GUIDELINE ON MEDICATION ERROR REPORTING SYSTEM (MERS)

Pharmaceutical Services Programme
Ministry of Health Malaysia

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Second Edition

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Summary Medication Error Reporting System (MERS) is a national reporting system which was introduced by the Pharmaceutical Services Programme, Ministry of Health Malaysia since 2009. It serves as a platform to encourage healthcare professionals to report any medication error encountered.

This guideline describes the management of medication error and the step-by-step process on how to fill and submit report to the Medication Error Reporting System (MERS).

Replaces Document

1) Guideline On Medication Error Reporting First Edition July 2009
2) Medication Error Reporting System (MERS) User Manual 2017

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Applies to All government and private healthcare facilities

Audience Healthcare professionals

Updated Date February 2021

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CONTENT

Content

ACKNOWLEDGEMENT

First and foremost we like to express our sincere gratitude to the authors and individuals involved directly or indirectly for their valuable and constructive comments in the establishment of this guidelines.

We wish to thanks all Medication Safety Liaison Officers in the state level for their support and efforts towards promoting and improving medication safety practice in the hospitals and health clinics.

Not to forget, our extend appreciation to all the healthcare personnel in the hospitals and health clinics for their commitment, teamwork and initiative in ensuring safe medication practice.

Last but not least, we would like to acknowledge and thanks to all healthcare professionals for their constant reporting medication errors and every efforts taken to prevent medication errors in their facilities.

Pharmaceutical Services Programme
Ministry of Health Malaysia

EDITORIAL MEMBERS

INTRODUCTION

INTRODUCTION

Medication safety is one of the vital components in patient safety. Unfortunately medication errors do occur and often go undetected. Some medication errors may result in serious patient morbidity and mortality. Error detection through an active management and effective reporting system discloses medication error and encourage safe practice. Hence, Medication Error Reporting System also known as MERS was introduced in 2009 as a mechanism tool and platform for monitoring medication errors at the national level. The reporting system will encourage all healthcare professionals to report any medication errors encountered. In 2013, MERS was upgraded to online system to provide easier access on reporting and sharing the lesson learnt from incident that happened.

The primary objective of medication error reporting is to obtain information and maintain a database on the occurrence of all medication errors related to medication use in prescribing, dispensing, administration, monitoring and others process involved in medication management system. The reports which submitted through MERS will be analysed to establish risk reduction strategies and promote safe medication use.

Findings from MERS will provide important knowledge that can be used as a guide in developing strategies, policies and action plan to strengthen the current healthcare system. This system requires a collective effort from various parties and a change in the way of management of 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.

All the report submitted will maintain confidentiality with regards to the identity of patients and the healthcare professionals involved.

DEFINITIONS

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Medication Error

Any **preventable event** that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Actual Error

- Medication error occurred and **reached the patient**.
- If the error is detected by the patient, it is considered as **actual error**.

Near Miss

- Medication error that has the potential to cause an adverse event (patient harm) but **did not reach the patient** because of chance or because it is intercepted in the medication use process.
- If the healthcare personnel detected **and corrected the error BEFORE it reaches the patient**, it is considered as **near miss**.

References
1. World Health Organization (WHO)
2. United States National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
3. Agency for Healthcare Research and Quality (AHRQ)

ABOUT THIS GUIDELINE

PURPOSE OF THIS GUIDELINE

1. This guideline serves as a reference for healthcare professionals on how to report medication errors.
2. To emphasize on the quality reporting of medication errors

SCOPE OF REPORTING

- Medication Error Reporting System (MERS) is used to report all medication errors (including near miss and actual error) involving any medicine used both in public and private healthcare facilities.
- Cases that shall not be reported to MERS include:

  a) Administrative errors
  e.g. no countersign for List A medications, doctor signed prescription without official chop and prescribed medication which is not available in the facility's formulary.

  b) Doctor prescribed drug that the patient is allergic to without previous patient history. In this case, please report to the National Centre for Adverse Drug Reactions Monitoring.

  c) Pharmacist's intervention due to treatment optimization (e.g. suggest to increase the insulin dose because the blood glucose is not well-controlled with the current dose).

REPORTING MEDIUM

Medication error reports can be submitted online or manually.

a) ONLINE

Submit reports through https://mers.pharmacy.gov.my

b) MANUAL

Refer Appendices : Medication Error (ME) Report Form

1. Reporters are encouraged to submit reports online.
2. The manual reporting form is to be submitted to the person-in-charge for medication error reporting in the facility.
3. If your facility is not listed in the system, especially the private healthcare facilities, kindly e-mail to mers@moh.gov.my.

MANAGEMENT OF MEDICATION ERROR

MANAGEMENT OF MEDICATION ERROR

1) REPORTING MEDICATION ERROR

- Detect and report any medication error encountered.
- Reportable events include both actual errors and the errors that have been detected and corrected before reach the patient.
- Document and report immediately after detected the error in accordance to the standard process/ work flow of the facilities.

2) ANALYSIS AND MONITORING OF MEDICATION ERROR

- Analyse medication error reports regularly and the findings are shared with all the staff.
- Conduct root cause analysis (RCA) to identify the root cause of the error and action(s) to eliminate it (refer to Guidelines on Implementation Incident Reporting & Learning System 2.0 for Ministry of Health Malaysia Hospital First Edition 2017)

3) ESTABLISHING ERROR PREVENTIVE STRATEGIES

- Establish Patient/ Medication Safety committee to discuss all patient safety related issues.
- Establish/ Implement error prevention strategies that focus on system design/ safe behavioural practices and are monitored continuously.
- Include medication safety elements in the ward check list/ pharmacy visit list/ audit.

MANAGEMENT OF MEDICATION ERROR

4) DISSEMINATION OF INFORMATION

- Organize continuous education/learning sessions to share all the medication errors and the error preventive strategies among the staff.

5) QUALITY IMPROVEMENT PROGRAMME

- Record and analyse all the drug selection, preparation, labelling and filling errors identified during routine checking processes for the quality improvement activities in the facility (e.g. establishing policies/protocols/guidelines, staff awareness and education).

6) ADOPT JUST CULTURE

- Adopt JUST CULTURE model of shared accountability for safe system design and behavioural changes supported by the high level managements. Just culture encourages individuals to speak up and to report a medication error, allows for the proper judgement of the medication error and provides learning opportunities for all healthcare professionals.

- There is a visible commitment on patient safety goals within the organization (e.g. specific medication safety indicators/ objectives are included in the facility's plan).

- Facility adopts no-blame culture in managing medication error.

- There is a good cooperation among healthcare professionals in order to work together and provide better care for patients.

MEDICATION ERROR REPORTING SYSTEM (ONLINE)

Who can report?

Only healthcare professionals can register to the online Medication Error Reporting System (MERS) and submit a report.

How to report?

1. Go to https://mers.pharmacy.gov.my.
2. Log in using your username and password. If you haven't registered to the system, kindly do so and follow User Guide I: Registration.
3. Fill in the form and submit.

How to complete the reporting form?

The medication error reporting form contains 6 parts:

Part A : Error Details

Part B : Location and Error Outcome

Part C : Patient's Particulars

Part D : Product Details

Part E : Attachment

Part F : Reporter's Details

For the step-by-step guide, kindly refer to:

- User Guide I : User Registration (Reporter)
- User Guide II : Forget Password/ Unblock Account
- User Guide III : Create Medication Error Report
- User Guide IV : Amend Report (Enquiry)

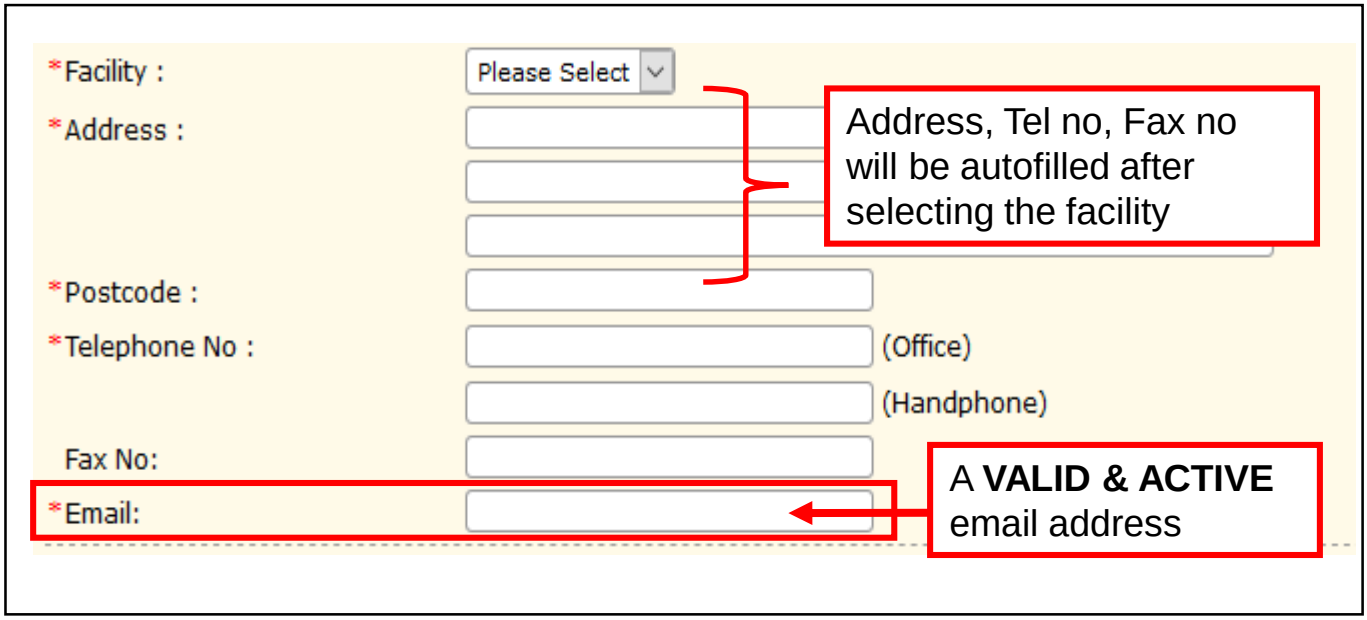
MEDICATION ERROR REPORTING SYSTEM (ONLINE)

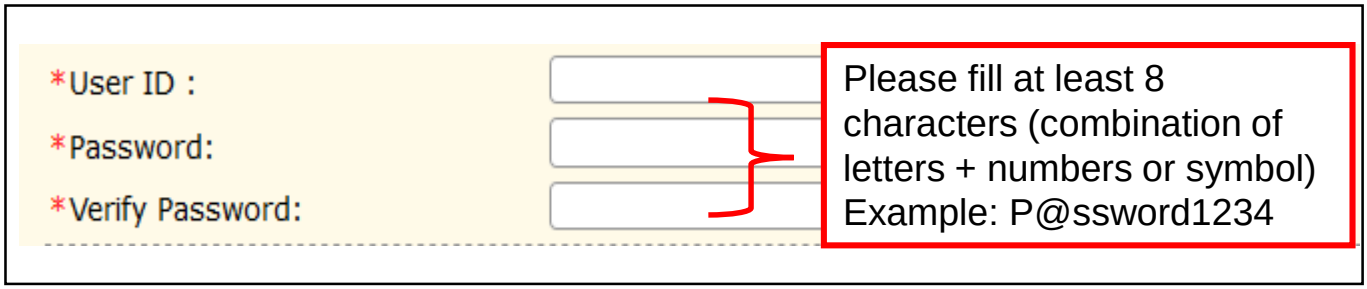
User Guide I : User Registration (Reporter)

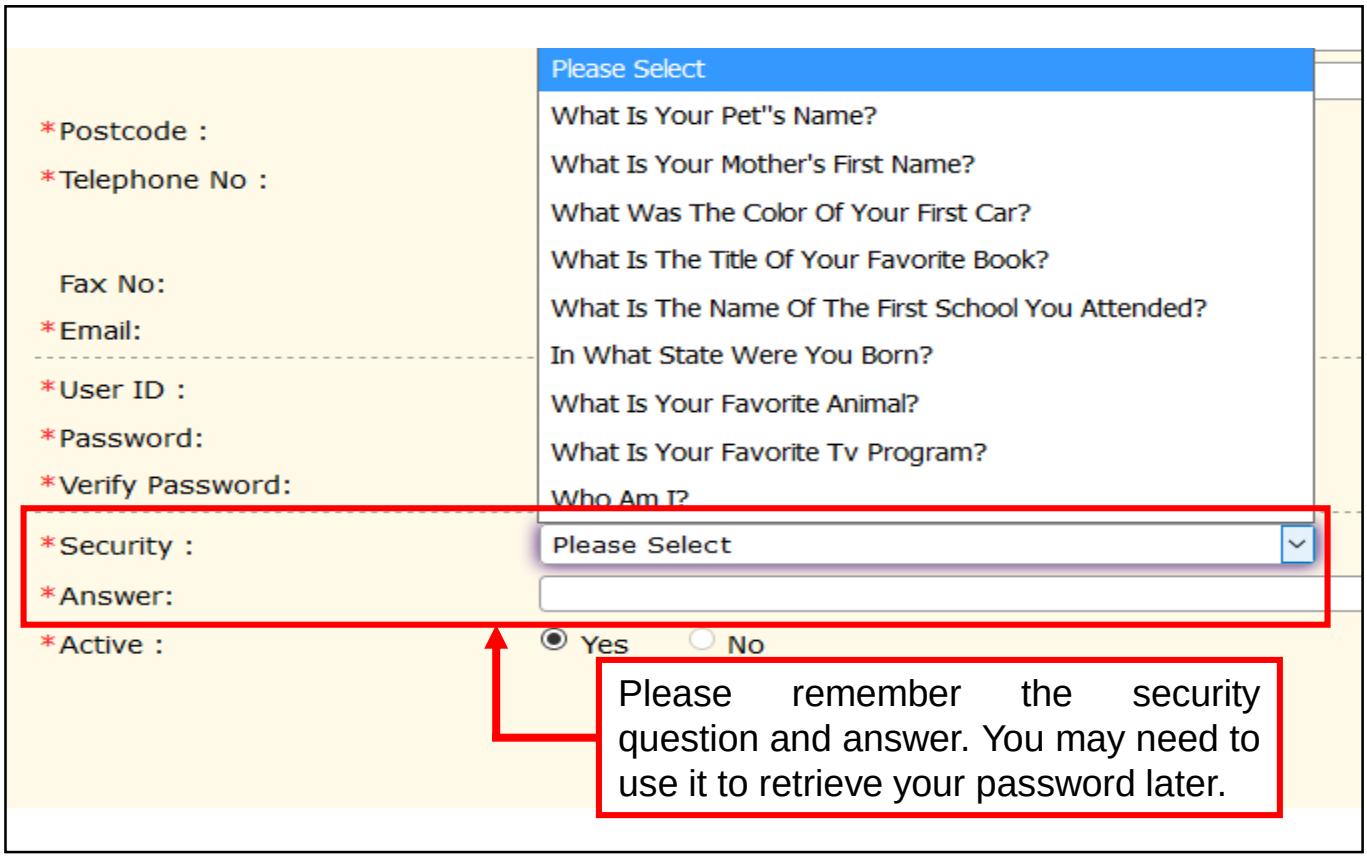
1. Go to https://mers.pharmacy.gov.my

2. Click on the link as shown below.

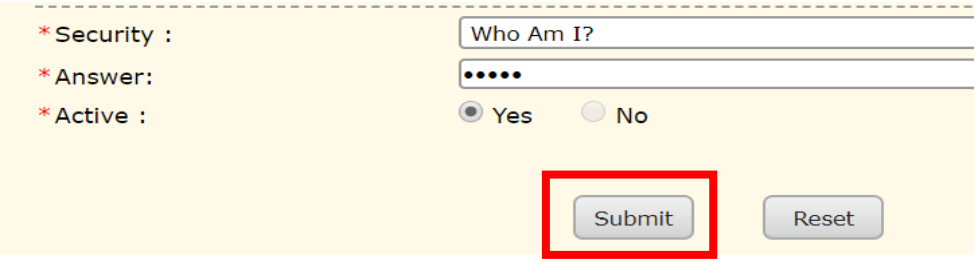
3. Fill in all the particulars.





