/mm³) may have a delayed onset.</td>
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<tr>
<td>Neurological disorders</td>
<td>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.</td>
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**How to report?**

1. Report online by completing the online ADR report form at [http://www.drugoffice.gov.hk/adr.html](http://www.drugoffice.gov.hk/adr.html); or

2. Download an ADR report form (also available at [http://www.drugoffice.gov.hk/adr.html](http://www.drugoffice.gov.hk/adr.html)) and return the completed report by:
   (i) mail using the self-addressed ADR report form or send to the Pharmacovigilance Unit, Drug Office, Department of Health at Room 1856, Wu Chung House, 213 Queen’s Road East, Wanchai, Hong Kong; or
   (ii) fax to 2186 9845; or
   (iii) email to adr@dh.gov.hk
Follow up reports

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

What happen to the report?

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

All ADR reports are reviewed by a team of 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.

Through monitoring and analysis of ADR reports, signals related to safety profile of medicines such as unexpected ADRs, unusual presentation of a known ADR, 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 Drug Office to conduct necessary actions such as changes in marketing authorization or providing early warnings to healthcare professionals.

Contact for further information

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