PHARMACY DEPARTMENT
HOSPITAL ENCHE' BESAR HAJJAH KHALSOM, KLUANG
MINISTRY OF HEALTH MALAYSIA

GUIDELINE ON MEDICATION SAFETY

2021

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Introduction

Medication safety is an important element in providing the right treatments to patients and considered as a practice policy in Hospital Enche' Besar Hajjah Khalsom (HEBHK). All personnel involved in the process of providing treatment to patients should practise medication safety. A variety of methods and strategies introduced in order to increase the level of medication safety, for example the introduction to list of Look Alike Sound Alike Medications, High Alert Medications, Drug Allergy Cards and others.

This Guideline on Medication Safety serves as a guidance and provides the healthcare professionals in HEBHK information regarding the aspect of medication safety. It is a compilation of guidelines and references from the Ministry of Health Malaysia as well as the workflow of Pharmacy Department HEBHK.

Medication Error (ME)

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

Medication error that may cause harm to patient but was detected before administration is classified as near miss and need to be reported in Medication Error Reporting System (MERS) and analysed for future improvement.

Medication error that was detected by patient or already administered to patient is categorized as actual error. Investigation must be done and remedial actions taken, as well as incident report have to be made and included in MERS.

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.

ERROR OUTCOME CATEGORY

NO ERROR	
CATEGORY A	Circumstances or events that have the capacity to cause error. Example: Illegible handwriting, use of abbreviation, incorrect quantity wrongly fill floor stock (error did not happen but might happen if no checking or clarification made)
ERROR, NO HARM	
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: Pharmacist dispensed incorrect medication to the patient. But the patient realized that the medicine is incorrect and return it back to 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 patient's file which has lead to wrong medications prescribed during previous visit. MO was informed. Close glucose monitoring was planned for this patient. Blood glucose level was reported as mild elevation only.
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 contributed to or resulted in the patient's death.

TYPES OF MEDICATION ERROR

TYPE	DEFINITION
1. 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.
2. 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.
3. 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).
4. Unauthorised drug error	Dispensing or administration to the patient of medication not authorised by a legitimate prescriber.
5. 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.
6. Dosage-form error	Dispensing or administration to the patient of a drug product in a different dosage form than that ordered by the prescriber.
7. Drug-preparation error	Drug product incorrectly formulated or manipulated before administration.
8. Route of administration error	Use of wrong route of administration of the correct drug.
9. Administration-technique error	Inappropriate procedure or improper technique in the administration of a drug other than wrong route.
10. 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.

TYPE	DEFINITION
11. 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.
12. Compliance error	Inappropriate patient behaviour regarding adherence to a prescribed medication regimen.
13. Other medication error	Any medication error that does not fall into one of the above predefined categories.

MEDICATION ERROR REPORT FORM

Pharmaceutical Services Programme
Ministry of Health Malaysia
www.pharmacy.gov.my
Tel: 03-78413200 Fax: 78602268

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

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,
46790 Petaling Jaya, Selangor.

INCIDENT REPORTING FORM

SULIT

MINISTRY OF HEALTH MALAYSIA
PATIENT SAFETY INCIDENT REPORTING FORM

IR 2.0/2017

DATE OF REPORTING:____/____/_____

*Borang boleh diisi dalam **Bahasa Malaysia***

SECTION A: TO BE COMPLETED BY THE REPORTER OF THE INCIDENT

INCIDENT DESCRIPTION (Please fill in the blanks)

1.	**NAME OF FACILITY/ INSTITUTION**		**PATIENT'S NAME**	
2.	**DATE OF INCIDENT**	☐☐ / ☐☐ / ☐☐☐☐	**IF UNCERTAIN** APPROXIMATE DATE:____/____/____	
3.	**TIME OF INCIDENT**	☐☐ : ☐☐ AM/ PM	**IF UNCERTAIN** APPROXIMATE TIME:____:____AM /PM	
4.	**PATIENT'S RN/ OTHER INDENTIFICATION NUMBER** :_____ **AGE**:_____ **ETHNIC**:_____ **GENDER** : MALE / FEMALE / UNKNOWN (please circle) **STATUS** : ALIVE / DECEASED **DIAGNOSIS** : _____ **LANGUAGE BARRIER**: YES / NO			
5.	**TYPE OF PATIENT** (please tick one) ☐ INPATIENT ☐ DAY CARE ☐ OUTPATIENT ☐ OTHERS: SPECIFY ☐ A&E ☐ _____ **LOCATION/ WARD / CLINIC** : _____	**DEPARTMENT(S) INVOLVED** (please tick) ☐ MEDICAL ☐ O&G ☐ ONCOLOGY ☐ SURGICAL ☐ PHARMACY ☐ GERIATRIC ☐ ORTHOPAEDIC ☐ RADIOLOGY & IMAGING ☐ REHABILITATION ☐ PAEDIATRIC ☐ A&E ☐ ICU/ OCU ☐ LABORATORY ☐ PSYCHIATRY ☐ OTHERS: SPECIFY _____		