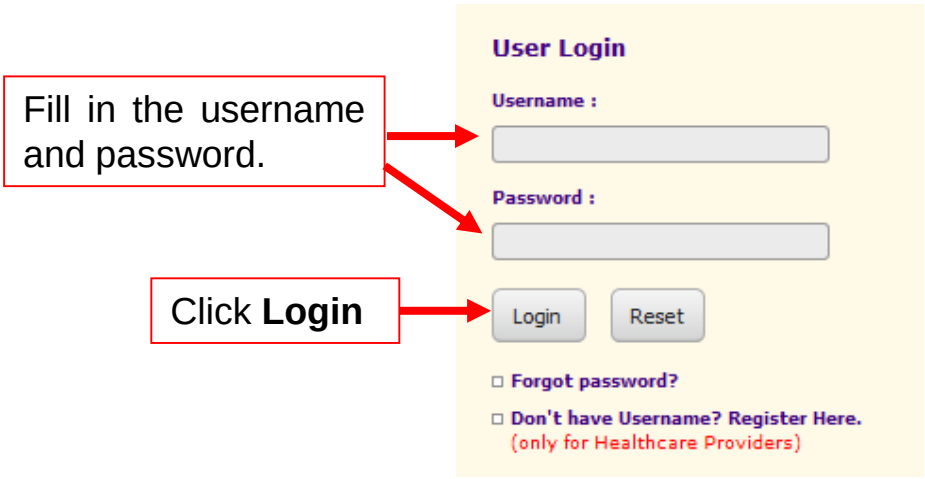


4. Click **SUBMIT** button after all the particulars are completely filled.



5. Message would appear upon successful registration.

6. Once registered successfully, key in your username and password.



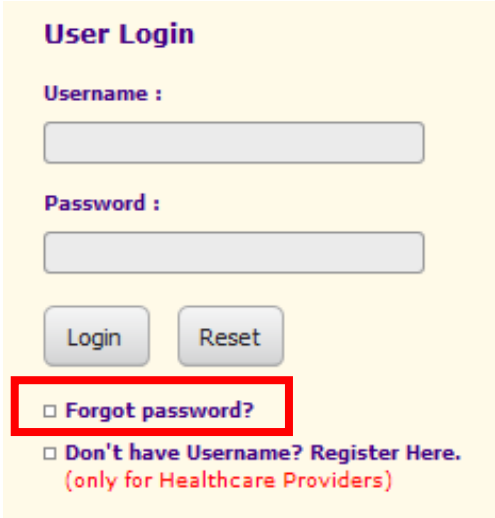
1. If your facility is not listed, kindly e-mail to mers@moh.gov.my along with your facility's details.
2. Please use a valid and active email
3. Avoid using IC number for user ID
4. Registration for user other than reporter such as Reporter HQ, Verifier, JKN Viewer will be done by Pharmacy Practice & Development Division, MOH. Kindly e-mail to mers@moh.gov.my.

MEDICATION ERROR REPORTING SYSTEM (ONLINE)

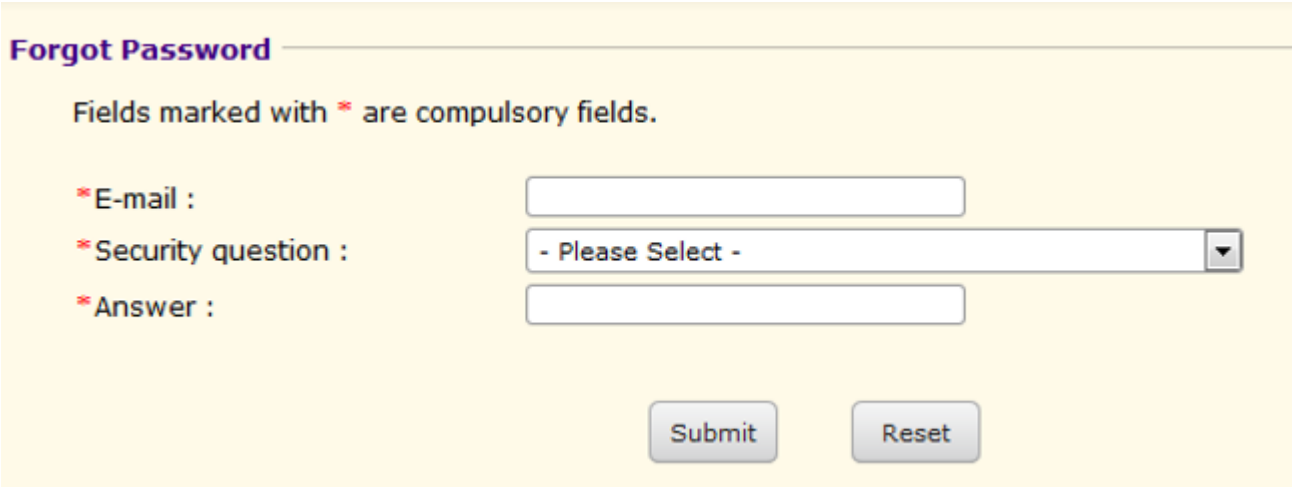
User Guide II: Forget Password/ Unblock Account

Forget Password

1. If you forgot your password, click on the ‘ forgot password’ .

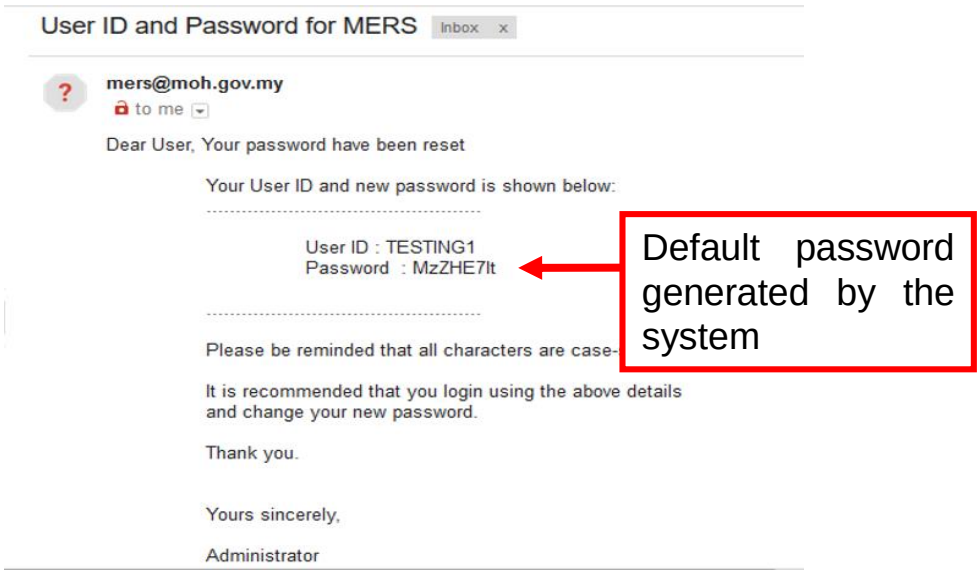


2. In order to obtain your password, you need to fill in your email, security question and answer. Make sure you remember the security question and answer. Then, click **SUBMIT**.



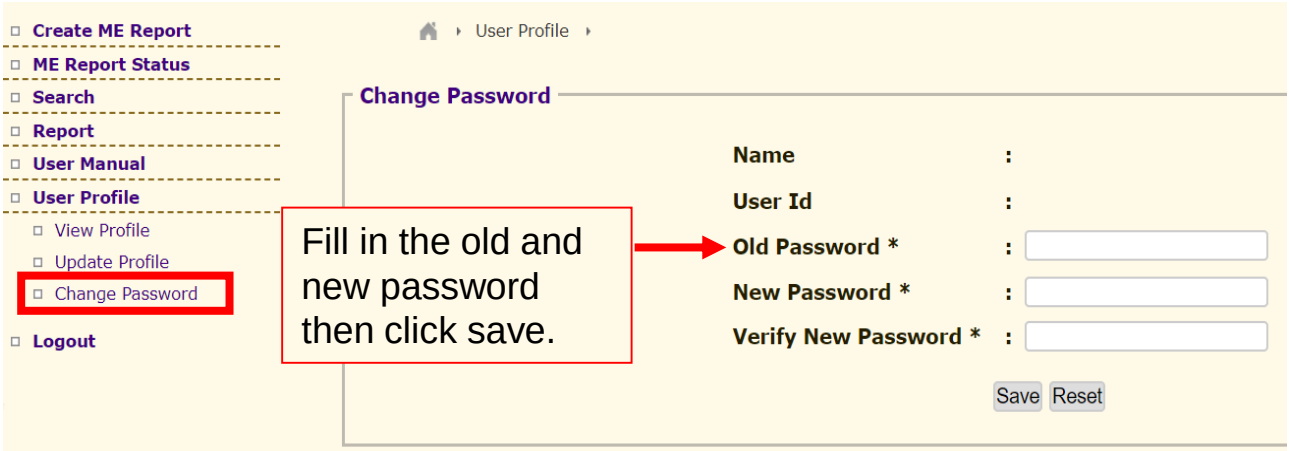
3. If all the details are correct, the system will automatically send a new password to your registered email.

Notification e-mail:



4. You may now log in using the user ID and the default password.

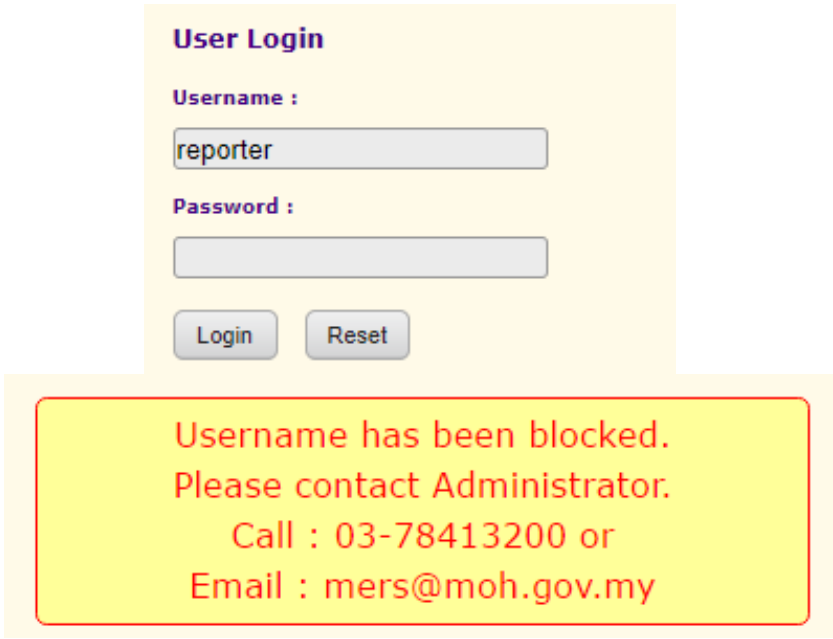
5. You may change your password in the [User Profile] > [Change Password].



Unblock Account

User access will be blocked if failed to log in after 3 attempts.

1. If your account has been blocked, kindly contact the administrator through email **mers@moh.gov.my** to reset your password.



2. E-mail details:

   Title: To unblock MERS user account

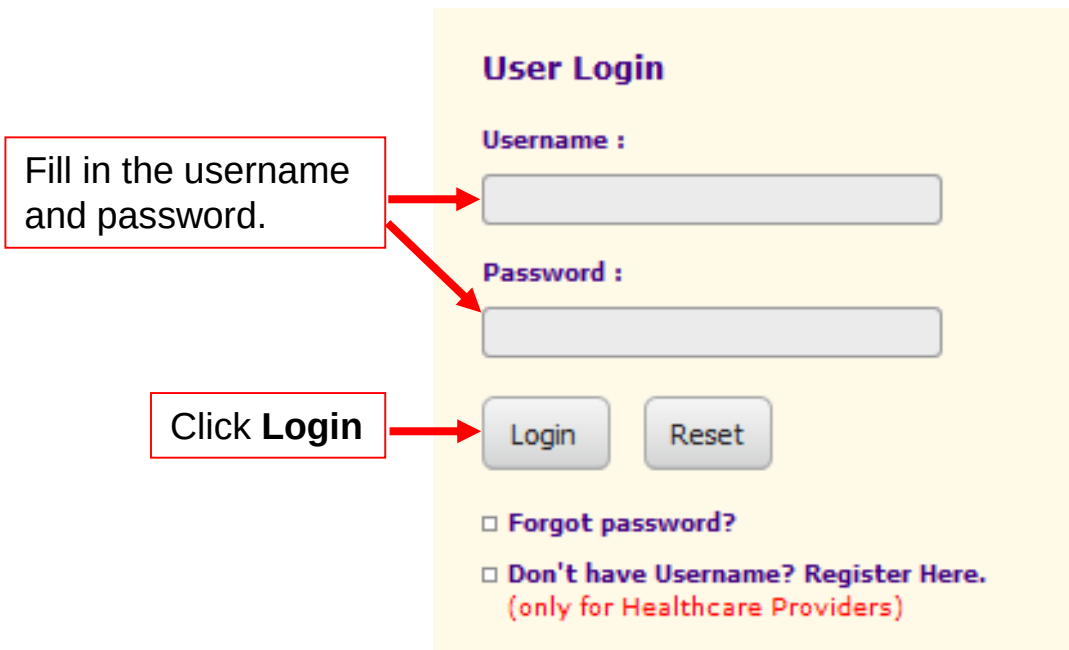
   Information to be included:
   a) Full name of the user/ Name registered for that account
   b) Username
   c) Facility name
   d) E-mail address

MEDICATION ERROR REPORTING SYSTEM (ONLINE)

User Guide III : Create Medication Error Report

1. Go to https://mers.pharmacy.gov.my

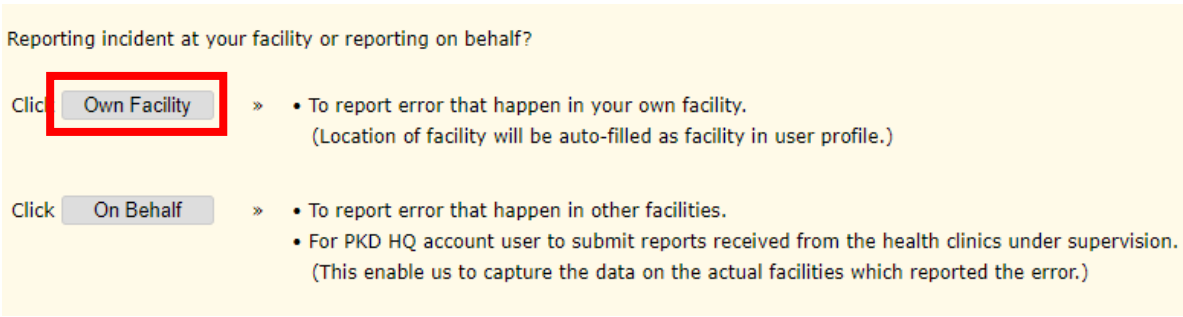
2. Log in with your Username and Password



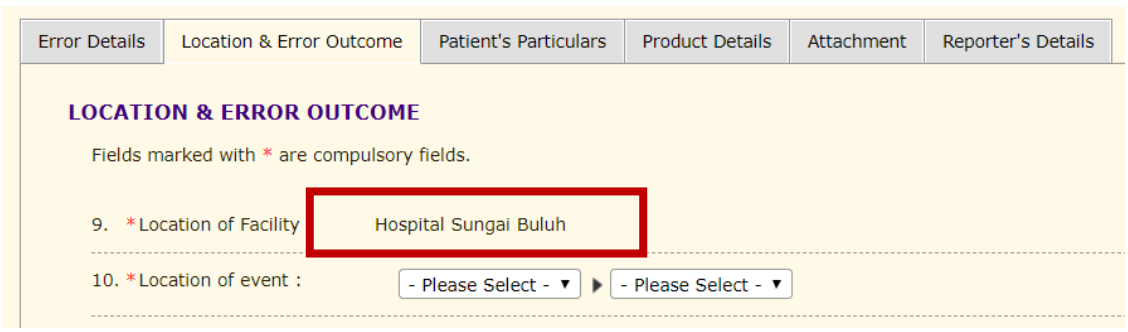
3. Click on Menu [Create ME Report]

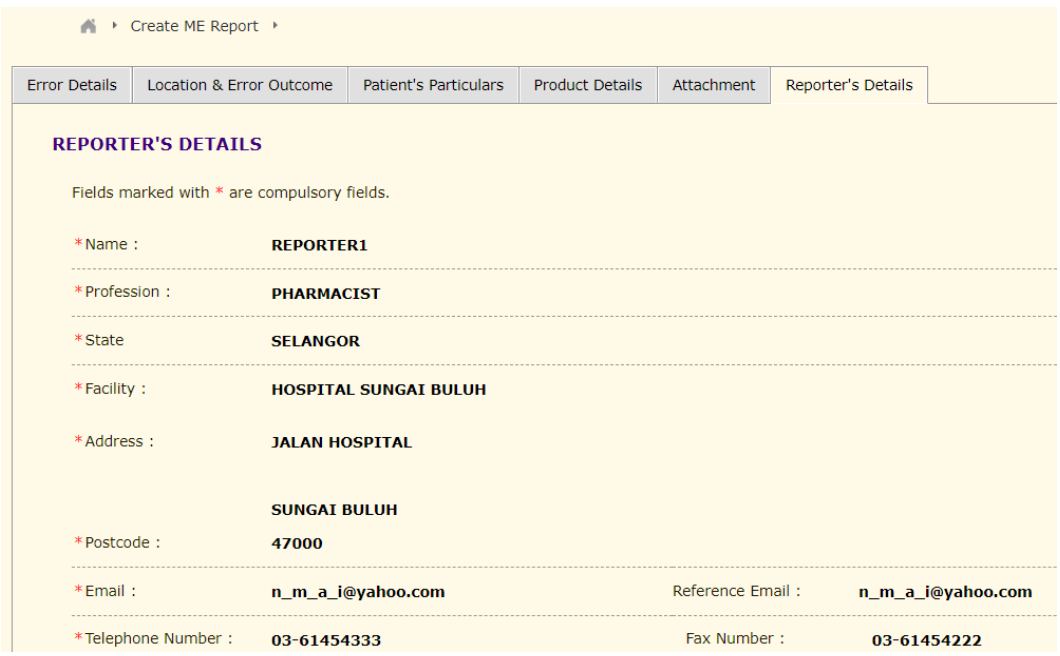
4. A pop-up window will appear. Choose either:

   a) OWN FACILITY (if you are reporting for your own facility).

