



GUIDELINE ON MEDICATION ERROR REPORTING

Ministry of Health Malaysia

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ON
MEDICATION ERROR
REPORTING**

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First Edition

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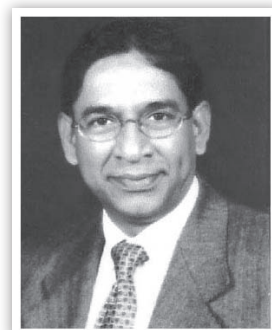
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ACKNOWLEDGEMENT

The Pharmaceutical Services Division
Ministry of Health
would like to express our heartfelt gratitude to
members of the Patient Safety Council of Malaysia (PSCoM),
Medication Safety Technical Advisory Committee (MedSTAC),
Medication Safety Committee, Pharmaceutical Services Division
and
other contributors for their valuable and constructive comments
in the completion of this guideline.



Director General of Health
Ministry of Health Malaysia



Pharmacotherapy remains the primary mode of treatment for patients today. In the Ministry of Health Malaysia alone, a total of 33.6 million prescriptions were dispensed at the outpatient pharmacy while 7.9 million prescriptions were filled for inpatients in the year 2008 compared to 32 million and 6.9 million prescriptions respectively the previous year. This shows a significant increase in the number of prescriptions filled and dispensed by pharmacy and the growing trend is very likely to continue in the years ahead.

The large amount of medications used as well as the availability of new and potent medicines requires us to further enhance the awareness on medication safety. Recognizing the importance of ensuring patient safety, such initiative must be targeted at all levels and should look into the various systems and processes involved in the entire medicines management cycle.

It is indeed very encouraging that the Pharmaceutical Services Division, Ministry of Health Malaysia has continuously implement quality improvement efforts towards increasing patient safety. The formation of the Medication Safety Technical Advisory Committee (MedSTAC), a committee under the Patient Safety Council of Malaysia certainly serves as an effective mechanism to enhance medication safety. I would like to commend the Pharmaceutical Services Division for steering this committee.

I hope the Medication Error Reporting System established will create a paradigm shift for the healthcare team towards developing a non-punitive culture. The



resulting exchange of knowledge and experience will surely help to promote the implementation of safety measures associated with medications, hence preventing costly and tragic losses. To ensure successful implementation, I urge all healthcare providers from both the public and private sectors to participate in this reporting system.

Finally, I wish to thank all of you who have contributed precious time and effort in developing this guideline as one of the benchmarks in ensuring a safe healthcare system for all Malaysians.

Thank you.

With Best Regards,



TAN SRI DATO' SERI DR. HJ. MOHD ISMAIL MERICAN
Director General of Health Malaysia



Senior Director Pharmaceutical Services
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The Pharmaceutical Services Division, Ministry of Health Malaysia had introduced the Pharmacy Quality Assurance Program since the 1980's. Data collected related to medication safety includes prescriptions intervened, wrongly dispensed medications and wrongly filled medications (but detected before dispensing) at hospitals and clinics. However, the information obtained was only limited to prescribing and dispensing practices. There were no data available on other processes in the medicines management cycle such as preparation and administration of medications. Hence, there is a need for a reporting system that incorporates all processes involved in the management of medicines to collect and collate relevant information for necessary remedial actions.

With guidance and cooperation of the Medication Safety Technical Advisory Committee, the Pharmaceutical Services Division has embarked on a reporting system called the Medication Error Reporting System (MERS). The aim of this system is to establish a database on medication errors which includes all error reports related to medication use in the prescribing, administration, dispensing and preparation.

Subsequently, a Medication Safety Centre under the Pharmaceutical Services Division has been established to manage the system. Reviews of the medication error reports will be carried out by the National Medication Error Committee, which comprises of members from the public and private sectors. Dissemination of information and sharing of knowledge and experience will be the primary



focus towards improving systems related to medication safety. As reporting of medication errors is done on a voluntary basis, the crucial task now is to encourage all healthcare providers to report medication errors so that risk reduction strategies can be formulated to promote safe medication use.

