

藥物質量通報系統介紹及須知

1. 藥物質量問題通報的重要性：

打擊偽造和不符合標準的藥物流通於本澳市場，確保本澳市場流通的藥物的質量、有效性及安全性，保障市民用藥安全及健康。

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）及天然藥物的質量問題。

3. 通報內容：

通報者資料、藥物質量問題的資料及可疑藥物的資料等。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。

4. 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。

5. 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。

6. 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問題通報系統進行通報。
- 如有疑問，請致電：8598 3233

7. 其他注意事項：

- ❖ 請用黑色或深色原子筆填寫通報表三大項目：通報者資料、藥物質量問題的資料及可疑藥物的資料，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。(如藥物檢驗報告)
- ❖ 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。

8. 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 Drug Quality Reporting System

1. The importance of drug quality problem reporting system:

Combating the circulation of counterfeit and substandard drugs in the Macao market. Ensuring the quality, effectiveness and safety of drugs for the sake of protecting the safe use of drugs and public health.

2. Reporting items:

Any drug quality problem 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. Reporting contents:

Reporter information, details of drug quality problem and information of suspicious drug etc.. Reporter must fill in his/her name, contacted phone number, institution, address and email whenever possible.

4. 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.

5. Form request:

The 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.

6. Ways to contact and report:

Use any of the following ways to submit your filled 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 drug quality problem 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

7. Other reminders:

- ❖ Please fill in the three major columns of the form with a black or dark color ball-pen encompassing reporter information, details of drug quality problem and information of suspicious drug. 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. drug test 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).

8. 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 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.