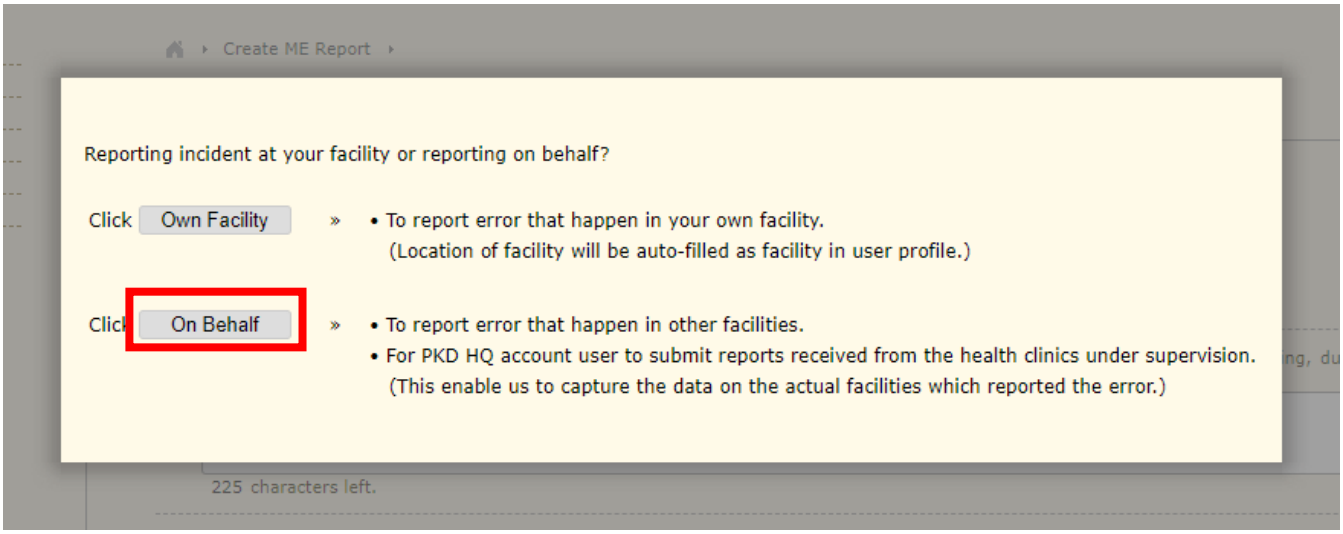


By choosing “Own Facility”, the column location of facility and all the reporter’s details will be auto-filled based on the user profile.





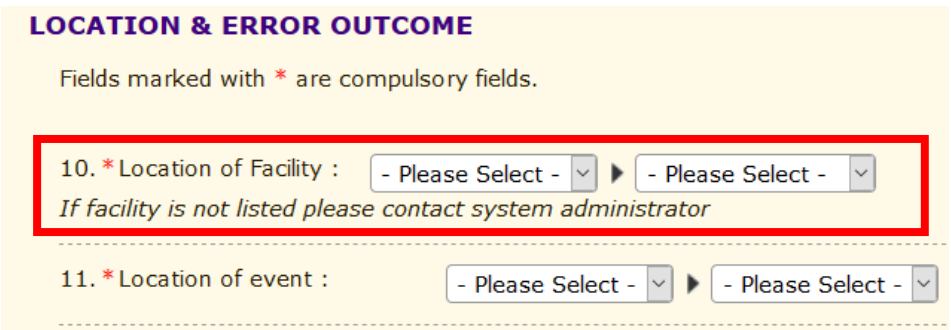
b) ON BEHALF (if you are reporting for other facilities)



By choosing “On Behalf”, you need to fill in the location of facility and the reporter’s details.

For example, when a medication error occurred at Klinik Kesihatan A, reporter who is using PKD HQ account to report a medication error need to choose “On Behalf” instead of “Own Facility”.

Please choose the exact location of facility where the error occurred (Klinik Kesihatan A).



Part A: Error Details

* 1. Date of Event

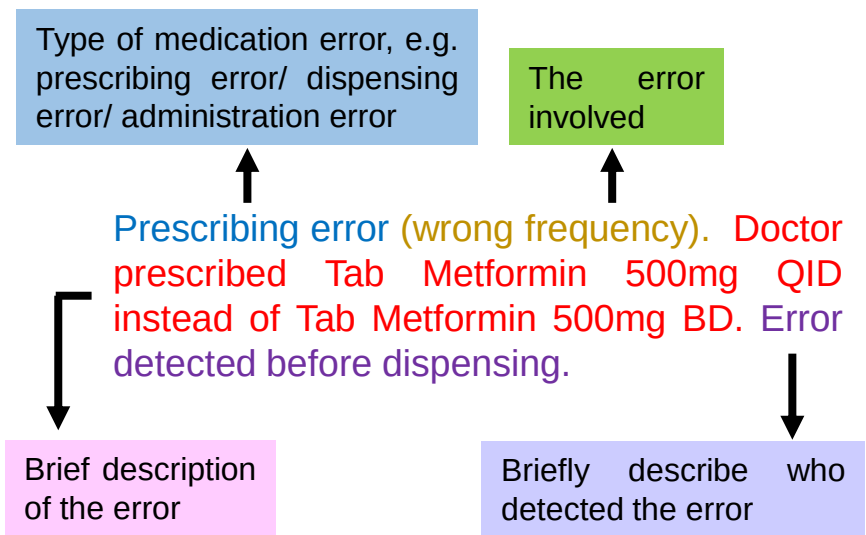
Date when the error happened, not the date when the error was reported.

* 2. Time of Event

Time when the error occurred.

* 3. Description of error

What happened? Sequence of event? When error was detected? (no need to include the name of the personnel who did the error / patient's information).



Examples:

1. Dispensing error (wrong drug). Pharmacist dispensed Tab Akurit-2 instead of Tab Akurit-4. Patient had taken T Akurit-2 for 2 weeks.

2. Administration error (wrong patient). Nurse wrongly administered 50ml of Metronidazole to patient A who is allergic to Metronidazole instead of Patient B. Error detected by the specialist during ward round.

* 4. Contributing factor

Indicate the possible error cause(s) and contributing factor(s). Multiple options may be selected.

* 5. Category made the initial error

Who started the initial error?

Examples:

Process in which the error occurs	Category made the initial error *(under normal circumstances)*
Prescribing	Specialist, MO, HMO, AMO, Dentist, Nurse
Dispensing	Pharmacist, PRP, PA, PA(Trainee)
Administration	Specialist, MO, HMO, AMO, Nurse, Nurse(Trainee)
Data Entry	Specialist, MO, HMO, AMO, Dentist, Pharmacist, PRP, PA, PA(Trainee)
Monitoring	Specialist, MO, HMO, AMO, Dentist, Pharmacist, PRP, PA, PA(Trainee)
Registration	Registration counter staff (e.g. PRA)
Preparation of Drugs	Pharmacist, PRP, PA, PA(Trainee), Nurse
Documentation	Pharmacist, PRP, PA, PA(Trainee), Nurse

6. Category also involved in the error

Who also involved causing the error to occur?

* 7. Category detected the error

Who detected the error?

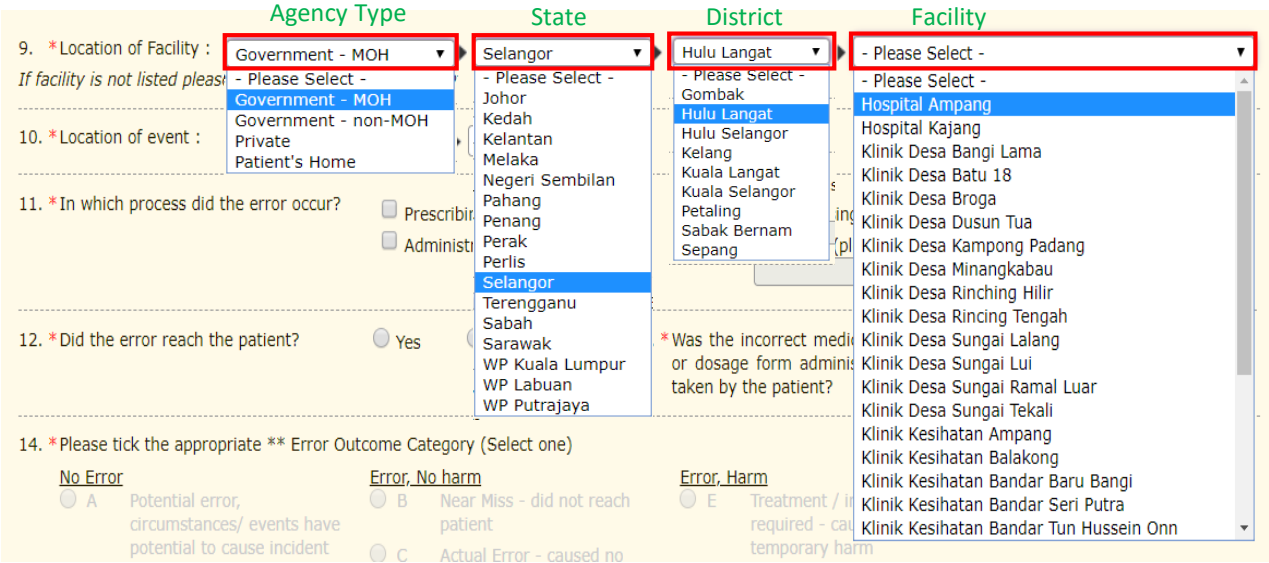
8. Recommendation/ Remedial action taken

Describe the corrective / preventive action taken to avoid the occurrence of similar errors.

Part B: Location and Error Outcome

* 9. Location of Facility

Facility where the error occurred.



If your facility is not listed in the system, kindly e-mail to mers@moh.gov.my.

* 10. Location of Event

Location where the error occurred (not where the error detected). Location of event is related to the process in which the error occur.

Examples:

Process in which the error occurs	Location of event
Prescribing	Clinic/ Ward/ A&E
Dispensing	Pharmacy
Administration	Clinic/ Ward/ A&E
Data entry	Clinic/ Ward/ A&E/ Pharmacy
Monitoring	Clinic/ Ward/ A&E
Registration	Registration counter
Preparation of Drugs	Clinic/ Ward/ A&E/ Pharmacy
Documentation	Clinic/ Ward/ A&E/ Pharmacy

Part B: Location and Error Outcome

*** 11. In which process did the error occur.**

(Note: You may select more than 1 option given).

Examples:

Location of event	In which process did the error occur
Ward	Prescribing, Dispensing, Administration, Others
A&E	Prescribing, Administration, Others
Clinic	Prescribing, Administration, Others
Pharmacy	Data Entry, Labelling, Filling, Dispensing
Others	Registration

*** 12 Did the error reach the patient?**

- Yes, if medication reaches the patient
- No, if medication didn't reach the patient
- An "error of omission" does reach the patient

*** 13.Was the incorrect medication, dose or dosage form administered to or taken by the patient?**

- Yes, if the incorrect medication reaches the patient and is administered
- No, if the incorrect medication reaches the patient but not administered

*** 14. Error Outcome Category**

In selecting the patient outcome category, select the highest level severity that applies during the course of the event. For example, if a patient suffers a severe anaphylactic reaction (Category H) and requires treatment (Category F) but eventually recovers completely, the event should be coded as Category H.

Select only one of the medication error categories or subcategories, whichever best fits the error that is being reported.

Error Outcome Category

NO ERROR	
Category A	Circumstances or events that have the capacity to cause error. Example: Illegible handwriting, use of abbreviation, incorrect storage of medication/ mix up drugs
ERROR, NO HARM *[Note: Harm is defined as temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention.]*	
Category B	An error occurred but the error did not reach the patient (An "error of omission" does reach the patient). Example: Error detected before dispensing to the patient.
Category C	An error occurred that reached the patient but did not cause patient harm. •Medication reaches the patient and is administered. •Medication reaches the patient but not administered. Example: a) Pharmacist dispensed incorrect medication to ward. Nurse administer the incorrect medication to patient. b) Pharmacist dispensed incorrect medication to the patient. The patient realized that the medicine is incorrect and return it back to the pharmacy.
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. Example: Other patient's profile was accidentally placed inside the patient's file which has led to wrong medications prescribed during previous visit. MO was informed. Close glucose monitoring was planned for this patient. The blood glucose level was reported as mild elevation only.

Error Outcome Category

ERROR, HARM Root cause analysis (RCA) reports are required and should be attached (Refer 20.)	
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 contributed to or resulted in the patient's death.

Note

Please refer the direct result on the patient (e.g. death, type of harm, additional patient monitoring) which stated in the medication error report (No.15) and Guide For Categorizing Medication Errors to determine the severity of the error outcome.

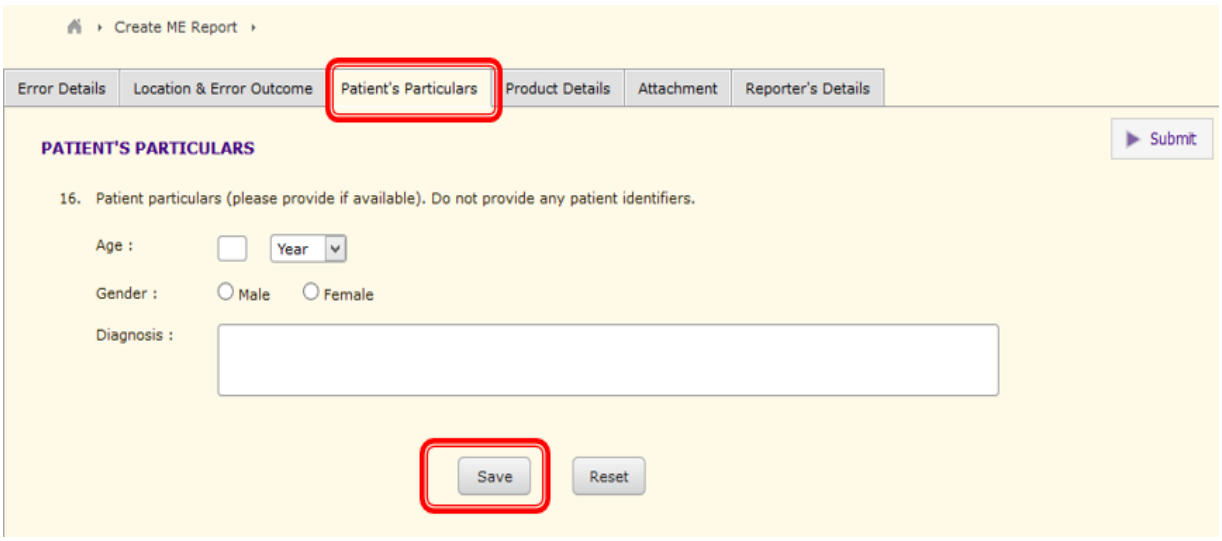
* **15. Describe the direct result on the patient** *(e.g. death, type of harm, additional patient monitoring).*

Example: No harm, harm (please specify, e.g. tachycardia/ bradycardia/ seizure attack), additional patient monitoring includes, vital signs monitoring, sign & symptoms of toxicity, blood glucose monitoring, TDM level monitoring, Glasgow coma scale, etc.