In conclusion, I would like to express my heartfelt appreciation to the drafting team as well as all those who have strived together with us in our endeavour to develop this important guideline. It is also my fervent hope that the guideline will serve its purpose well in our challenge to reduce medication errors and ultimately ensure patient safety.

Thank you.



EISAH A. RAHMAN
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia



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INTRODUCTION

One of the important missions of the healthcare providers is to help patients make the best use of medications and very importantly, strive to ensure patient safety. Medication safety is one of the major components in patient safety but unfortunately medication errors do occur and often go undetected. Some medication errors may result in serious patient morbidity and mortality, thus we need to further strengthen the current system with a mechanism to monitor and make recommendations for remedial actions when errors occur and are reported. The proposed mechanism is a 'Medication Error Reporting System' through which medication errors will be monitored and preventive measures can be defined. This system requires a collective effort from various parties and a change in the way we manage medication errors. We need to be able to discuss errors openly, encourage reporting of errors and maintain a culture that is non-punitive and blamelessness. With this, healthcare providers will be able to learn from the errors.

MEDICATION ERROR

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such an event may be related to professional practices, healthcare products, procedures and systems including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

Medication errors may be committed by both inexperienced and experienced personnel like doctors, pharmacists, dentists and other healthcare providers, patients, manufacturers, caregivers and others.

MEDICATION SAFETY CENTRE (MedSC) AND CONFIDENTIALITY

In Malaysia, medication error reporting is at the moment on a voluntary basis. Under the Malaysian Medication Error Reporting System, it is proposed that a Medication Safety Centre (MedSC) be established. The MedSC will solicit and encourage reporting of medication errors and will maintain strict confidentiality with regards to the identity of patients and the healthcare providers involved.

ESTABLISHMENT AND MEMBERSHIP OF THE NATIONAL MEDICATION ERROR COMMITTEE (NMEC)

1. There shall be established a National Medication Error Committee (hereinafter referred to as “the Committee”) consisting of the following members:
 - a. the Senior Director of Pharmaceutical Services, Ministry of Health (MOH) – Chairperson
 - b. the Director of Pharmacy Practice and Development, MOH
 - c. a representative from the Medical Development Division, MOH
 - d. fourteen other members to be appointed by the Director General of Health:
 - i. a physician from MOH
 - ii. a hospital pharmacist from MOH
 - iii. a physician from a university hospital
 - iv. a pharmacist from any local universities with expertise in clinical pharmacy practice
 - v. a physician from the Association of Private Hospitals of Malaysia (APHM)
 - vi. a hospital pharmacist from the Malaysian Armed Forces
 - vii. a Family Medicine Specialist from MOH
 - viii. a representative from the Malaysian Medical Association

- ix. a representative from the Federation of Private Medical Practitioners Association
 - x. a representative from the Community Pharmacy Chapter, Malaysian Pharmaceutical Society (MPS)
 - xi. a representative from the Private Hospital Pharmacy Chapter, MPS
 - xii. a representative from the Malaysian Dental Association
 - xiii. a representative from the Malaysian Nursing Board
 - xiv. a representative from the Malaysian Medical Assistants Board
2. A member appointed under this guideline shall, unless he sooner resigns, holds office for a period of three years.
 3. The Senior Director of Pharmaceutical Services, MOH shall preside at the meetings of the Committee. In his absence, the Director of Pharmacy Practice and Development will act as Chairperson.
 4. The Committee may at any time and without assigning any reason, suspend or terminate the appointment of any member appointed under this guideline.
 5. Terms of Reference for the Committee members are:
 - a. to study and grade the medication error reports received;
 - b. to propose remedial actions in relation to the medication errors; and
 - c. to actively promote medication error reporting in Malaysia

SECRETARIAT

The Medication Safety Centre (MedSC)
is the Secretariat to the Committee.

MEETINGS

1. Five members including the chairperson shall form a quorum
2. The Committee may invite any person not appointed under this Guideline to attend any meeting of the Committee but such person shall not have the right to vote at the meeting
3. The Committee shall meet at least twice a year.

