# 藥物不良反應（ADR）通報系統介紹及須知

## 1. 藥物不良反應：

藥物不良反應是指正常劑量的藥物用於預防、診斷、治療疾病或調節生理功能時所出現有害的、不理想的和意料之內/外的反應。

## 2. 通報項目：

任何涉及西藥（包括生物製劑、人類血液製品及放射性藥物在內的化學藥物）、中藥（包括中成藥、中藥材及中藥飲片）及天然藥物的不良反應。

## 3. 通報甚麼類型的藥物不良反應：

通報內容涵蓋所有可疑的藥物不良反應，如：(1)非預期的（無論嚴重與否或是否符合該藥物說明書及標籤的資料）; (2)嚴重的（無論預期與否）; (3)任何正常的處方和劑量導致病患病情惡化、住院或延長住院時間、持久性或嚴重的殘疾或喪失行為能力、生活受到威脅或死亡等；(4)藥物濫用、過量使用及療效不足；(5)藥物與藥物 / 食物交互作用等。

## 4. 通報條件：

無論不良反應為嚴重 / 非嚴重個案、確定 / 不確定是由藥物引起的懷疑個案，或任何未獲得所有的相關性資料之個案，皆可通報。

## 5. 通報內容：

通報者資料、病人基本資料、不良反應有關資料、可疑藥物的資料、併用藥物及其他相關資料等。

**6.** 通報者無需提供病人姓名，識別代號欄請由通報者填寫作為通報者確認及追蹤病人之用。請務必填寫通報者的姓名、聯絡電話、服務機構、地址等，如有電郵資料亦請填寫。

## 7. 跟進資料：

藥物監督管理局在獲取通報後，會通知通報者的個案編號，通報者如需提供進一步的補充資料，請在新的通報表上填寫該個案編號。

## 8. 表格索取：

每個個案使用一張表格，填妥後交往藥物監督管理局。

表格可於澳門特別行政區政府入口網站及藥物監督管理局網站（https://www.isaf.gov.mo）下載，亦可於藥物監督管理局索取。

## 9. 聯絡及通報方法：

以下述任一方式遞交通報資料：

- 親臨或郵寄（澳門投寄免付郵費）：
  澳門何賢紳士大馬路政府（青茂）辦公大樓 19 樓
- 傳真：2852 4016
- 電郵：fv@isaf.gov.mo
- 本地醫療專業人員及藥物註冊持有人亦可透過登入藥物監督管理局網站內藥物不良反應及藥物質量通報系統進行通報。
  如有疑問，請致電：8598 3233

## 10. 其他注意事項：

- 請用黑色或深色原子筆填寫通報表的五大項目：通報者資料、病人基本資料、不良反應有關資料、可疑藥物的資料、併用藥物及其他相關資料，各項資料請盡可能詳列。
- 填表時，若遇資料不明的情況，請使用：
  **UNK**：不知道；　**NA**：不適用；或
  **NI**：填表時尚無數據（如臨床檢查報告）。
- 如果表格欄位空間不足時，可另行使用A4大小紙張繕寫，並請註明相關欄位編號及名稱。

## 11. 收集個人資料聲明：

- 根據第8/2005號法律《個人資料保護法》的規定，為維護病人及通報者的權益，表格內提供資料完全保密，只用作跟進處理所通報的個案的用途。
- 上述資料有可能使用於統計及研究方面，但所得的統計數字及研究成果不會以能識別個人身份資料的形式公佈。
- 基於履行法定義務，上述資料可能轉交予警察當局、司法機關或其他有權限實體。
- 通報者有權依法申請查閱、更正或更新所提供的個人和其他有關的資料。

# Introduction and Guidelines of ADR Reporting System

## 1. Adverse drug reaction:

Adverse drug reaction is an expected or unexpected noxious and undesirable patient's response suspected to be associated with the use of drugs under normal doses for diagnosis, treatment, prevention of a disease or modification of physiological function.

## 2. Reporting items:

Any adverse reaction involving Western medicines (including biological agents, human blood products and radiopharmaceuticals), Chinese medicines (including Chinese proprietary medicines, Chinese herbal medicines and Chinese medicine decoction pieces) and natural medicines.

## 3. Types of adverse drug reaction to be reported:

Report all suspected ADRs such as: (1) unexpected (regardless of severity or even not consistent with drug information or labeling); (2) serious - whether expected or not; (3) reactions to drug that occurs at normally prescribed or at any dose leading to worsening of patient's condition, hospitalization or prolonged inpatient hospitalization, persistence or significant disability or incapacity, life-threatening or deaths; (4) Drug abuse, overdose, and poor efficacy; (5) Drug-drug/food interaction, etc.

## 4. Requirement for reporting :

Whether the suspected adverse reaction is serious or non-serious, with or without causality to drug use, or without obtaining all relevant information, it is eligible for a report to be made. Reporting an ADR does not imply a causal link.

## 5. Reporting contents:

Reporter information, patient data, details of adverse reaction, information of suspicious and concurrent drugs and other relevant information.

**6.** The reporter does not need to provide patient's name but instead an identification code, which serves for the reporter to trace his/her patient. Reporter must fill in his/her name, contacted phone number, institution, address and email whenever possible.

## 7. Follow-up information :

Acknowledgement with a unique reference number will be issued to the reporter for each report received by Pharmaceutical Administrative Bureau. When follow-up information is provided by the reporter, please address this reference number in the new report form.

## 8. Form request:

The ADR report form can be downloaded from the government portal of Macau SAR and Pharmaceutical Administration Bureau website (https://www.isaf.gov.mo). It is also available at the Pharmaceutical Administration Bureau. Use a separated form for each case being reported and send your completed form to Pharmaceutical Administration Bureau through any of the following means.

## 9. Ways to contact and report:

Use any of the following ways to submit your filled ADR report form：

- In person or by mail (free postage for Macau posting)：
  Avenida do Comendador Ho Yin, Edifício de Escritórios do Governo (Qingmao), 19.º andar, Macau
- Fax：28524016
- Email：fv@isaf.gov.mo
- Local health professionals and drug license holder can also report adverse drug reaction by logging on to the online ADR and drug quality reporting system on the Pharmaceutical Administration Bureau website.

For any enquiries, please call: 8598 3233

## 10. Other reminders:

- Please fill in the four major columns of the form with a black or dark color ball-pen encompassing reporter information, patient data, details of adverse reaction, information of suspicious and concurrent drugs and other relevant information. Please fill in the form as detail as possible.
- Please use the following abbreviations to fill in the indicated space in case of the information is unclear at the time of filling the form:
  **UNK:** Unknown **NA:** Not applicable
  **NI:** Data not available yet. (e.g. medical examination report)
- If space provided is insufficient, enclosed onto this form with additional blank A4 size paper and indicate the row, column and name of relevant section(s).

## 11. Personal data collection statement:

- In accordance with the provisions of Law no. 8/2005 on the "Protection of Personal Data", in order to safeguard the rights and interests of patients and reporters, the information provided in the ADR report form is completely confidential and is only used for follow-up of the reported cases.
- The above information may be used in statistics and research, but the statistics data and research results obtained will not be published in the way of disclosure of any personal identity.
- For the purpose of fulfilling the legal obligation, the above information may be transferred to police authorities, judicial authorities or other competent entities.
- The reporter has the right to apply in accordance with provision of the law for review, correction or updating of the personal and other relevant information provided.