Part C: Patient's Particulars

16. Patient's particulars: age, gender and diagnosis.

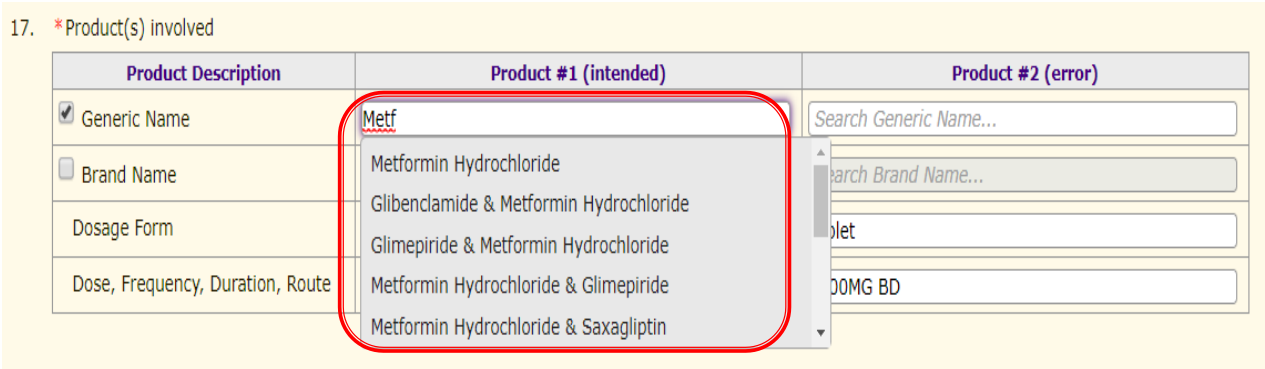
Click on the **Patient's Particulars** tab and complete the form, then click save. Patient's particulars are optional fields but reporters are encouraged to fill in these particulars.



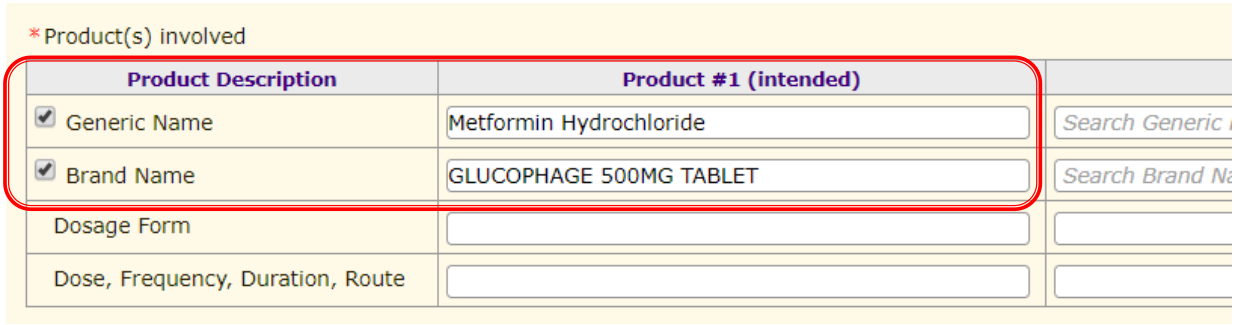
Part D: Product Details

17.1 & 17.2 Generic Name ± Brand Name

* i) Tick the "Generic Name" and type in the first few alphabets, then choose from the dropdown list.



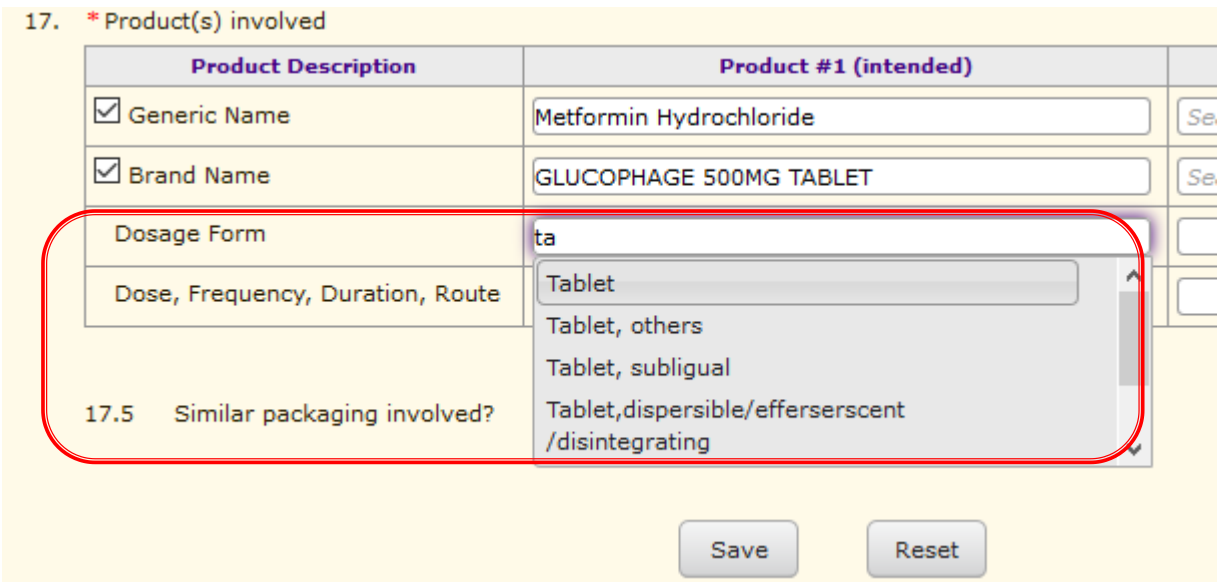
OR ii) Choose a Brand Name of the product from the dropdown list and the Generic Name will be auto filled (Brand name is optional).



1. Generic name is **MANDATORY.**
2. Brand name is **OPTIONAL**. If the brand name is not listed, please untick the brand name and proceed with other product particulars.
3. If you wish to add in any product in the system, kindly e-mail the product details to mers@moh.gov.my.

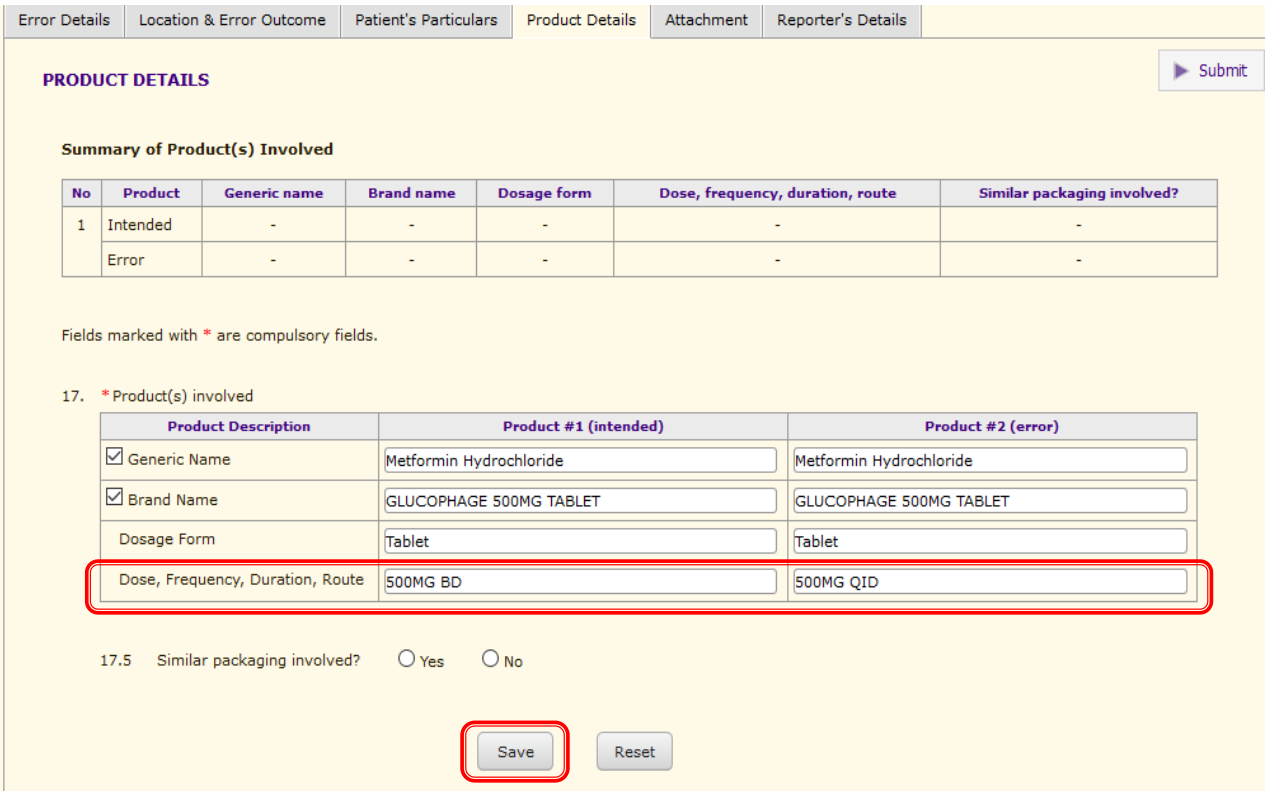
17.3 Dosage Form

Type in the first few alphabets in the dosage form column, then choose from the dropdown list.



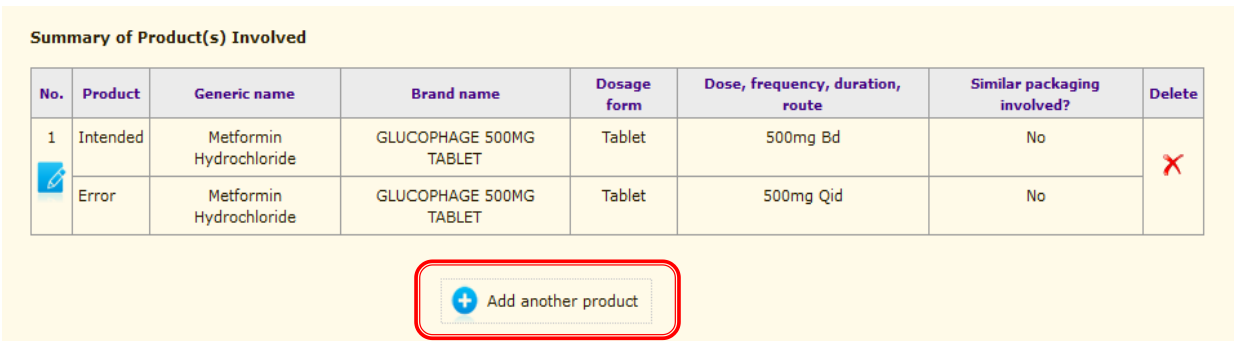
17.4 Dose, Frequency, Duration, Route

Fill in the dose, frequency, duration, route column. Then, click SAVE.



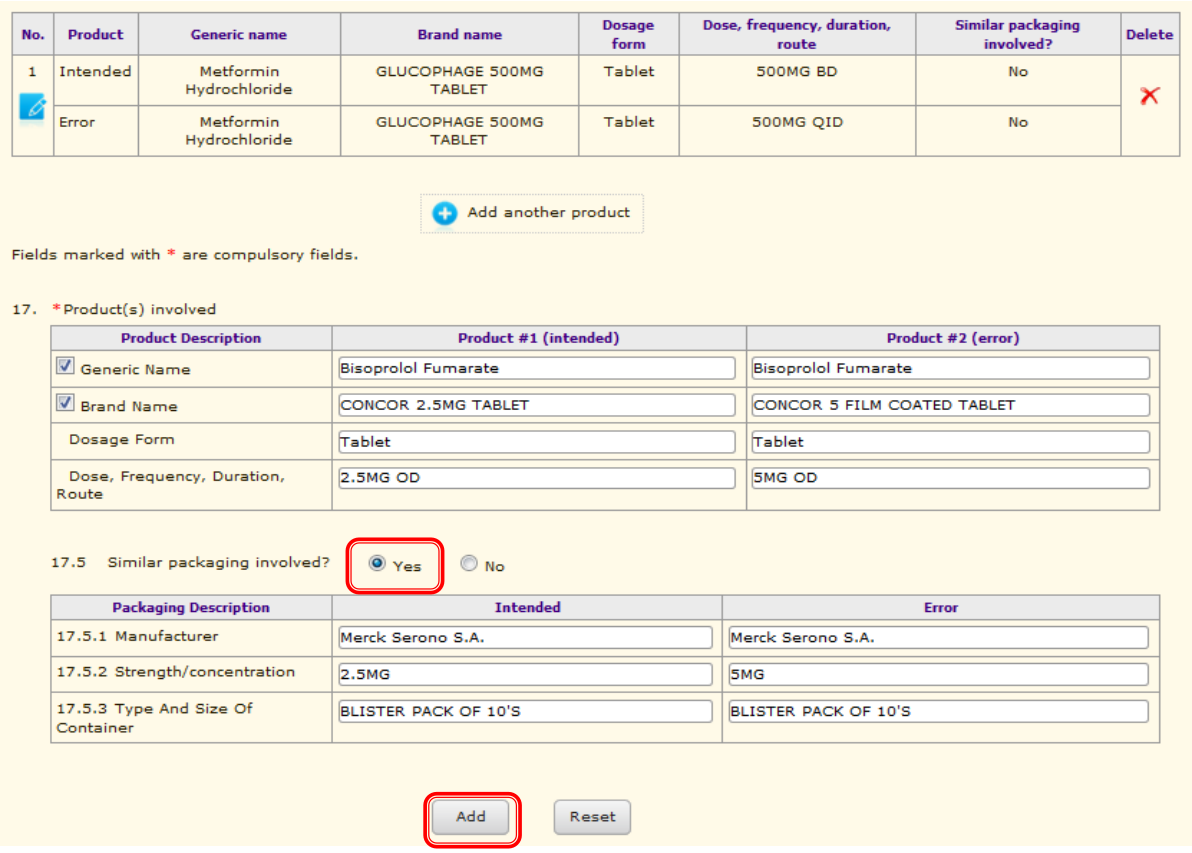
What if the error involved more than one product?

Click on ‘Add another product’ button if more than one product is involved and repeat the above steps.



17.5 Is the error involved similar packaging?

If similar packaging is involved, click YES and fill in the details (17.5.1, 17.5.2, 17.5.3). Then, click ADD.



No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route	Similar packaging involved?	Delete
1	Intended	Metformin Hydrochloride	GLUCOPHAGE 500MG TABLET	Tablet	500MG BD	No	
	Error	Metformin Hydrochloride	GLUCOPHAGE 500MG TABLET	Tablet	500MG QID	No	

Add another product

Fields marked with * are compulsory fields.

17. *Product(s) involved

Product Description	Product #1 (intended)	Product #2 (error)
Generic Name	Bisoprolol Fumarate	Bisoprolol Fumarate
Brand Name	CONCOR 2.5MG TABLET	CONCOR 5 FILM COATED TABLET
Dosage Form	Tablet	Tablet
Dose, Frequency, Duration, Route	2.5MG OD	5MG OD

17.5 Similar packaging involved? Yes No

Packaging Description	Intended	Error
17.5.1 Manufacturer	Merck Serono S.A.	Merck Serono S.A.
17.5.2 Strength/concentration	2.5MG	5MG
17.5.3 Type And Size Of Container	BLISTER PACK OF 10'S	BLISTER PACK OF 10'S

Add Reset

Examples:

a) Incorrect drug

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Chlorpromazine Hydrochloride		Tablet	25mg Tds
	Error	Carbamazepine		Tablet	100mg Od

b) Incorrect frequency

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Amoxycillin Trihydrate & Potassium Clavulanate	AUGMENTIN TABLET 625MG	Tablet	625mg TDS
	Error	Amoxycillin Trihydrate & Potassium Clavulanate	AUGMENTIN TABLET 625MG	Tablet	625mg BD

Examples:

c) Incorrect patient

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Perindopril Erbumine		Tablet	INCORRECT PATIENT
	Error	Perindopril Erbumine		Tablet	4mg OD

d) Incorrect dosage form

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Chloramphenicol	CHLORAMPHENICOL EAR DROPS 5%	Drops,ear	2 Drops BD
	Error	Chloramphenicol	CHLORAMPHENICOL EYE DROPS 0.5% W/V	Drops, Eye	2 Drops BD

e) Incorrect dose

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Ranitidine Hydrochloride		Tablet	150mg BD
	Error	Ranitidine Hydrochloride		Tablet	50mg BD

f) Incorrect quantity

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Gliclazide		Tablet	60 Tablets
	Error	Gliclazide		Tablet	30 Tablets

g) Polypharmacy

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Perindopril Erbumine		Tablet	4mg OD
	Error	Losartan Potassium		Tablet	Polypharmacy

Examples:

h) Omission (*not filled/not prescribed/not served)

Summary of Product(s) Involved

No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Amlodipine Besylate		Tablet	10mg OD
	Error	Amlodipine Besylate		Tablet	* Not Prescribed