ADVISORS

The Committee may appoint any person or persons as it may think necessary as advisors.

SCOPE OF MEDICATION ERROR REPORTING

All medication errors involving any medicine used both in public and private sectors should be reported.

OBJECTIVES AND IMPACT OF MEDICATION ERROR REPORTING

The primary objective of medication error reporting is to obtain information on the occurrence of medication errors, maintain a database of medication errors, analyse reports, propose remedial actions and monitor the situations in an effort to minimise the reoccurrence of such errors and, ultimately, to improve patient safety.

PROCEDURES FOR REPORTING

1. General

All Medication Error Reports should be sent to:

Medication Safety Centre
Pharmaceutical Services Division
Ministry of Health Malaysia
P.O. Box 924, Jalan Sultan
46790 Petaling Jaya
Selangor

or

Fax to 03-79682268 or call 03-78413200 for enquiries

2. Reporting Format

Medication Error should be reported using the prescribed format which is available from the Pharmaceutical Services Division website (www.pharmacy.gov.my.)

Refer page 12-15 for the Medication Error (ME) Report Form.

TYPES OF MEDICATION ERROR

TYPE	DEFINITION
a Prescribing Error	Incorrect drug product selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route of administration, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors.
b Omission error	The failure to administer an ordered dose to a patient before the next scheduled dose or failure to prescribe a drug product that is indicated for the patient. The failure to administer an ordered dose excludes patient's refusal and clinical decision or other valid reason not to administer.
c Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual healthcare facility).
d Unauthorised drug error	Dispensing or administration to the patient of medication not authorised by a legitimate prescriber.
e Dose error	Dispensing or administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of multiple doses to the patient, i.e. one or more dosage units in addition to those that were ordered.
f Dosage form error	Dispensing or administration to the patient of a drug product in a different dosage form than that ordered by the prescriber.
g Drug preparation error	Drug product incorrectly formulated or manipulated before dispensing or administration.
h Route of administration error	Wrong route of administration of the correct drug.
i Administration technique error	Inappropriate procedure or improper technique in the administration of a drug other than wrong route.
j Deteriorated drug error	Dispensing or administration of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised.
k Monitoring error	Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.
l Compliance error	Inappropriate patient behavior regarding adherence to a prescribed medication regimen.
m Other medication error	Any medication error that does not fall into one of the above predefined types.

CLASSIFICATION OF MEDICATION ERROR SEVERITY

NO ERROR

Category A	Potential error, circumstances/events that have the potential to cause incident.
------------	--

ERROR, NO HARM

Category B	An error occurred but the error did not reach the patient (an 'error of omission' does reach the patient).
Category C	An error occurred that reached the patient but did not cause patient harm.
Category D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

ERROR, HARM

Category E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
Category F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation.
Category G	An error occurred that may have contributed to or resulted in permanent patient harm.
Category H	An error occurred that required intervention necessary to sustain life.

ERROR, DEATH

Category I	An error occurred that may have contributed to or resulted in the patient's death.
------------	--

The committee will evaluate all medication errors reports for proper classification of the error or potential error.

BASIC PRINCIPLES OF EFFICIENT REPORTING

Whenever possible, the decision to report should be taken whilst the patient is still with the healthcare provider so that he/she can easily be interviewed about the errors and its details.

All reports must have:

- Identifiable reporter
- Date of incident
- Error description
- Name of drug(s) involved
- 5 W's and 1 H: Who, What, When, Why, Where and How of the incident

MANAGING MEDICATION ERRORS

Quality improvement programs should provide guidance for patient support, staff education and counseling and risk management processes when medication errors are detected. Incident reporting and procedures, appropriate counseling, education and intervention programs should be established in all healthcare facilities.

Recommended actions to be taken when a medication error is encountered:

- Provide the necessary corrective and supportive therapy to the patient
- Document and report immediately after discovery of the error in accordance to standard operating procedure.
- For clinically significant errors, information gathering and investigation should be initiated immediately. Information should include what happened, when and where the incident occurred, possible causes as to why

the incident occurred, how the incident occurred and who was involved. Appropriate product evidence (product, packaging, labeling etc) should be retrieved and retained for future reference until the investigation has been completed.

