药物不良反应（ADR）通报系统介绍及须知

1. 药物不良反应：

药物不良反应是指正常剂量的药物用于预防、诊断、治疗疾病或调节生理功能时所出现有害的、不理想的和意料之内/外的反应。

2. 通报项目：

任何涉及西药（包括生物制剂、人类血液制品及放射性药物在内的化学药物）、中药（包括中成药、中药材及中药饮片）及天然药物的不良反应。

3. 通报甚么类型的药物不良反应：

通报内容涵盖所有可疑的药物不良反应，如：(1)非预期的（无论严重与否或是否符合该药物说明书及标签的资料）；(2)严重的（无论预期与否）；(3)任何正常的处方和剂量导致病患病情恶化、住院或延长住院时间、持久性或严重的残疾或丧失行为能力、生活受到威胁或死亡等；(4)药物滥用、过量使用及疗效不足；(5)药物与药物 / 食物交互作用等。

4. 通报条件：

无论不良反应为严重 / 非严重个案、确定 / 不确定是由药物引起的怀疑个案，或任何未获得所有的相关性资料之个案，皆可通报。

5. 通报内容：

通报者资料、病人基本资料、不良反应有关资料、可疑药物的资料、并用药物及其他相关资料等。

6. 通报者无需提供病人姓名，识别代号栏请由通报者填写作为通报者确认及追踪病人之用。请务必填写通报者的姓名、联络电话、服务机构、地址等，如有电邮资料亦请填写。

7. 跟进资料：

药物监督管理局在获取通报后，会通知通报者的个案编号，通报者如需提供进一步的补充资料，请在新的通报表上填写该个案编号。

8. 表格索取：

每个个案使用一张表格，填妥后交往药物监督管理局。

表格可于澳门特别行政区政府入口网站及药物监督管理局网站（https://www.isaf.gov.mo）下载，亦可于药物监督管理局索取。

9. 联络及通报方法：

以下述任一方式递交通报资料：

- 亲临或邮寄（澳门投寄免付邮费）：
  澳门何贤绅士大马路政府（青茂）办公大楼 19 楼
- 传真：2852 4016
- 电邮：fv@isaf.gov.mo
- 本地医疗专业人员及药物注册持有人亦可透过登入药物监督管理局网站内药物不良反应及药物质量通报系统进行通报。
  如有疑问，请致电：8598 3233

10. 其他注意事项：

- 请用黑色或深色原子笔填写通报表的五大项目：通报者资料、病人基本资料、不良反应有关资料、可疑药物的资料、并用药物及其他相关资料，各项资料请尽可能详列。
- 填表时，若遇资料不明的情况，请使用：
  UNK：不知道；　**NA**：不适用；或
  NI：填表时尚无数据（如临床检查报告）。
- 如果表格栏位空间不足时，可另行使用A4大小纸张缮写，并请注明相关栏位编号及名称。

11. 收集个人资料声明：

- 根据第8/2005号法律《个人资料保护法》的规定，为维护病人及通报者的权益，表格内提供资料完全保密，只用作跟进处理所通报的个案的用途。
- 上述资料有可能使用于统计及研究方面，但所得的统计数字及研究成果不会以能识别个人身份资料的形式公布。
- 基于履行法定义务，上述资料可能转交予警察当局、司法机关或其他有权限实体。
- 通报者有权依法申请查阅、更正或更新所提供的个人和其他有关的资料。

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.