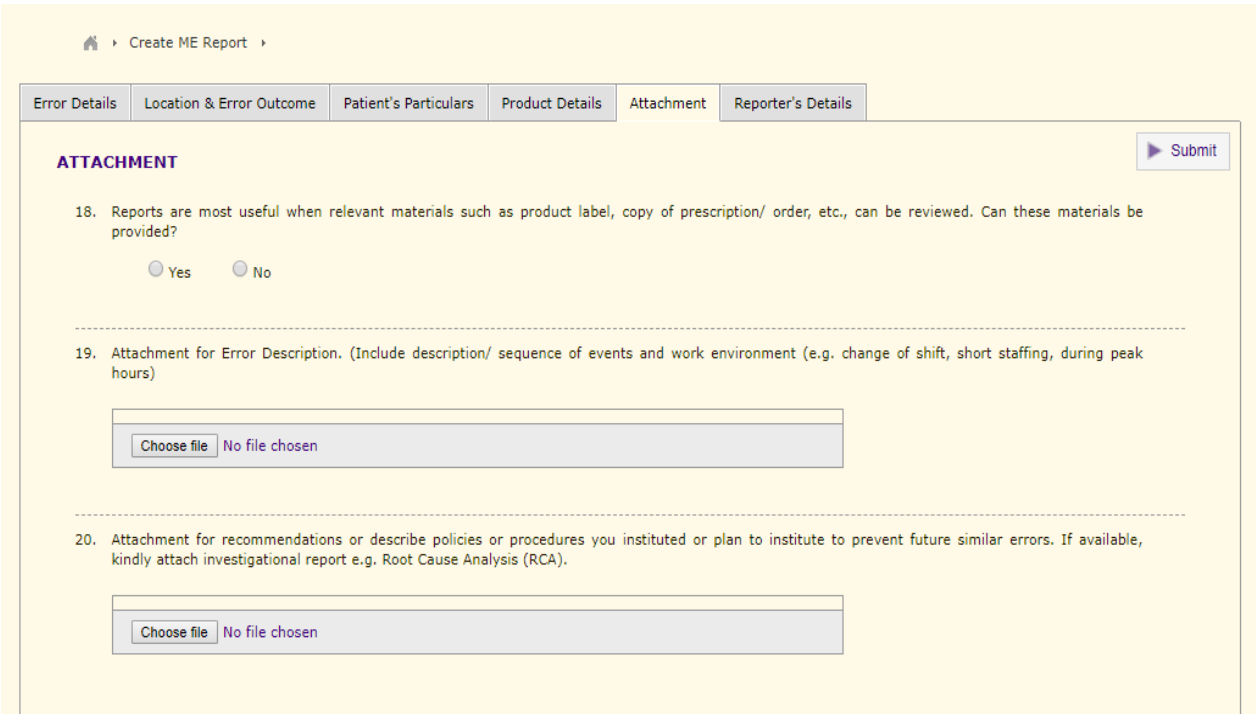
i) Illegible handwriting

Summary of Product(s) Involved

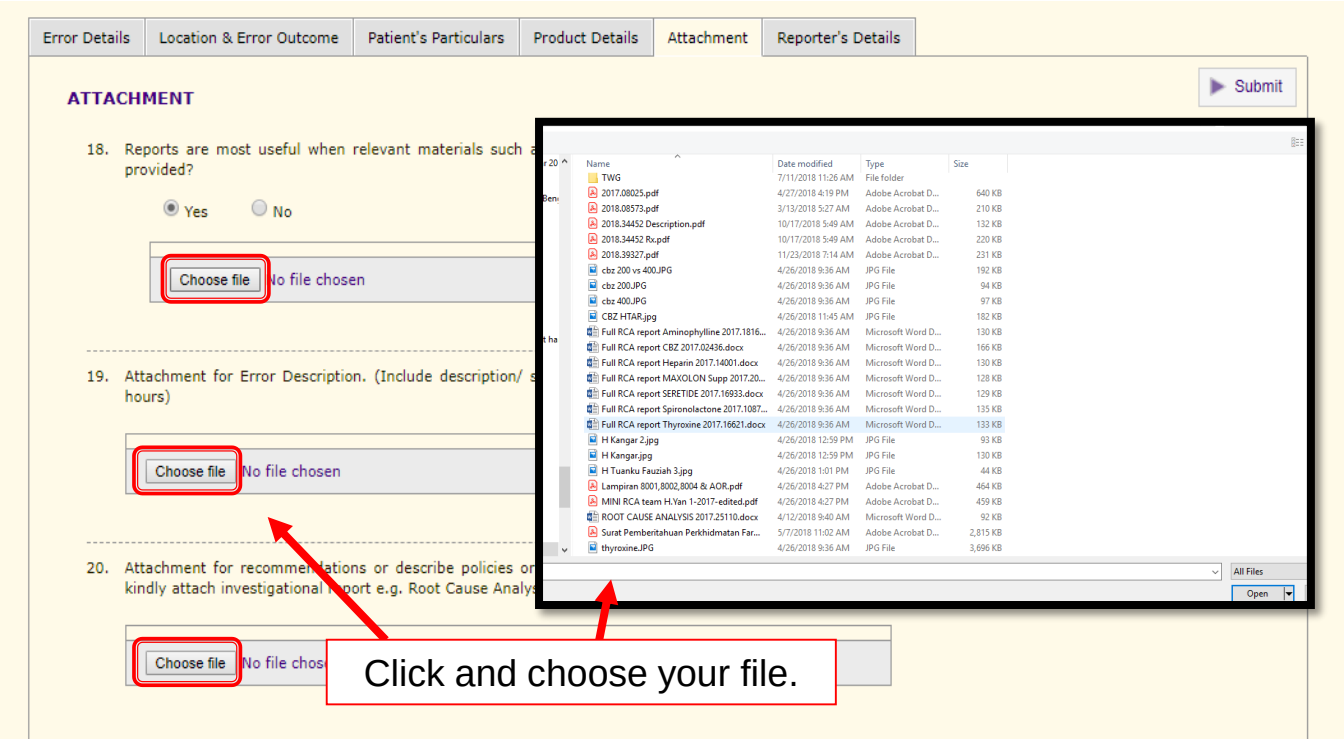
No.	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route
1	Intended	Metformin Hydrochloride		Tablet	500mg BD
	Error	Metformin Hydrochloride		Tablet	Illegible Handwriting

Part E: Attachment

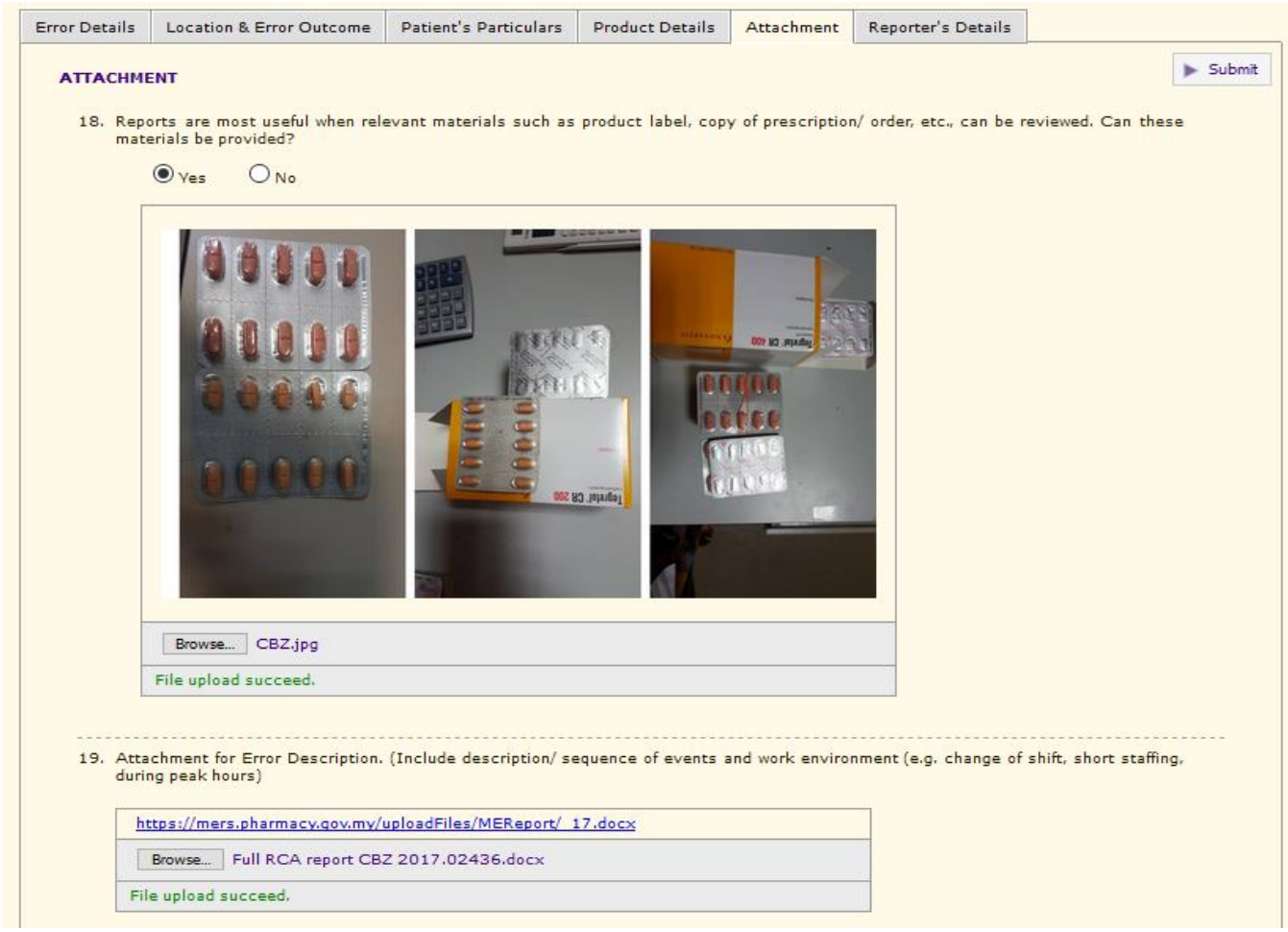
18. Relevant materials such as product label, copy of prescription/ order.
19. Attachment for error description.
20. Attachment for recommendations/ Root Cause Analysis (RCA).



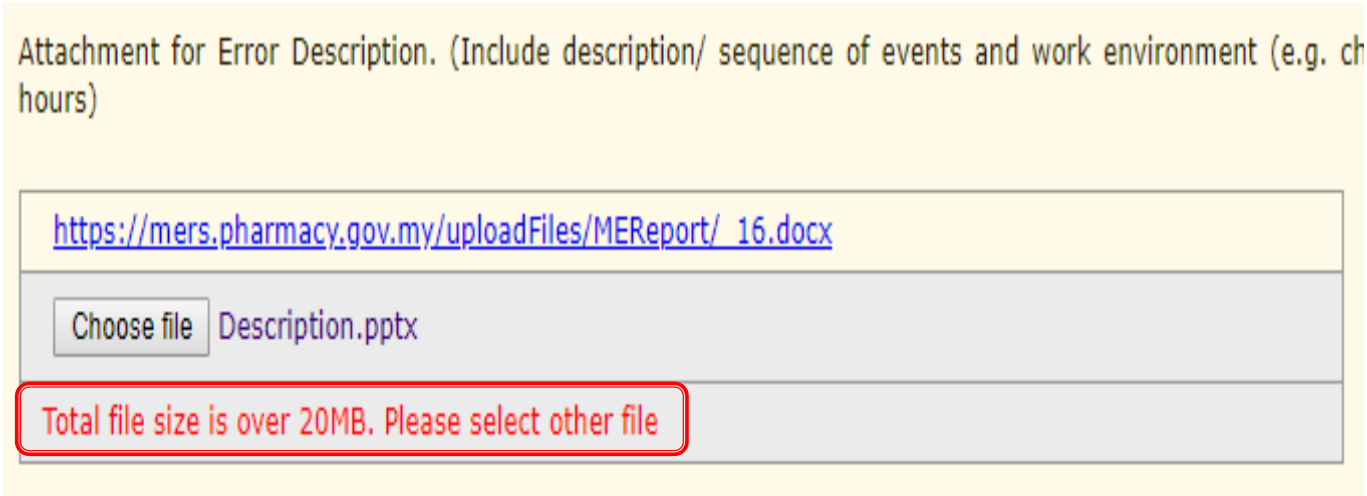
To upload the attachment, click on the ‘Choose File’ button and choose your file.



Once uploading process is 100%, the attachment name will be written on the section where you attach your file/photo as shown below.



If file size is exceed 20MB, the system will notify as shown below

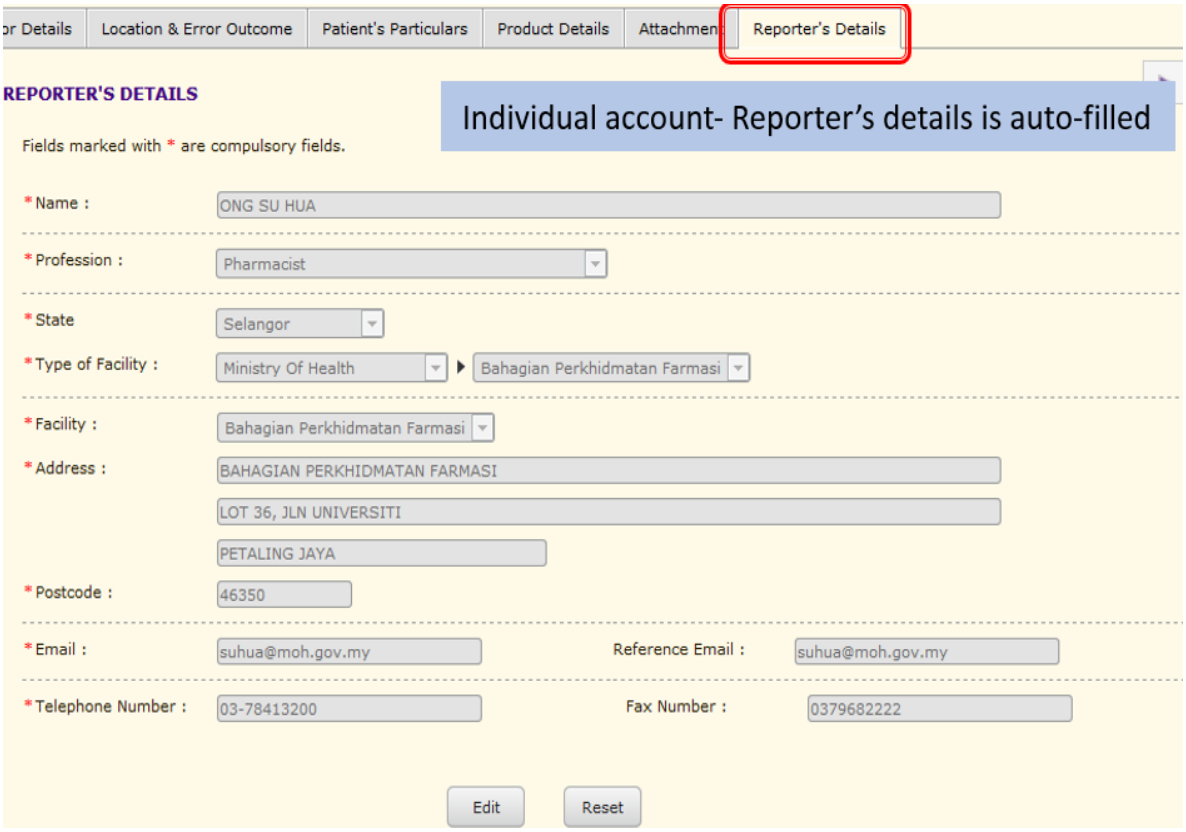


1. Supporting file type: png, jpeg, MS Word, MS Powerpoint, pdf.
2. Make sure your file size not exceed 20MB.
3. Kindly upload the relevant attachment based on the question.