- Reports on medication errors which include the corrective and preventive measures should be reviewed by the respective head of sections and the organizational head.

ANALYSIS AND USE OF MEDICATION ERROR REPORTS

- (a) All medication error reports that have been graded by the Committee will be compiled and analysed by the Medication Safety Centre secretariat.
- (b) Medication error data collected will be used in formulating strategies to further improve the quality and safety of medication use. Medication error reports help to ensure that the implementation of error-reduction programmes are focused at problem areas as identified through this Medication Error Reporting System. Useful information on medication error reduction or prevention to relevant bodies will help to strengthen efforts in improving patient safety in our healthcare system.

GLOSSARY AND ABBREVIATIONS

Glossary

Harm

Impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g. cardiopulmonary resuscitation, defibrillation, intubation, etc.)

Abbreviations

ME	:	Medication Error
MedSC	:	Medication Safety Centre
NMEC	:	National Medication Error Committee
MOH	:	Ministry of Health
NCCMERP	:	National Coordinating Council for Medication Error Reporting and Prevention, U.S Pharmacopeia

REFERENCES

1. National Coordinating Council for Medication Error Reporting Program and Prevention 2001
2. American Society of Hospital Pharmacists (ASHP) Report – ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm.* 1993; 50:305-314
3. Institute for Safe Medication Practices (www.ismp.org)
4. Adverse Drug Reaction Reporting System. National Pharmaceutical Control Bureau 2006
5. Michael Cohen 1999. Medication Errors
6. Institute of Medicine Committee on the Quality of Health Care in America Report – To Err is Human: Building a Safer Health System 1999



Pharmaceutical Services Division
 Ministry of Health Malaysia
 www.pharmacy.gov.my
 Tel: 03-78413200 Fax: 03-79682268

MEDICATION ERROR (ME) REPORT FORM

BPF/104/ME/01

Reporters do not necessarily have to provide any individual identifiable health information, including names of practitioners, names of patients, names of healthcare facilities, or dates of birth (age is acceptable)

<p>1 Date of event: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd/mm/yy</p> <p>Time of event: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> hh/mm (24 hr)</p>	<p>Type of Facility: * Government/ Private</p> <p><input type="checkbox"/> Hospital <input type="checkbox"/> Clinic <input type="checkbox"/> Pharmacy</p> <p><input type="checkbox"/> Others: _____</p>	<p>Location of event:</p> <p><input type="checkbox"/> Ward <input type="checkbox"/> A&E <input type="checkbox"/> Clinic <input type="checkbox"/> Pharmacy</p> <p><input type="checkbox"/> Others: _____</p>
<p>2 Please describe the error. Include description/ sequence of events and work environment (e.g. change of shift, short staffing, during peak hours). If more space is needed, please attach a separate page.</p>		
<p>3 In which process did the error occur?</p> <p><input type="checkbox"/> Prescribing</p> <p><input type="checkbox"/> Dispensing (includes filling)</p> <p><input type="checkbox"/> Administration</p> <p><input type="checkbox"/> Others (Please specify) : _____</p>		
<p>4 Did the error reach the patient? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Was the incorrect medication, dose or dosage form administered to or taken by the patient? <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>4.2 Please tick the appropriate ** Error Outcome Category (Select one)</p> <p>NO ERROR</p> <p><input type="checkbox"/> A Potential error, circumstances/ events have potential to cause incident</p> <p>ERROR, NO HARM</p> <p><input type="checkbox"/> B Actual Error - did not reach patient</p> <p><input type="checkbox"/> C Actual Error - caused no harm</p> <p><input type="checkbox"/> D Additional monitoring required - caused no harm</p>	
<p>4.1 Describe the direct result on the patient (e.g. death, type of harm, additional patient monitoring).</p>	<p>ERROR, HARM</p> <p><input type="checkbox"/> E Treatment/ intervention required - caused temporary harm</p> <p><input type="checkbox"/> F Initial/ prolonged hospitalization - caused temporary harm</p> <p><input type="checkbox"/> G Caused permanent harm</p> <p><input type="checkbox"/> H Near death event</p> <p>ERROR, DEATH</p> <p><input type="checkbox"/> I Death</p>	