6. **TYPE OF INCIDENT** (please tick one) ☐ **Actual** ☐ **Near Miss**

Examples of incidents that need to be reported: (Note that this list is not exhaustive)

☐	i.	Wrong surgery/procedure –wrong site, side or patient
☐	ii.	Unintended retained foreign body in patient after an operation/procedure
☐	iii.	Error in transfusion of blood/blood products
☐	vi.	Medication error (please fill in MERS form as well)
☐	v.	Patient fall in the facility
☐	vi.	Obstetric related incidents
☐	vii.	Adverse outcome of clinical procedure
☐	viii.	Pre-hospital care and ambulance service related incident
☐	ix.	Radiotherapy related incident
☐	x.	Patient suicide / attempted suicide
☐	xi.	Patient discharged to wrong family members / next-of -kin
☐	xii.	Assault/ battery of patient
☐	xiii.	Unanticipated Fire – Fire, flame, or unanticipated smoke, heat, or flashes occurring in the facility
☐	xiv.	**Others type of incident** :_____

7. **BRIEF DESCRIPTION OF WHAT HAPPENED** (Please fill in the blanks)
The description should explain what happen prior and during the incident and how it occurred. Do include any additional information which you think may lead to the incident.

1

PATIENT SAFETY UNIT
MEDICAL CARE QUALITY SECTION, MEDICAL DEVELOPMENT DIVISION, MINISTRY OF HEALTH MALAYSIA
2017

SULIT

PATIENT OUTCOME (please tick one) **& IMMEDIATE ACTION – ONLY FOR ACTUAL INCIDENT**

8. **OUTCOME OF INCIDENT**		NONE
		MILD
		MODERATE
		SEVERE
		DEATH
		CURRENTLY CANNOT BE DETERMINED

9. **IMMEDIATE ACTION FOLLOWING INCIDENT**	

REPORTED BY

10. **DESIGNATION:** (please tick one)

	NURSE		SPECIALIST
	HOUSE OFFICER		PHARMACIST
	MEDICAL OFFICER		OTHERS:

SIGNATURE OF REPORTER:

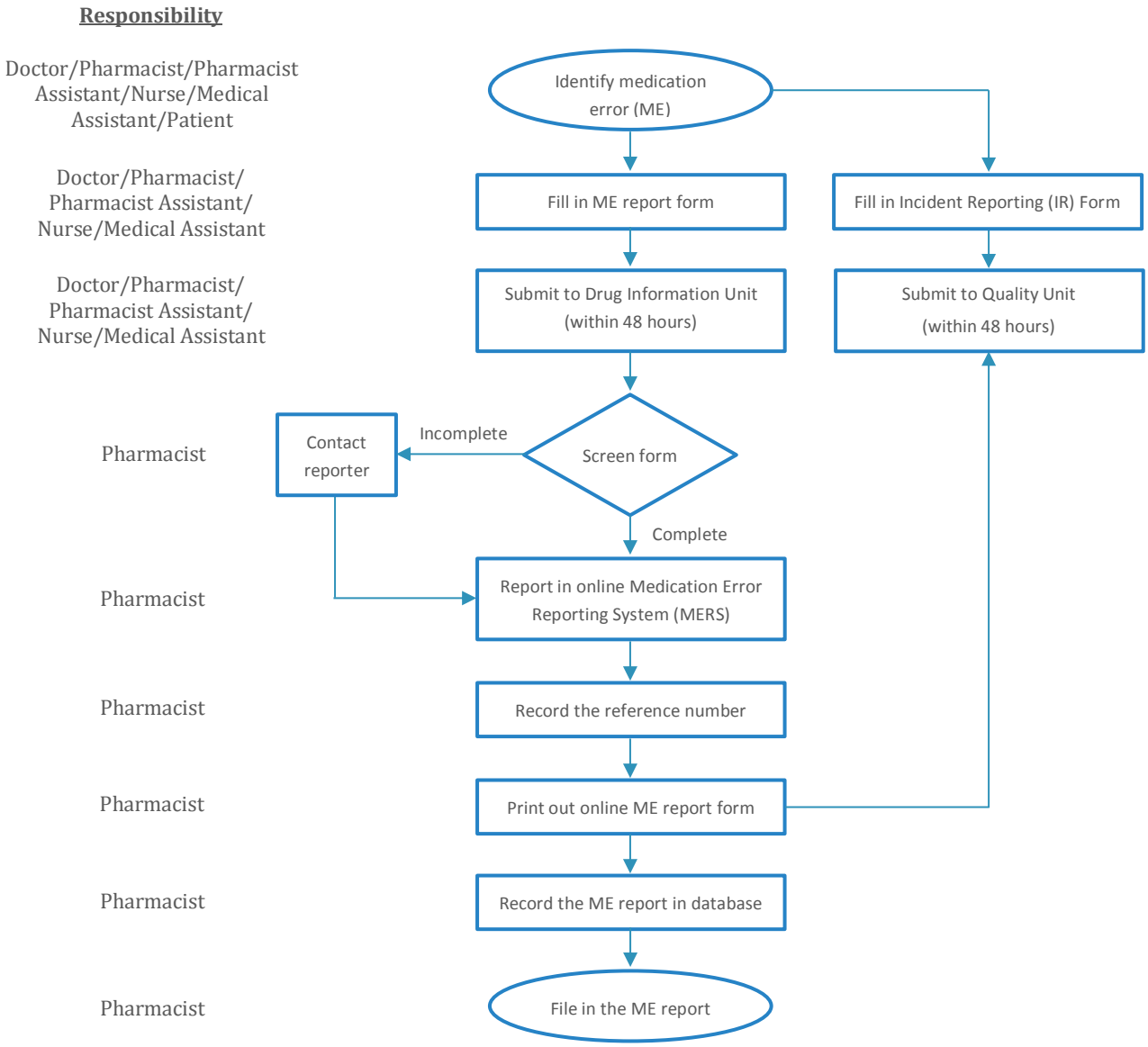
NAME:
DATE:

Note: As part of good leadership and clinical governance, please inform the incident to your Head of Department(s) immediately.

SECTION B : TO BE COMPLETED BY THE RISK MANAGER/ QUALITY MANAGER OF HOSPITAL

1. **ACTION TAKEN:** *Mandatory Root Cause Analysis:* *1) Incident with Severe or Death outcome* *2) Other incident/near miss based on the Risk Manager/ Quality Manager assessment* *3) Directive from State Health Department / Ministry.*	(Please tick) ☐ "PRESCRIPTION SLIP" ☐ MONITOR THE TREND FIRST ☐ RCA ☐ MIRCA (Multi-incident Root Cause Analysis) Additional comments :
2. **e-IR SUBMITTED?** Please submit to e-IR **within 5 days** from the date of the incident.	Date of Submission:_____-_____-_____
3. **RISK MANAGER/ QUALITY MANAGER OF HOSPITAL**	(please fill in the blanks) NAME: SIGNATURE: DESIGNATION: DATE:

FLOW CHART OF MEDICATION ERROR REPORTING IN HEBHK



REFERENCES

1. Guideline on Medication Error Reporting System, 2nd Edition, 2019. Pharmacy Practice and Development Division, Pharmaceutical Services Programme, Ministry of Health Malaysia.

High Alert Medications (HAMs)

High alert medications (HAMs) are defined as medications that bear a heightened risk of causing significant patient harm when these medications are used in error. HAMs or high-risk medications, in the context of safe use relating to certain situations, are associated with a significant risk of harm. Though medication mishaps with high alert medications may or may not be more common than other medications, the consequences following an error with these medications can be serious to the patient. The inherent risk of using HAMs, work environment (e.g. in the case of hospital inpatient settings), organizational culture and clinical scenarios (e.g. emergency and anaesthesia settings) could impose difficulties for healthcare professionals in ensuring patient safety while delivering health services. Similarly, there are also some conditions inherent to vulnerable groups, such as pregnant women, children and elderly, and clinical risk areas such as cancer patients. These are just some examples of high-risk situations.