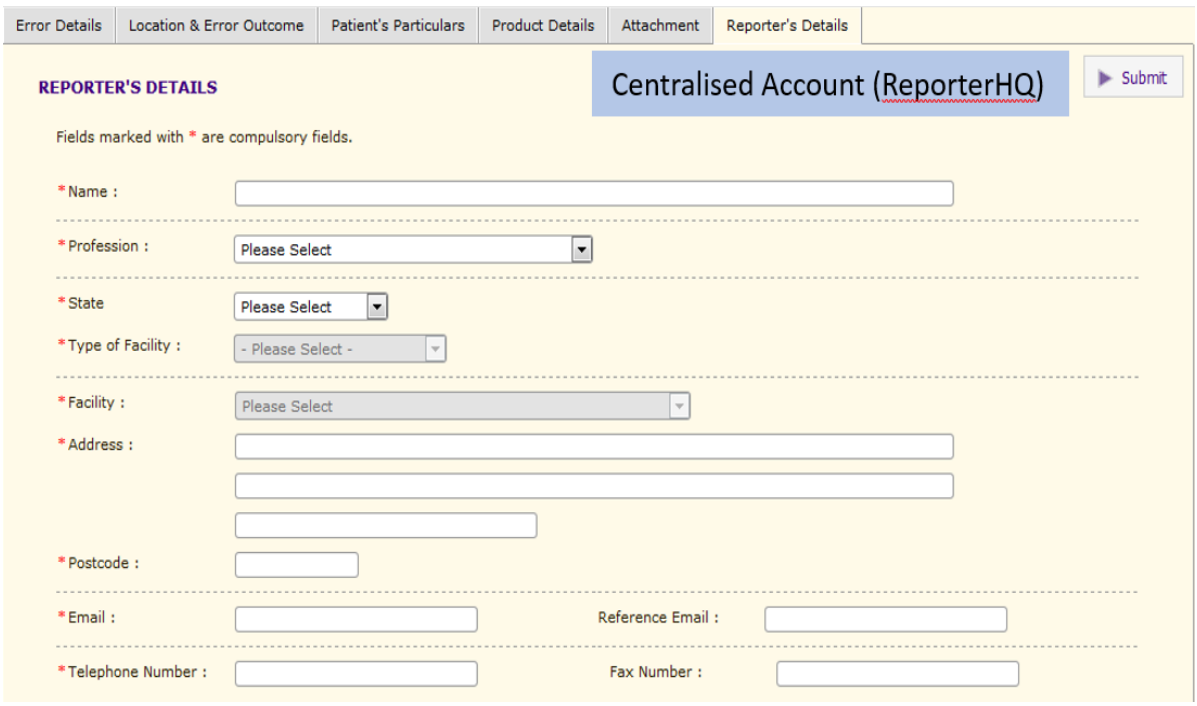
Part F: Reporter's Details

* 21. Reporter's Details

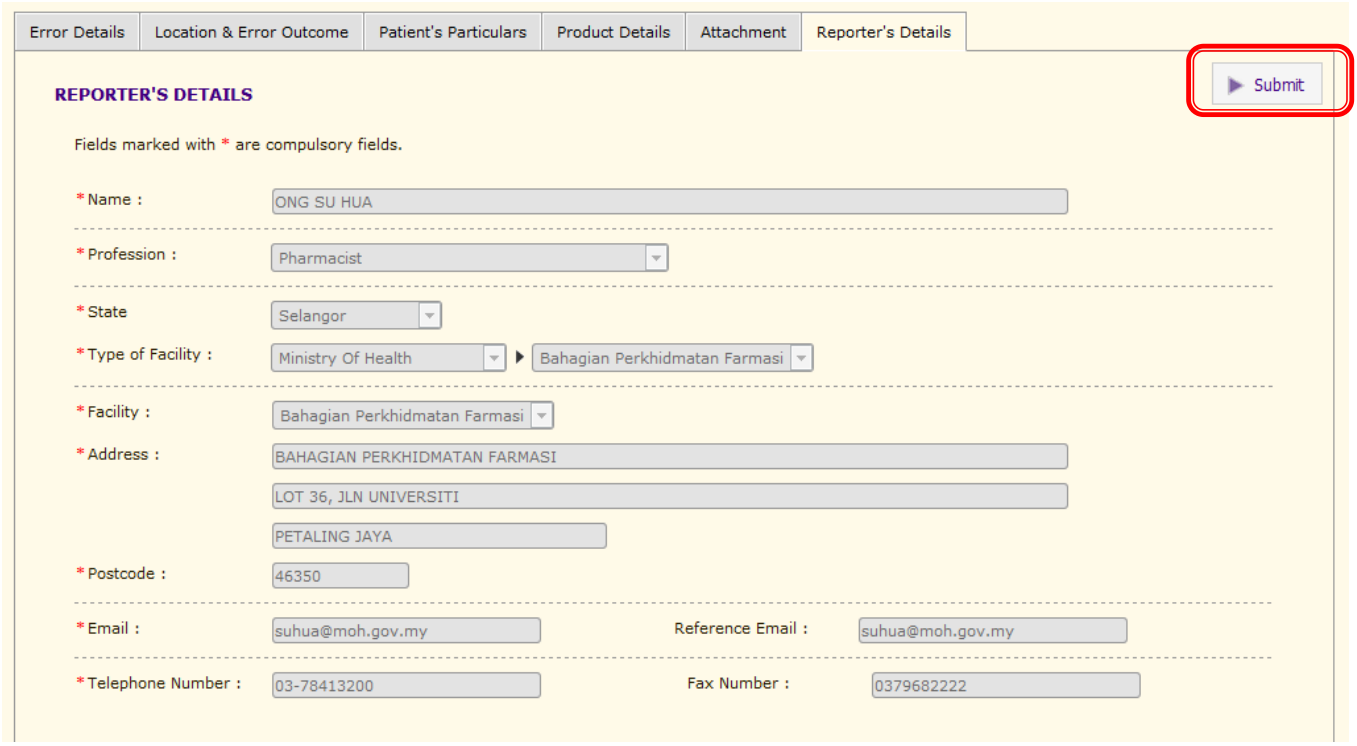
a) For individual account, the reporter's details will be auto-filled.



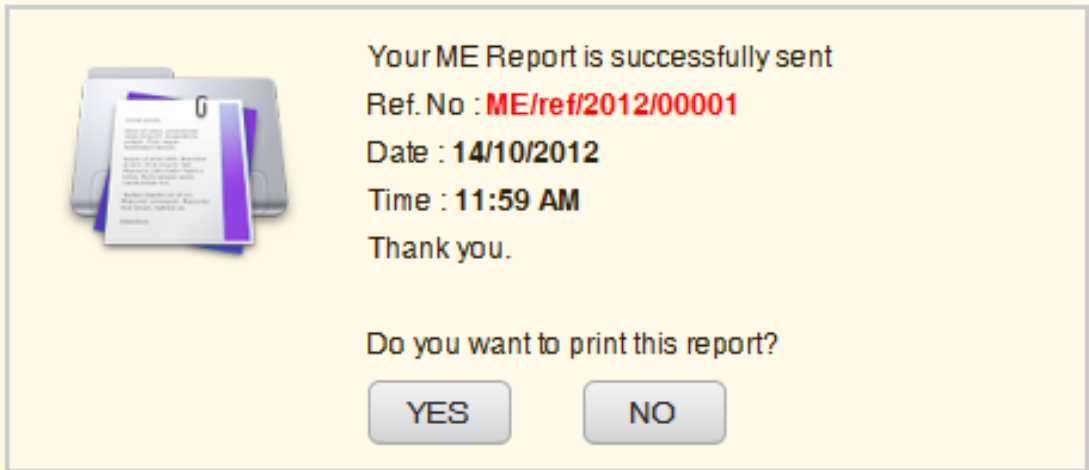
b) For centralised account (Reporter HQ), the reporter's details will be blank. Kindly fill in all particulars.



Click **SUBMIT** once all the tabs are completely filled.



"ME Report has been successfully sent" notification will appear, displaying your submission details. The report can be retrieved from ME Report Status > New Submission.



The report will be processed after submission. A notification e-mail will be sent to the reporter for clarification and amendments if necessary. The report can be retrieved from ME Report Status> Enquiry. (Kindly refer to User Manual 4: Amend Report (Enquiry)).

Report that have been saved but have not submitted will be keep as DRAFT. (ME Report Status> Draft)

Medication Error Report Status

Report Status	Action to be taken	Action by
Draft	ME Report saved but not submitted yet (Maximum 10 drafts). Reporter have to complete the ME report and **SUBMIT**.	Reporter
New Submission	ME Report have been submitted. Reporter is allowed to edit ME report during this phase.	Verifier
Enquiry	ME Report is not verified and return to reporter for feedback and amendment. Reporter must edit , save and **SUBMIT** the ME report.	Reporter
Amendment	Report have been edited, awaiting verification.	Verifier
Verified	Report have been verified, awaiting approval.	Approver
Return to reporter	ME Report is not approved/endorsed and return to reporter for clarification/ amendment. Reporter must edit , save and **SUBMIT** the ME report.	Reporter
Approved	Report have been approved, awaiting endorsement.	Endorser
Endorsed	Report have been endorsed.	-

MEDICATION ERROR REPORTING SYSTEM (ONLINE)

User Guide IV : Amend Report (Enquiry)

Medication Error Report Status

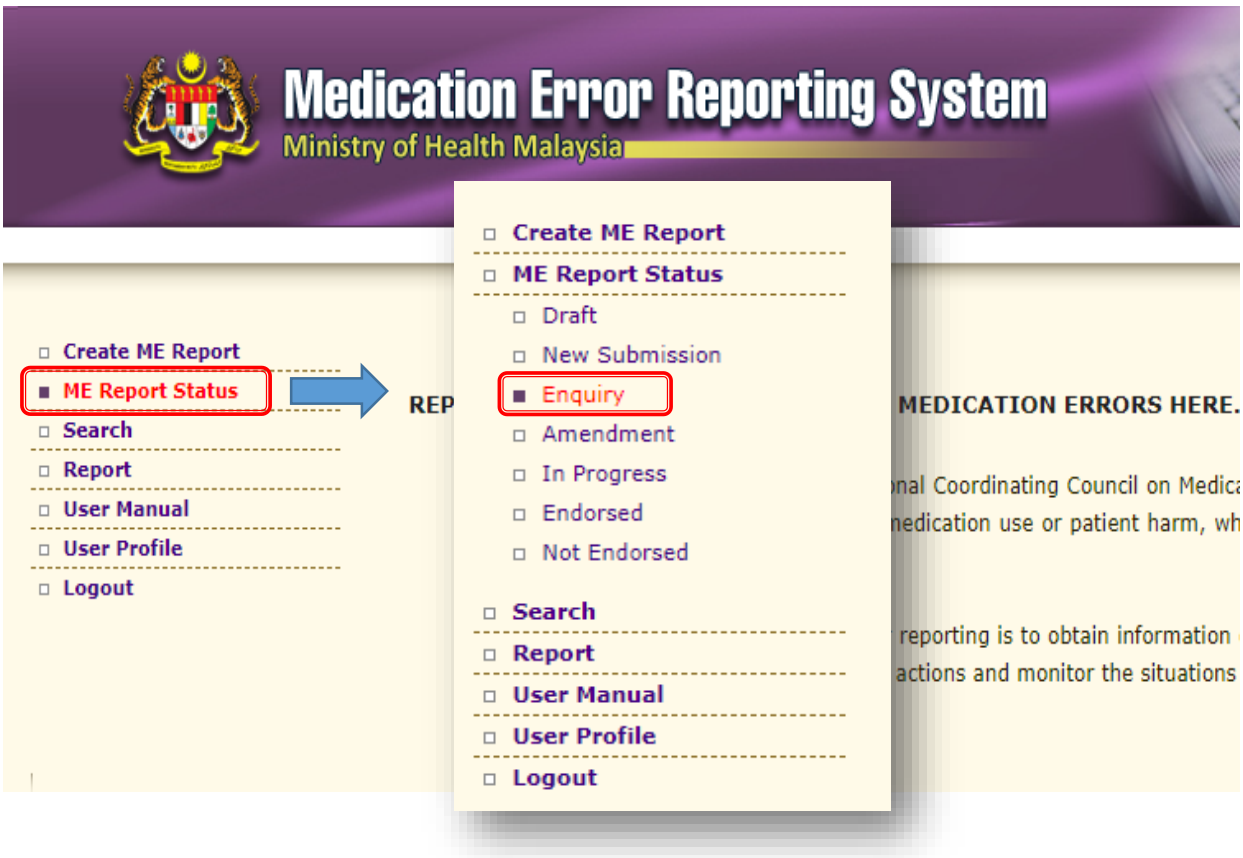
Report Status	Action to be taken	Action by
Draft	ME Report saved but not submitted yet. Reporter have to complete the ME report and **SUBMIT**.	Reporter
New Submission	ME Report have been submitted. Reporter is allow to edit ME report during this phase.	Verifier
Enquiry	Report is not verified/ not approved/ not endorsed and return to reporter for feedback and amendment. Reporter must edit , save and **SUBMITT** the ME report	Reporter
Amendment	Report have been edited, awaiting verification.	Verifier
Return to reporter	ME Report is not approved/endorsed and return to reporter for clarification/ amendment. Reporter must edit , save and **SUBMIT** the ME report.	Reporter

A notification e-mail will be sent to the reporter for clarification and amendments if necessary. Thus, please ensure the registered e-mail address is valid.

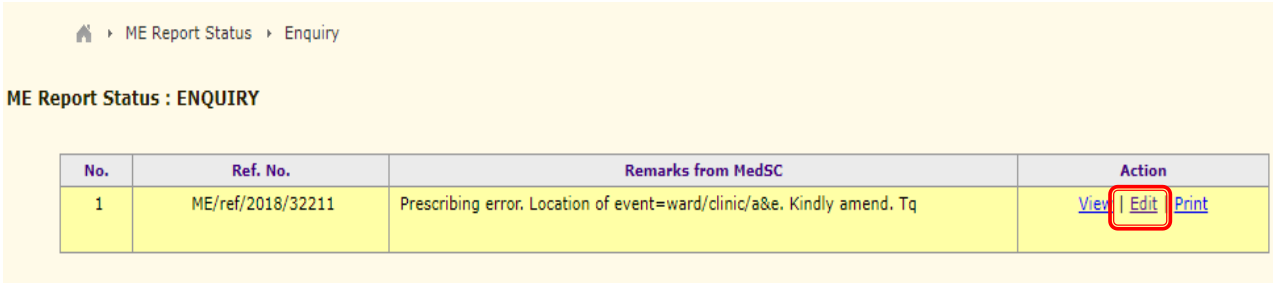
1) Click on the link in the e-mail to access the report to make amendment(s).

2) You will be directed to the MERS home page. Log in the system and you will be directed to the report. Your details must match with the reporter's account, if not, your access will be denied.

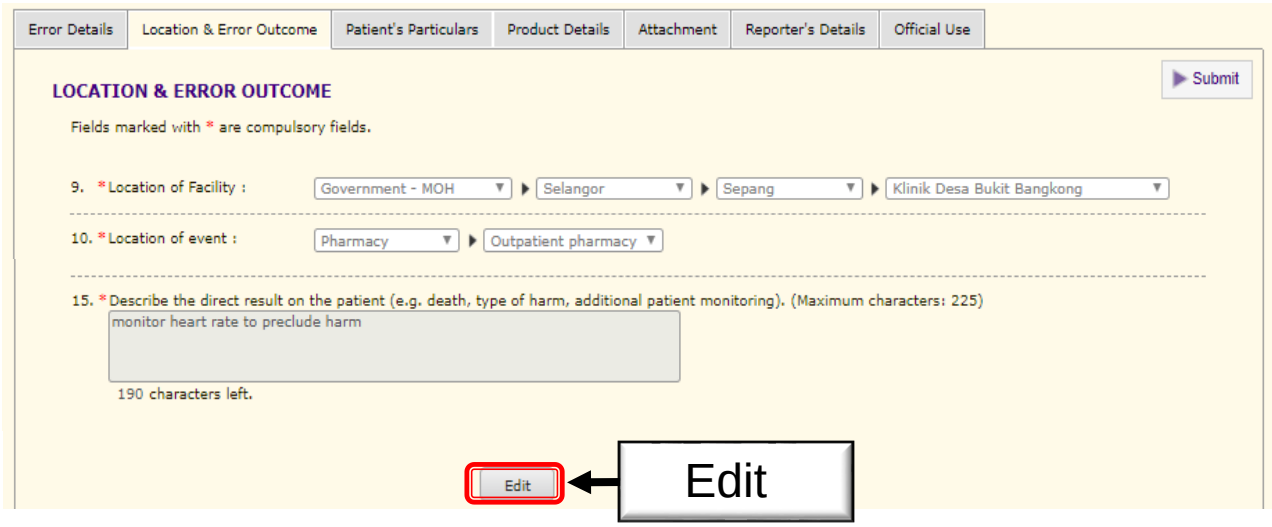
OR Alternatively, you can also access the report by choose form the menu bar [ME Report Status]> [Enquiry] after you log in to your account.