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5 Indicate the possible error cause(s) and contributing factor(s)

- 5 Indicate the possible error cause(s) and contributing factor(s)
- Inexperienced Personnel Peak hour Stock arrangement/ storage problem
 Failure to adhere to work procedure Illegible prescription Sound alike medication
 Look alike medication/ packaging Patient information/ record unavailable/ inaccurate Wrong labelling/ instruction on dispensing envelope or bottle/container
 Others (Please specify) : _____

- 6 Which category made the initial error?
- Doctor Pharmacist Doctor Pharmacist
 Nurse Pharmacist Asst. Nurse Pharmacist Asst.
 Asst. Medical Officer Others : _____ Asst. Medical Officer Others : _____

- 7 Other category also involved in the error?
- Doctor Pharmacist
 Nurse Pharmacist Asst.
 Asst. Medical Officer Others : _____

- 8 Which category detected the error or recognised the potential error?
- Doctor Pharmacist
 Nurse Pharmacist Asst.
 Asst. Medical Officer Others : _____

- 9 If available, please provide patient's particulars (Do not provide any patient identifiers).

Age: * years/ months Gender: Male Female Diagnosis: _____

- 10 Please complete the following for the product(s) involved. If more space is needed for additional products, kindly attach a separate page. For similar packaging, please fill 10.4 to 10.7

Product Description	Product # 1 (intended)	Product #1 (error)
10.1 Brand/ Product Name		
10.2 Generic Name (Active Ingredient)		
10.3 Dose, frequency, duration, route		
10.4 Manufacturer		
10.5 Dosage Form		
10.6 Strength/ Concentration		
10.7 Type and Size of Container		

* Please delete where not applicable

11 Reports are most useful when relevant materials such as product label, copy of prescription/ order, etc., can be reviewed. Can these materials be provided?

- No _____
 Yes, Please specify: _____

12 Suggest any recommendations, or describe policies or procedures you instituted or plan to institute to prevent future similar errors. If available, kindly attach investigational report e.g. Root Cause Analysis (RCA).

Reporter's Details

Name and Profession :	
Facility/ Address :	Postcode : <input type="text"/>
E-mail :	
Telephone number :	Fax Number :

For official use :

Date report received : dd/mm/yy

Ref. No.

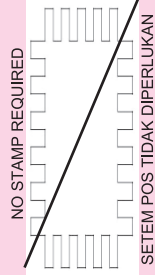
ME Type

ME Category

(Fold here)

Is Everyone's Responsibility

(Fold here)