HIGH ALERT MEDICATION LIST IN HEBHK

NO	CATEGORY	MEDICATIONS
1.	**Adrenergic agonists, IV**	➢ Adrenaline (Epinephrine) 1 in 1000 (1mg/ml) Inj ➢ Noradrenaline (Norepinephrine) 4mg/4ml Inj ➢ Phenylephrine 10mg/ml Inj ➢ Ephedrine 30mg/ml Inj
2.	**Adrenergic antagonists, IV**	➢ Propranolol 1mg/ml Inj ➢ Labetalol 25mg/5ml Inj ➢ Esmolol 10mg Inj
3.	**Anaesthetic Agents (General, Inhaled, IV)**	➢ Etomidate 20mg/10ml Inj ➢ Ketamine 500mg/10ml Inj ➢ Propofol 200mg/20ml Inj ➢ Dexmedetomidine HCl 100mcg/ml Inj ➢ Desflurane Liquid ➢ Sevoflurane Liquid
4.	**Antiarrhythmics, IV**	➢ Amiodarone 150mg/3ml Inj ➢ Digoxin 0.5mg/2ml Inj ➢ Lignocaine 100mg/5ml Inj
5.	**Antithrombotic Agents**	➢ Warfarin Sodium 1mg, 2mg, 3mg, 5mg ➢ Heparin 5000IU/ml ➢ Heparinised Saline 5000IU/ml ➢ Enoxaparin 40mg, 60mg Inj ➢ Fondaparinux 2.5mg/0.5ml Inj, 7.5mg/0.6ml Inj ➢ Tenecteplase 10,000 unit (50mg) Injection ➢ Streptokinase 1,500,000 IU Injection ➢ Urokinase 60,000 IU injection
6.	**Antivenom**	➢ Polyvalent Antivenom (Hemato, Neuro)
7.	**Chemotherapeutic Agents, Parental and Oral**	➢ *** All preparations that are clearly labelled as **CYTOTOXIC** agents*
8.	**Dialysis Solutions, Peritoneal and Hemodialysis**	➢ *** All kind of dialysis solutions, peritoneal and hemodialysis*
9.	**Dextrose, Hypertonic, 20% or Greater**	➢ Dextrose 20% (500ml) ➢ Dextrose 50% (10ml) ➢ Dextrose 50% (500ml)
10.	**Epidural or Intrathecal Medications**	➢ Bupivacaine Inj (Bupivacaine 0.5% Heavy Inj, Bupivacaine 0.5% Inj, Bupivacaine 0.5% with Adrenaline 1:200,000 Inj)

		➢ Bupi/Fentanyl Inj ➢ Ropivacaine Injection (2mg/ml Inj, 7.5mg/ml Inj) ➢ Levobupivacaine 5mg/ml Inj ➢ Ropi/Fentanyl Inj
11.	**Glyceryl Trinitrate 50mg/10ml Inj**	
12.	**Immunosuppressant Agents**	➢ All kind immunosuppressant agent
13.	**Inotropic Medications, IV**	➢ Dobutamine 250mg/20ml Inj ➢ Dopamine 200mg/5ml Inj
14.	**Insulin, Subcutaneous and IV**	➢ Insugen R / Actrapid ➢ Insugen N / Insulatard ➢ Insugen 30/70 / Mixtard
15.	**Magnesium Sulphate 2.49g in 5ml Inj**	
16.	**Moderate Sedation Agents, IV**	➢ Midazolam Inj (5mg/ml, 15mg/3ml)
17.	**Neuromuscular Blocking Agent**	➢ Atracurium Besylate 25mg/2.5ml Inj ➢ Rocuronium Bromide 10mg/ml Inj ➢ Suxamethonium Chloride 50mg/ml Injection
18.	**Opiates and Narcotics**	➢ Alprazolam 0.5mg Tab ➢ Clonazepam 2mg Tab ➢ Diazepam 5mg Rectal Supp ➢ Diazepam 5mg Tab ➢ Fentanyl 0.1mg/ml Inj ➢ Midazolam 7.5mg Tab ➢ Midazolam 15mg/3ml, 5ml/ml Inj ➢ Morphine 10mg Inj ➢ Morphine Sulphate 30mg SR Tab ➢ Morphine 10mg/5ml Syrup ➢ Pethidine 50mg, 100mg Inj ➢ Phenobarbitone 200mg Inj ➢ Phenobarbitone 30mg Tab ➢ Zolpidem Tartrate 10mg Tab ➢ ***And all other drugs clearly labelled as **Dangerous Drug (DD)***
19.	**Parenteral Nutrition Preparations**	➢ Smof Kabiven Central ➢ Smof Kabiven Peripheral ➢ Nutriflex Lipid Special