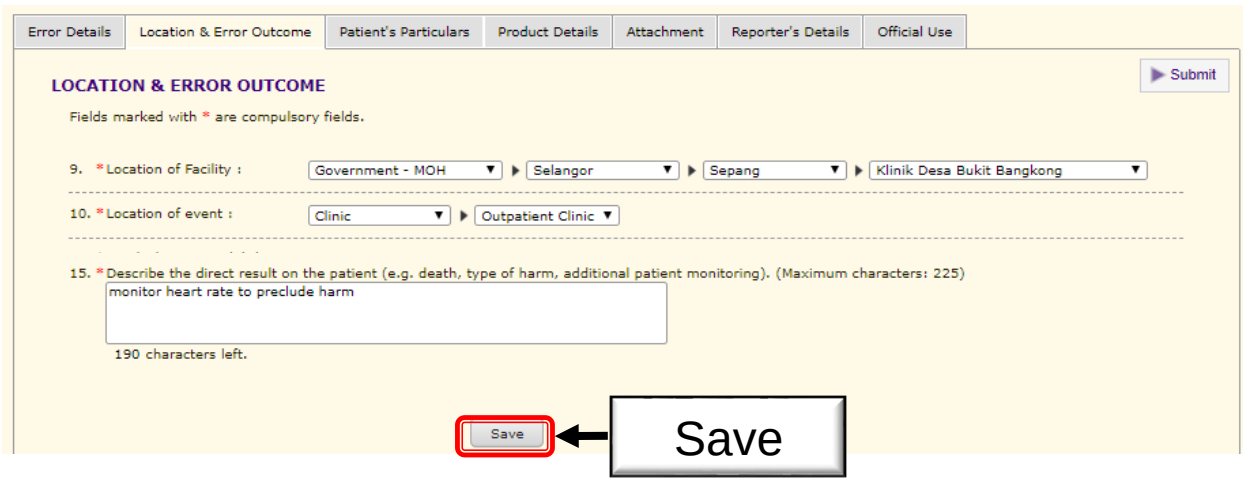
3. Read the remarks and click **EDIT** to amend report



4. Click EDIT tab at the bottom of the page to make the necessary amendment(s).



5. Click **SAVE** after making every changes/amendments.



Example:

Notification for report not approved/ not endorsed.

REMINDER : Report Not Approved

Administrator MERS [admin@mers.moh.gov.my]

To: ONG SU HUA

Dear ***Reporter***,

Your report(s) sent through MERS Online is highly appreciated.
Kindly take action upon the enquired report(s).

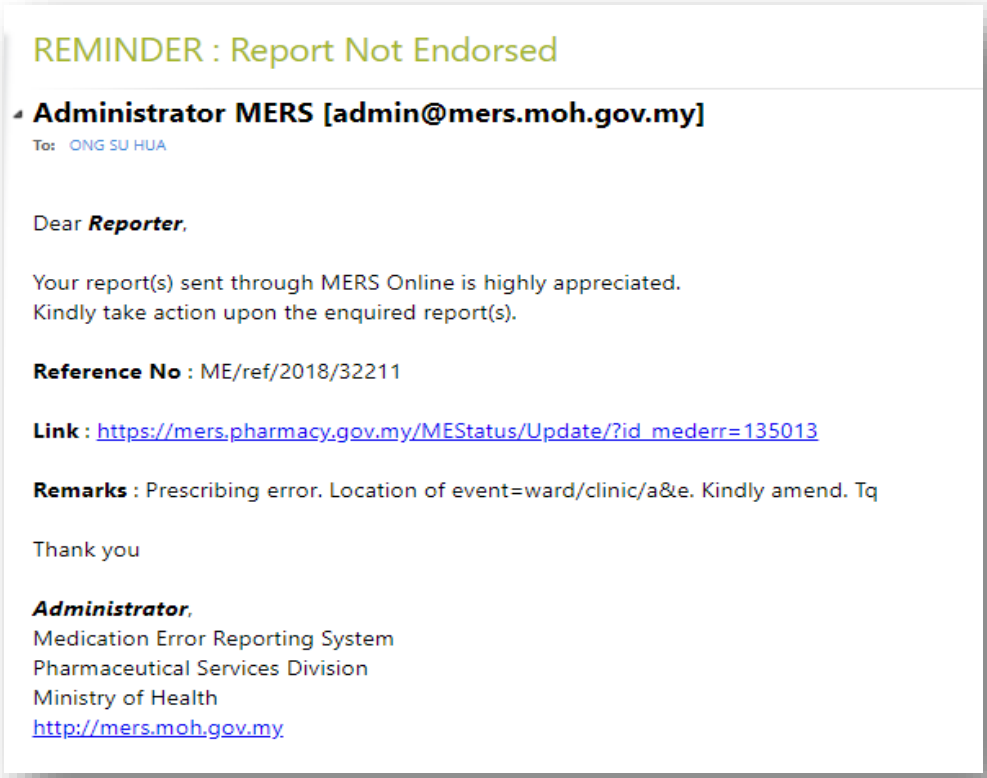
Reference No : ME/ref/2018/32211

Link : https://mers.pharmacy.gov.my/MEStatus/Update/?id_mederr=135013

Remarks : Prescribing error. Location of event=ward/clinic/a&e. Kindly amend. Tq

Thank you

Administrator,
Medication Error Reporting System
Pharmaceutical Services Division
Ministry of Health
http://mers.moh.gov.my



REMINDER : Report Not Endorsed

Administrator MERS [admin@mers.moh.gov.my]

To: ONG SU HUA

Dear ***Reporter***,

Your report(s) sent through MERS Online is highly appreciated.
Kindly take action upon the enquired report(s).

Reference No : ME/ref/2018/32211

Link : https://mers.pharmacy.gov.my/MEStatus/Update/?id_mederr=135013

Remarks : Prescribing error. Location of event=ward/clinic/a&e. Kindly amend. Tq

Thank you

Administrator,
Medication Error Reporting System
Pharmaceutical Services Division
Ministry of Health
http://mers.moh.gov.my

MEDICATION ERROR REPORTING SYSTEM (MANUAL)

Who can report?

Only healthcare professionals can submit report to Medication Error Reporting System (MERS).

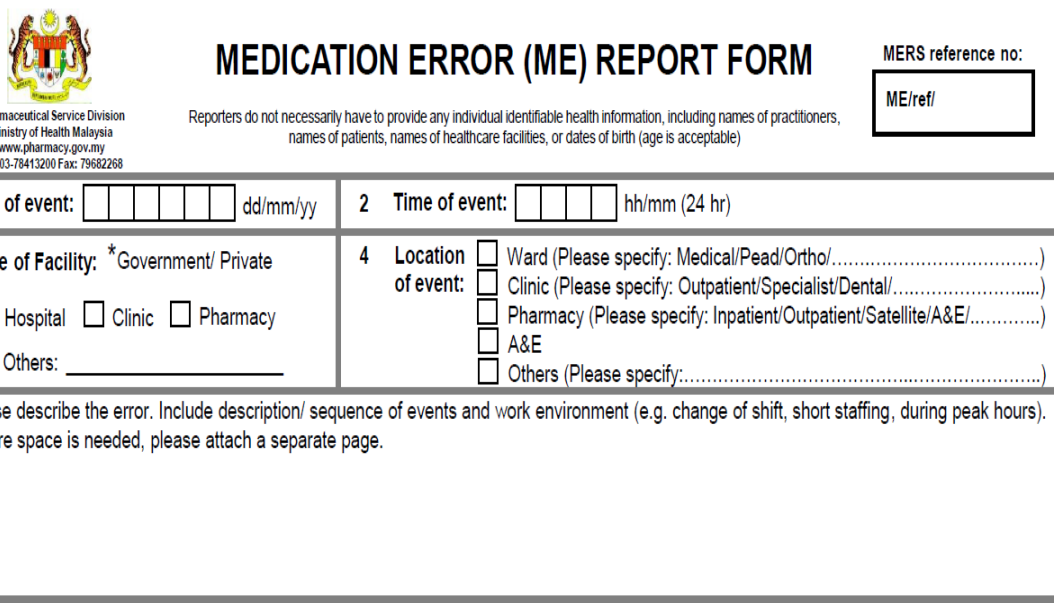
How to report?

Fill in the Medication Error Reporting Form (refer appendices) and submit to the following address:

Medication Safety Section
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor.

How to fill in the Medication Error Reporting Form?

* No 1-5 Describe the error occurred (date, time, type of facility, location of event and the brief description).



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

MEDICATION ERROR (ME) REPORT FORM

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)

MERS reference no: ME/ref/

1 Date of event: ☐☐☐☐☐☐ dd/mm/yy

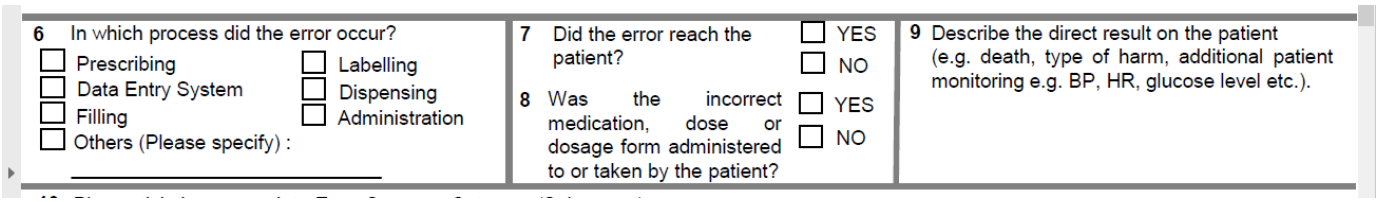
2 Time of event: ☐☐☐☐ hh/mm (24 hr)

3 Type of Facility: *Government/ Private
☐ Hospital ☐ Clinic ☐ Pharmacy
☐ Others: _____

4 Location of event:
☐ Ward (Please specify: Medical/Pead/Ortho/.....)
☐ Clinic (Please specify: Outpatient/Specialist/Dental/.....)
☐ Pharmacy (Please specify: Inpatient/Outpatient/Satellite/A&E/.....)
☐ A&E
☐ Others (Please specify:.....)

5 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.

Fields marked with * are compulsory fields.



*** 6. In which process did the error occur.**

(Note: You may select more than 1 option given).

Examples:

Location of event	In which process did the error occur
Ward	Prescribing, Dispensing, Administration, others
A&E	Prescribing, Administration, others
Clinic	Prescribing, Administration, others
Pharmacy	Data Entry, Labelling, Filling, Dispensing
Others	Registration

*** 7. Did the error reach the patient?**

- Yes, if medication reaches the patient
- No, if medication didn't reaches the patient
- An "error of omission" does reach the patient

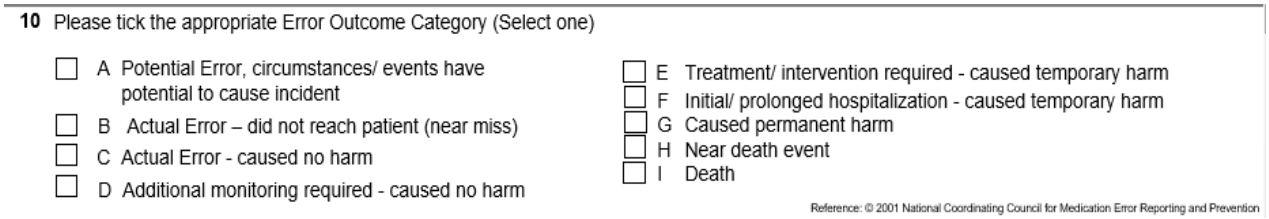
*** 8.Was the incorrect medication, dose or dosage form administered to or taken by the patient?**

- Yes, if medication reaches the patient and is administered
- No, if medication reaches the patient but not administered

*** 9. Describe the direct result on the patient** *(e.g. death, type of harm, additional patient monitoring).*

Example: Additional patient monitoring includes, vital signs monitoring, sign & symptoms of toxicity, blood glucose monitoring, TDM level monitoring, Glasgow coma scale, etc.

Fields marked with * are compulsory fields.



10 Please tick the appropriate Error Outcome Category (Select one)

- ☐ A Potential Error, circumstances/ events have potential to cause incident
- ☐ B Actual Error – did not reach patient (near miss)
- ☐ C Actual Error - caused no harm
- ☐ D Additional monitoring required - caused no harm
- ☐ E Treatment/ intervention required - caused temporary harm
- ☐ F Initial/ prolonged hospitalization - caused temporary harm
- ☐ G Caused permanent harm
- ☐ H Near death event
- ☐ I Death

Reference: © 2001 National Coordinating Council for Medication Error Reporting and Prevention

*10. Error Outcome Category

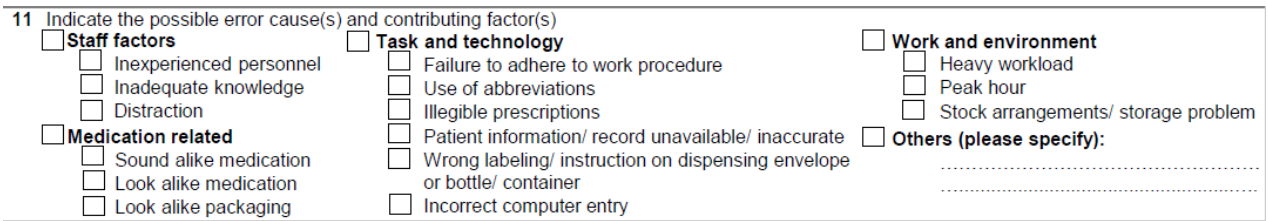
In selecting the patient outcome category, select the highest level severity that applies during the course of the event. For example, if a patient suffers a severe anaphylactic reaction (Category H) and requires treatment (Category F) but eventually recovers completely, the event should be coded as Category H.

Select only one of the medication error categories or subcategories, whichever best fits the error that is being reported.

NO ERROR	
Category A	Circumstances or events that have the capacity to cause error. Example: Illegible handwriting, use of abbreviation, incorrect storage of medication/ mix up drugs
ERROR, NO HARM *[Note: Harm is defined as temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention.]*	
Category B	An error occurred but the error did not reach the patient (An "error of omission" does reach the patient). Example: Error detected before dispensing to the patient.
Category C	An error occurred that reached the patient but did not cause patient harm. •Medication reaches the patient and is administered. •Medication reaches the patient but not administered. Example: a) Pharmacist dispensed incorrect medication to ward. Nurse administered the incorrect medication to patient. b) Pharmacist dispensed incorrect medication to the patient. The patient realised that the medicine was incorrect and returned it back to the pharmacy.

Fields marked with * are compulsory fields.

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. Example: Other patient's profile was accidentally placed inside the patient's file which has lead to wrong medications prescribed during previous visit. MO was informed. Close glucose monitoring was planned for this patient. The blood glucose level was reported as mild elevation only.
ERROR, HARM Root cause analysis (RCA) reports are required and should be attached (Refer 20.)	
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 contributed to or resulted in the patient's death


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

- ☐ **Staff factors**
  - ☐ Inexperienced personnel
  - ☐ Inadequate knowledge
  - ☐ Distraction
- ☐ **Medication related**
  - ☐ Sound alike medication
  - ☐ Look alike medication
  - ☐ Look alike packaging
- ☐ **Task and technology**
  - ☐ Failure to adhere to work procedure
  - ☐ Use of abbreviations
  - ☐ Illegible prescriptions
  - ☐ Patient information/ record unavailable/ inaccurate
  - ☐ Wrong labeling/ instruction on dispensing envelope or bottle/ container
  - ☐ Incorrect computer entry
- ☐ **Work and environment**
  - ☐ Heavy workload
  - ☐ Peak hour
  - ☐ Stock arrangements/ storage problem
- ☐ **Others (please specify):**
  - .....
  - .....

* 11. Contributing Factor(s)

What caused the described error to occur?
(Note: You may select more than 1 option given).

For question 12-14, please fill each box with one of the following option.

a. Specialist
b. Medical Officer (MO)
c. Houseman Medical Officer (HMO)
d. Pharmacist
e. Provisional Registered Pharmacist (PRP)
f. Nurse
g. Nurse (Trainee)
h. Assistant Medical Officer (AMO)
i. Assistant Medical Officer (AMO Trainee)
j. Pharmacist Assistant
k. Pharmacist Assistant (Trainee)
l. Patient/ Caregiver
m. Dentist
n. Others (Please specify: .....)

12 Which category made the initial error? [ ]

13 Other category also involved in the error? [ ]

14 Which category discovered the error or recognised the potential error? [ ]

* 12. Category made the initial error

Who started the initial error?

Examples:

Process in which the error occurs	**Category made the initial error** ***(under normal circumstances)***
Prescribing	Specialist, MO, HMO, AMO, Dentist, Nurse
Dispensing	Pharmacist, PRP, PA, PA(Trainee)
Administration	Specialist, MO, HMO, AMO, Nurse, Nurse(Trainee)
Data Entry	Specialist, MO, HMO, AMO, Dentist, Pharmacist, PRP, PA, PA(Trainee)
Monitoring	Specialist, MO, HMO, AMO, Dentist, Pharmacist, PRP, PA, PA(Trainee)
Registration	Registration counter staff (e.g. PRA)
Preparation of Drugs	Pharmacist, PRP, PA, PA(Trainee), Nurse
Documentation	Pharmacist, PRP, PA, PA(Trainee), Nurse

13. Category also involved in the error

Who also involved causing the error to occur?

* 14. Category detected the error

Who detected the error occurred?

Fields marked with * are compulsory fields.

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

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

15. Patient's particulars: age, gender and diagnosis.

Patient's particulars are optional fields but reporters are encouraged to fill these particulars.