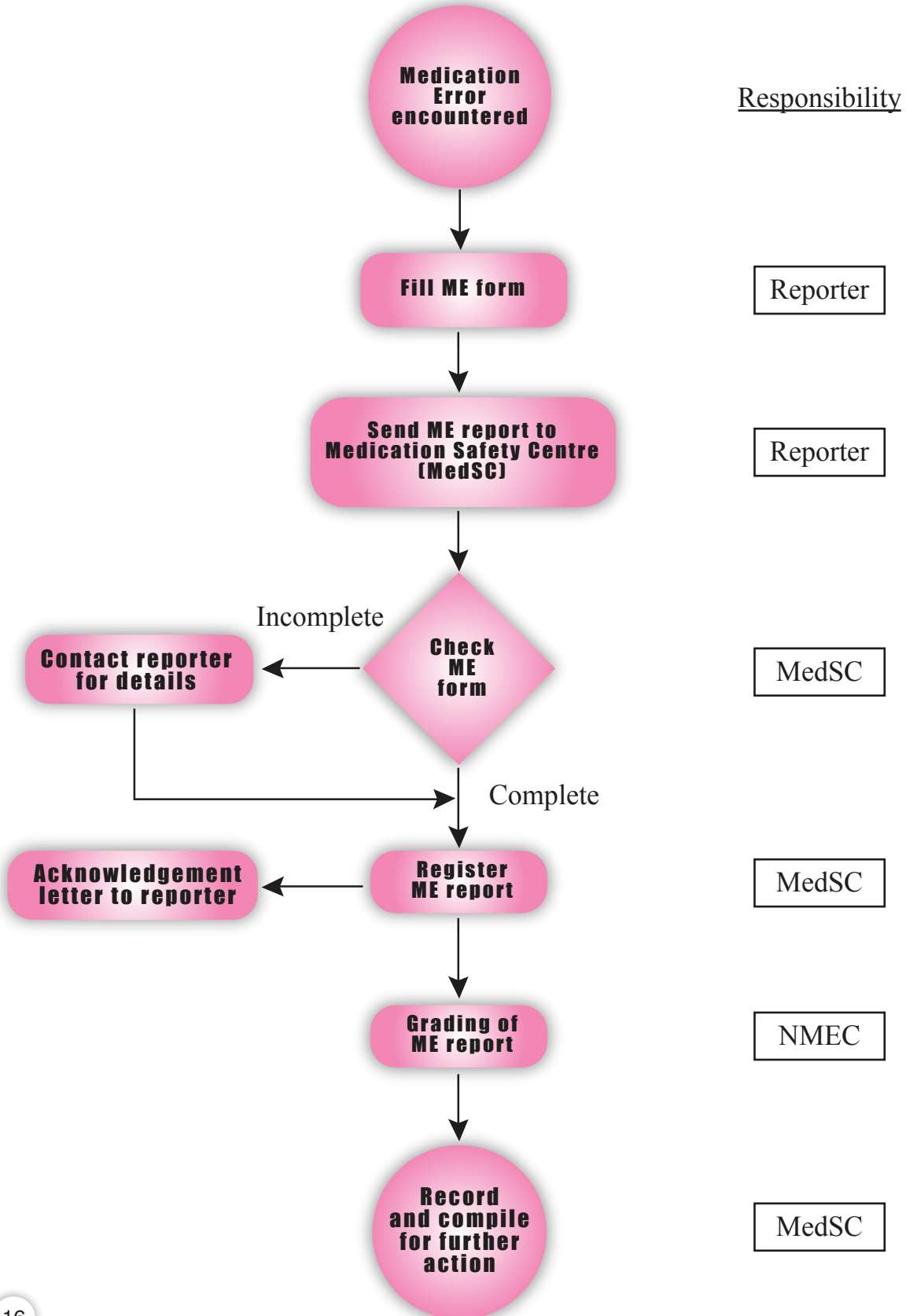


**REPLY PAID / JAWAPAN BERBAYAR
MALAYSIA**

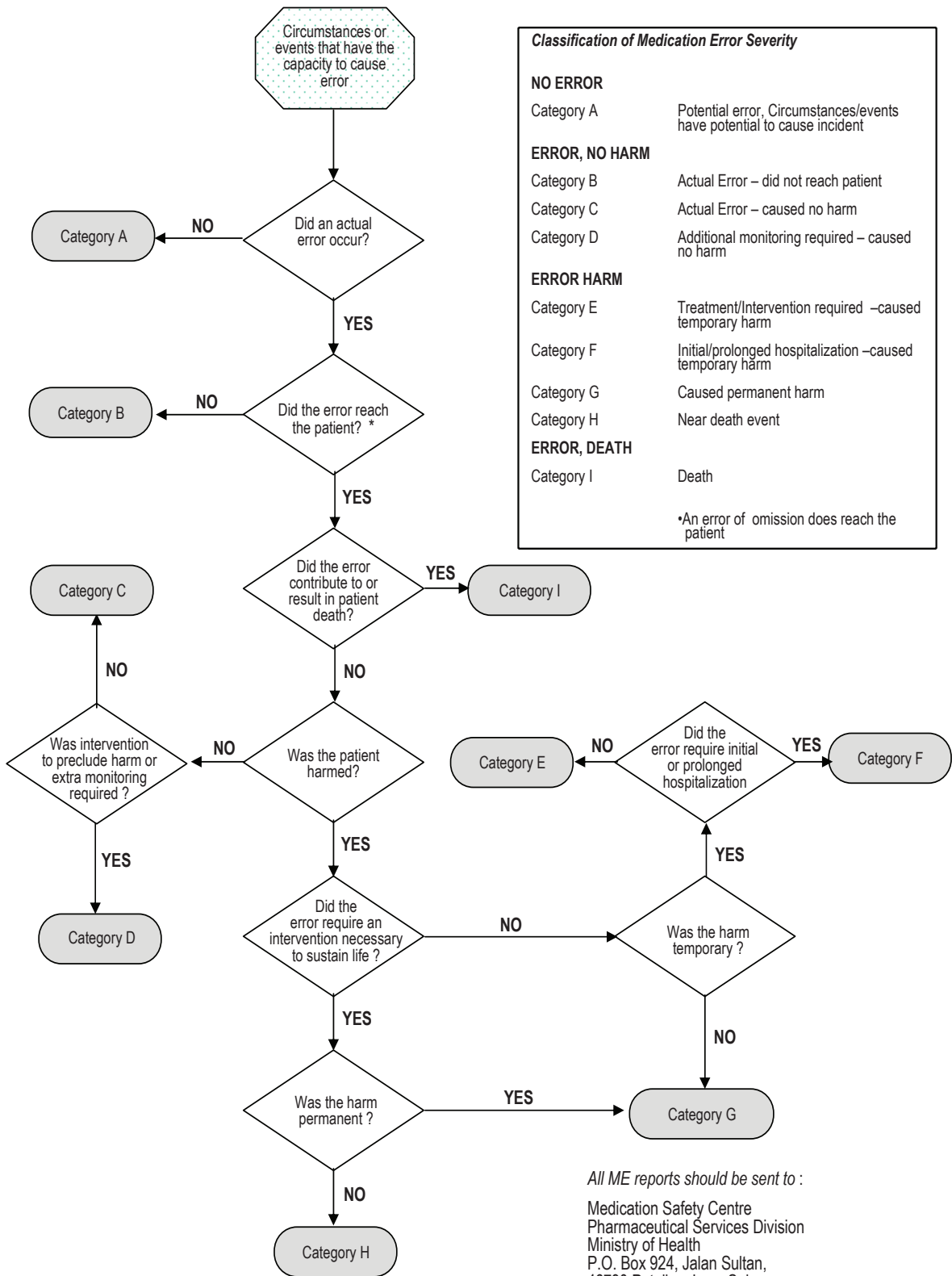
No. Lesen : BRS 0915 SEL

Medication Safety Centre (MedSC),
Pharmaceutical Services Division,
Ministry Of Health Malaysia,
P.O. Box 924, Jalan Sultan,
46790 Petaling Jaya, Selangor.

MEDICATION ERROR (ME) REPORTING FLOWCHART



GUIDE FOR CATEGORIZING MEDICATION ERRORS



Classification of Medication Error Severity	
NO ERROR	
Category A	Potential error, Circumstances/events have potential to cause incident
ERROR, NO HARM	
Category B	Actual Error – did not reach patient
Category C	Actual Error – caused no harm
Category D	Additional monitoring required – caused no harm
ERROR HARM	
Category E	Treatment/Intervention required –caused temporary harm
Category F	Initial/prolonged hospitalization –caused temporary harm
Category G	Caused permanent harm
Category H	Near death event
ERROR, DEATH	
Category I	Death
*An error of omission does reach the patient	

All ME reports should be sent to :
 Medication Safety Centre
 Pharmaceutical Services Division
 Ministry of Health
 P.O. Box 924, Jalan Sultan,
 46790 Petaling Jaya, Selangor.
 or
 Tel: 03-78413200 Fax: 03-79682268
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