16 **Product Details:** Please complete the following for the product(s) involved. Kindly attach a separate page for additional products.

Product Description	Product # 1 (intended)	Product # 1(error)
16.1 Generic Name (Active Ingredient)		
16.2 Brand / Product Name		
16.3 Dosage Form		
16.4 Dose, frequency, duration, route		

Please fill in 16.5-16.7 if error involved similar product packaging:

Product Description	Product # 1 (intended)	Product # 1(error)
16.5 Manufacturer		
16.6 Strength / Concentration		
16.7 Type and Size of Container		

* Please delete where not applicable

* 16. Product details. (Fill in the relevant column).

Fill in 16.5-16.7 if the error involved similar packing.

17 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

_____
_____

18 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).

17. Attachment.

You are encouraged to attach the relevant materials such as product label, copy of prescription/ order/ Root Cause Analysis (RCA) report as supporting documents.

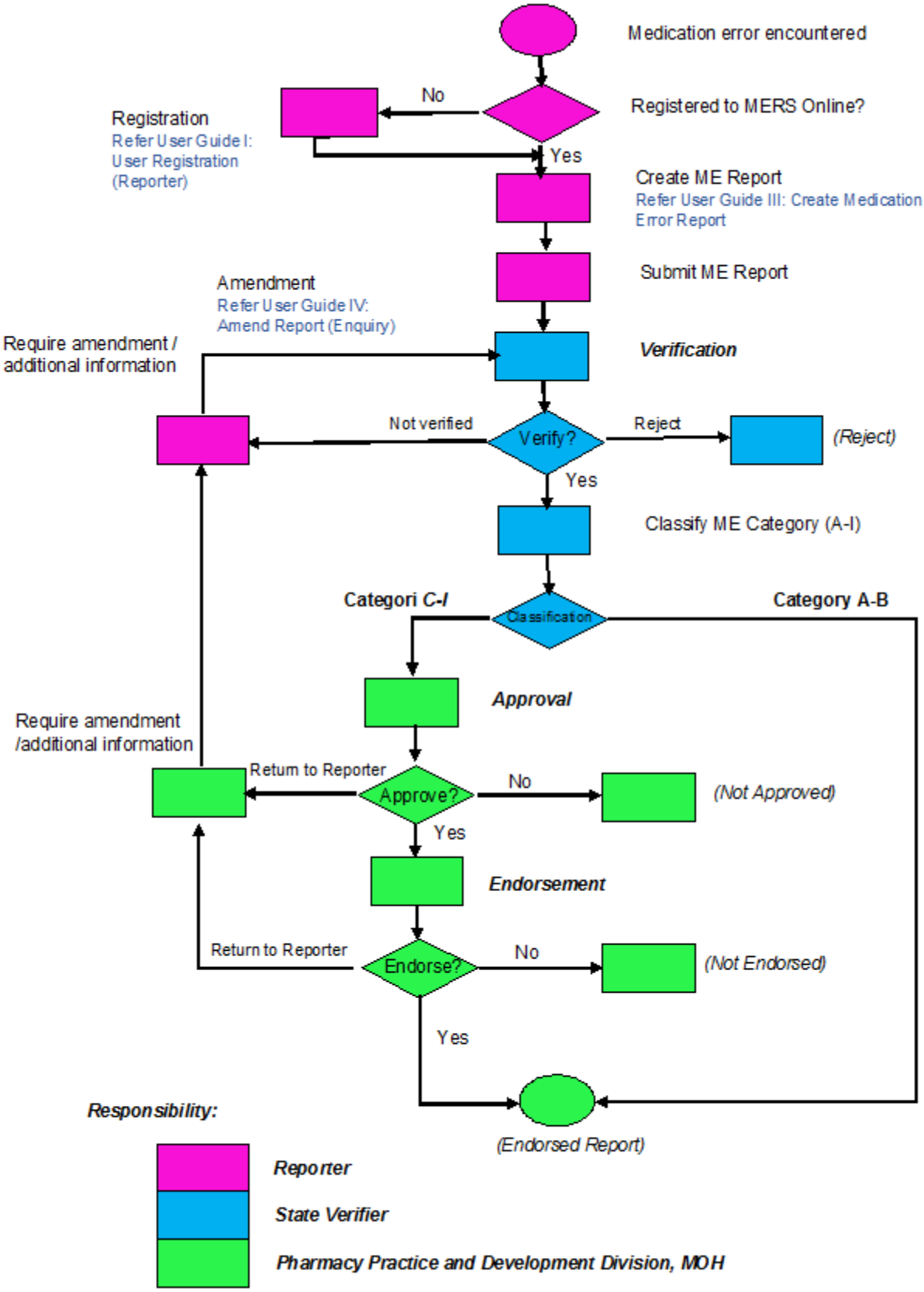
18. Recommendation/ Remedial action taken

Describe the corrective / preventive action taken to avoid the error so it would not occur

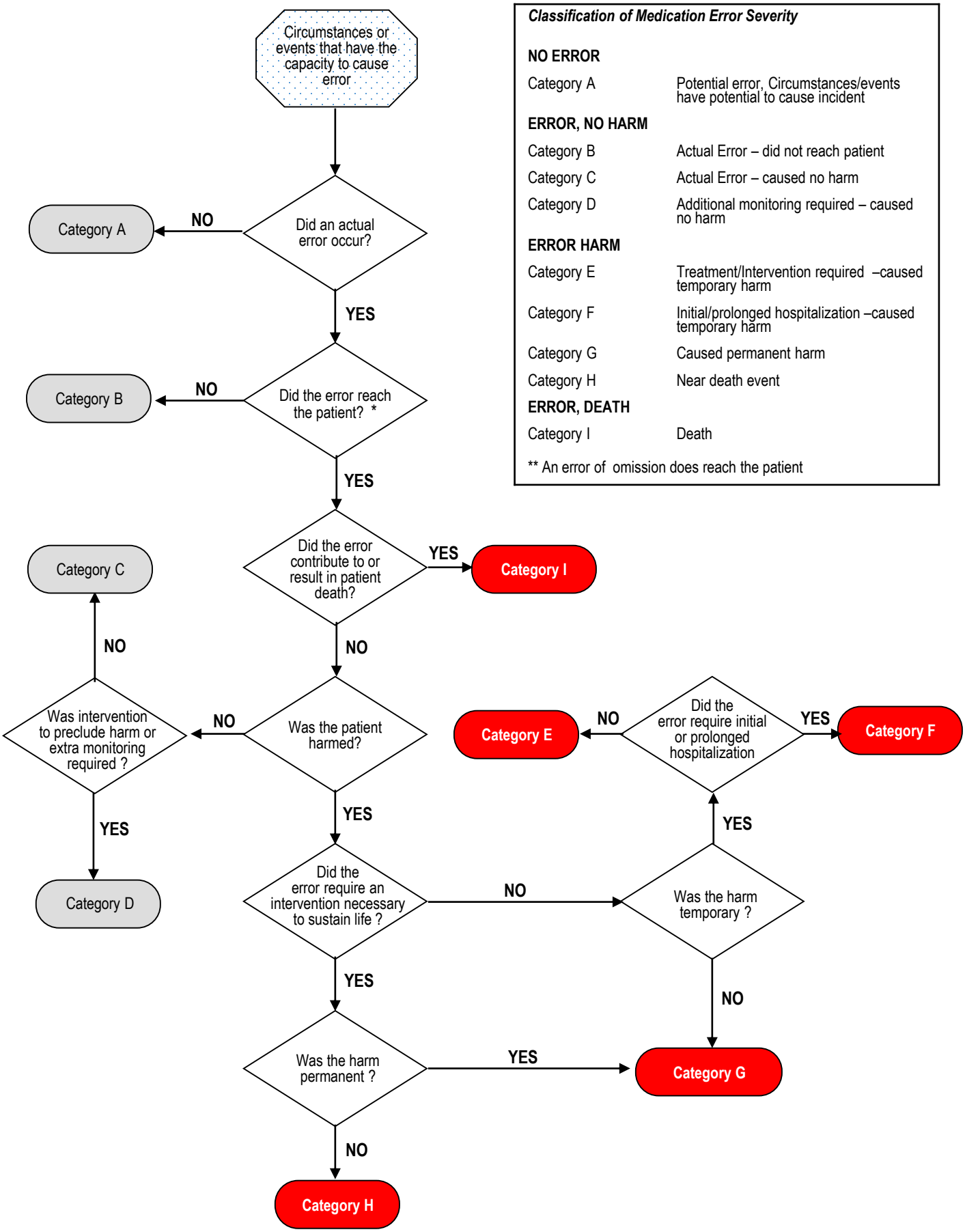
APPENDICES

- Flow Chart (MERS Online)
- Guide For Categorizing Medication Errors
- Types of Medication Error
- Case Examples
- Medication Error Reporting Form (Manual)

Flow Chart (MERS Online)



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

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, 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 that reach the patient
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 health care 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 duplicate doses to the patient, i.e. one or more dosage units in addition to those that were ordered or prescribing more or less than standard dose defined in practice
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

Types of Medication Error

Type		Definition
g.	Drug-preparation error	Drug product incorrectly formulated or manipulated before administration
h.	Route of administration error	Use of 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 behaviour regarding adherence to a prescribed medication regimen
m.	Other medication error	Any medication error that does not fall into one of the above predefined categories

Case Examples

No	Scenario	Location of event	Process of error	Reach/ Not Reach	Taken/ Not Taken	Near Miss/ Actual Error
1	Prescribing error detected by the pharmacy staff before dispense the medication to the patient at the dispensing counter.	Ward/ Clinic/ A&E	Prescribing	Not Reach	Not Taken	Near Miss
2	Prescribing error detected by the patient at the dispensing counter.	Ward/ Clinic/ A&E	Prescribing & Dispensing	Reach	Not Taken	Actual Error
3	Prescriber did not prescribe the medication that is indicated for the patient. Error detected by the pharmacy staff before dispensing.	Ward/ Clinic/ A&E	Prescribing	Not Reach	Not Taken	Near Miss
4	Prescriber did not prescribe the medication that is indicated for the patient. Error detected by the patient at the dispensing counter.	Ward/ Clinic/ A&E	Prescribing	Reach	Not Taken	Actual Error
5	Prescriber did not prescribe the medication that is indicated for the patient. Error detected by the patient and return to the pharmacy for clarification.	Ward/ Clinic/ A&E	Prescribing & Dispensing	Reach	Taken/ Not Taken	Actual Error
6	Medication error detected by the pharmacy staff at the dispensing counter.	Pharmacy > Out-patient Pharmacy	Data entry/ Labelling/ Filling	Not Reach	Not Taken	Near Miss
7	Pharmacist enter wrong drug in the computerized system. Label printed out wrongly and the pharmacist assistant filled the drug based on the wrong label. Error detected before dispensing.	Pharmacy > Out-patient Pharmacy	Data entry & Labelling & Filling	Not Reach	Not Taken	Near Miss
8	Medication error detected by the patient at the dispensing counter.	Pharmacy > Out-patient Pharmacy	Data entry/ Labelling/ Filling/ Dispensing	Reach	Not Taken	Actual Error

Case Examples

No	Scenario	Location of event	Process of error	Reach/ Not Reach	Taken / Not Taken	Near Miss/ Actual Error
9	Wrong medication dispensed to the patient and patient return to the pharmacy for clarification.	Pharmacy> Outpatient Pharmacy	Dispensing	Reach	Taken/ Not Taken	Actual error
10	Wrong medication/ dosage supplied by the in-patient pharmacy and the error detected by nurse / doctor / pharmacist before / during drug administration.	Pharmacy> In- patient Pharmacy	Dispensing	Not Reach	Not Taken	Near miss
11	Medication not filled by the pharmacy and the error detected by nurse	Pharmacy> In-patient Pharmacy	Filling & Dispensing	Not Reach	Not Taken	Near miss
12	Wrong medication/ dosage given to the patient and the error detected by the patient	Ward	Administration	Reach	Taken/ Not Taken	Actual Error
13	Medication not supplied by the pharmacy and the error detected by nurse during administration. Patient didn't missed the dose.	Pharmacy> In-patient Pharmacy	Dispensing	Not Reach	Not Taken	Near Miss
14	Medication not supplied by the pharmacy and patient missed the dose.	Pharmacy> In-patient Pharmacy	Dispensing & Administration	Reach	Not Taken	Actual Error
15	Medication not served in the ward.	Ward	Administration	Reach	Not Taken	Actual Error

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

MEDICATION ERROR (ME) REPORT FORM

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)

MERS reference no: ME/ref/

1 Date of event: ☐☐☐☐☐☐ dd/mm/yy

2 Time of event: ☐☐☐☐ hh/mm (24 hr)

3 Type of Facility: *Government/ Private

☐ Hospital ☐ Clinic ☐ Pharmacy

☐ Others: _____

4 Location of event:

☐ Ward (Please specify: Medical/Pead/Ortho/……)
☐ Clinic (Please specify: Outpatient/Specialist/Dental/……)
☐ Pharmacy (Please specify: Inpatient/Outpatient/Satellite/A&E/……)
☐ A&E
☐ Others (Please specify:……)

5 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.

6 In which process did the error occur?

☐ Prescribing ☐ Data Entry System
☐ Filling ☐ Labelling
☐ Dispensing ☐ Administration
☐ Others (Please specify) :
_____

7 Did the error reach the patient? ☐ YES ☐ NO

8 Was the incorrect medication, dose or dosage form administered to or taken by the patient? ☐ YES ☐ NO

9 Describe the direct result on the patient (e.g. death, type of harm, additional patient monitoring e.g. BP, HR, glucose level etc.).

10 Please tick the appropriate Error Outcome Category (Select one)

☐ A Potential Error, circumstances/ events have potential to cause incident
☐ B Actual Error – did not reach patient (near miss)
☐ C Actual Error - caused no harm
☐ D Additional monitoring required - caused no harm
☐ E Treatment/ intervention required - caused temporary harm
☐ F Initial/ prolonged hospitalization - caused temporary harm
☐ G Caused permanent harm
☐ H Near death event
☐ I Death

Reference: © 2001 National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

11 Indicate the possible error cause(s) and contributing factor(s).

☐ **Staff factors**
- ☐ Inexperienced personnel
- ☐ Inadequate knowledge
- ☐ Distraction

☐ **Medication related**
- ☐ Sound alike medication
- ☐ Look alike medication
- ☐ Look alike packaging

☐ **Task and technology**
- ☐ Failure to adhere to work procedure
- ☐ Use of abbreviations
- ☐ Illegible prescriptions
- ☐ Patient information/ record unavailable/ inaccurate
- ☐ Wrong labeling/ instruction on dispensing envelope or bottle/ container
- ☐ Incorrect computer entry

☐ **Work and environment**
- ☐ Heavy workload
- ☐ Peak hour
- ☐ Stock arrangements/ storage problem

☐ **Others (please specify):**
……
……

For question 12-14, please fill each box with one of the following option.

a. Specialist
b. Medical Officer (MO)
c. Houseman Medical Officer (HMO)
d. Pharmacist
e. Provisional Registered Pharmacist (PRP)
f. Nurse
g. Nurse (Trainee)
h. Assistant Medical Officer (AMO)
i. Assistant Medical Officer (AMO Trainee)
j. Pharmacist Assistant
k. Pharmacist Assistant (Trainee)
l. Patient/ Caregiver
m. Dentist
n. Others (Please specify: ……)

12 Which category made the initial error? ☐

13 Other category also involved in the error? ☐

14 Which category discovered the error or recognised the potential error? ☐

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

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

16 Product Details: Please complete the following for the product(s) involved. Kindly attach a separate page for additional products.

Product Description	Product # 1 (intended)	Product # 1(error)
16.1 Generic Name (Active Ingredient)		
16.2 Brand / Product Name		
16.3 Dosage Form		
16.4 Dose, frequency, duration, route		

If error involved similar product packaging, please fill in 16.5-16.7.

Product Description	Product # 1 (intended)	Product # 1(error)
16.5 Manufacturer		
16.6 Strength / Concentration		
16.7 Type and Size of Container		

* Please delete where not applicable

17 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

_____

_____

18 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 :	
Profession :	
Facility and Address :	Postcode : ☐☐☐☐☐
E-mail :	
Telephone number :	Fax Number :

For official use :

Date report received : ☐☐☐☐☐☐ dd/mm/yy

Ref. No. ☐☐☐☐☐☐

ME Type ☐

ME Category ☐

(Fold here)

Medication Safety

Is Everyone's Responsibility

(Fold here)

NO STAMP REQUIRED

SETEM POS TIDAK DIPERLUKAN

REPLY PAID / JAWAPAN BERBAYAR
MALAYSIA
No. Lesen : BRS 0915 SEL

Medication Safety Section
Pharmacy Practice and Development Division
Pharmaceutical Services Programme
Ministry of Health Malaysia
P.O. Box 924, Jalan Sultan,
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