		➢ SMOF Lipid 20% ➢ ***And all other preparations clearly labelled as **TPN***
20.	**Potassium Salt Injections**	➢ Potassium Chloride 1g/10ml Inj ➢ Potassium Dihydrogen Phosphate 1.361g/10ml Inj
21.	**Sodium Chloride Solution (Greater than 0.9%)**	➢ Sodium Chloride 20% Inj (10ml) ➢ Sodium Chloride 3% Inj (500ml)
22.	**Oxytocin 10 unit/ml Injection**	
23.	**Moderate and Minimal Sedation Agent, Oral, for Children**	➢ Chloral Hydrate, Midazolam, Ketamine [using the parenteral form]

KEMENTERIAN KESIHATAN MALAYSIA
HOSPITAL ENCHE' BESAR HAJJAH KHALSOM, KLUANG

MEMO JABATAN FARMASI DAN BEKALAN

Ruj. Tuan: **Tarikh:** 21 Julai 2021
Ruj. kami: (47) HEBHK/FARM/98/100-5-11

TAJUK	**EDARAN** **1) *POLICY ON MANAGEMENT OF HIGH ALERT MEDICATIONS (HAMs) 4th EDITION, 2021* &** **2) *LIST OF LOOK ALIKE SOUND ALIKE MEDICATIONS IN HEBHK (APRIL 2021)***	
DARIPADA	Ketua Pegawai Farmasi	**s.k:** Pengarah Hospital PF Y/M Farmasi Float DIU
KEPADA	**KETUA JABATAN KLINIKAL** **PENYELIA JURURAWAT** **KETUA JURURAWAT** **PENOLONG PEGAWAI PERUBATAN**	

Dengan segala hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Jabatan Farmasi & Bekalan telah menerbitkan ***Policy on Management of High Alert Medications (HAMs) 4th Edition, 2021*** dan Senarai HAMs di HEBHK bagi menggantikan *Policy on Management of High Alert Medications 3rd Edition, 2019*. Sehubungan itu, pihak Y.Brs. Dr/tuan/puan dimohon untuk menggunakan garis panduan yang terkini dalam pengurusan ubat-ubatan HAMs.

3. Selain itu, Jabatan Farmasi & Bekalan juga telah mengemaskini **Senarai Ubat-ubatan *Look Alike, Sound Alike* (LASA).** *Policy on Management of High Alert Medications (HAMs)*, Senarai HAMs di HEBHK dan Senarai Ubat-ubatan LASA versi terkini boleh diakses melalui:-

Laman web Hospital Enche' Besar Hajjah Khalsom
https://hklg.moh.gov.my/ >> Garis Panduan Farmasi >> Policy on Management of High Alert Medications 2021 / High Alert Medication List 2021 / List of Look Alike Sound Alike Medications in HEBHK (April 2021)

4. Mohon kerjasama Y.Brs. Dr/tuan/puan memaklumkan pengemaskinian polisi dan senarai HAMs berserta senarai LASA terkini kepada semua anggota bawah seliaan. Diharap polisi dan senarai ini dapat membantu anggota penjagaan kesihatan dalam pengurusan ubat-ubatan HAMs dan LASA yang selamat.

Sekian, terima kasih.

..2/-

"PRIHATIN RAKYAT: DARURAT MEMERANGI COVID-19"
"WAWASAN KEMAKMURAN BERSAMA 2030"
"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(PERIANAIGEE A/P MUNIANDY) RPh 2434
Ketua Pegawai Farmasi
Hospital Enche' Besar Hajjah Khalsom, Kluang
Samb.☎ : 4102
Emel : jperia@moh.gov.my

Policy on Management of High Alert Medications can be downloaded from HEBHK official portal https://hklg.moh.gov.my/#garis-panduan-farmasi

REFERENCES

1. Guideline on Safe Use of High Alert Medications (HAMs), 2nd Edition, 2020. Pharmacy Practice and Development Division, Pharmaceutical Services Programme, Ministry of Health Malaysia.

Look Alike Sound Alike (LASA) Medications

Look Alike Sound Alike (LASA) medications involve medications that are visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics. Confusing medication names and similar product packaging may lead to potentially harmful medication errors.

Common risk factors associated with LASA medications includes:

- Illegible handwriting
- Incomplete knowledge of drug names
- Newly available products
- Similar packaging or labelling
- Similar strengths, dosage forms, frequency of administration
- Similar clinical use

STRATEGIES TO AVOID ERRORS WITH LOOK ALIKE SOUND ALIKE MEDICATIONS

1. Procurement

a) Minimise the availability of multiple medicines strengths.

b) Whenever possible, avoid purchase of medicines with similar packaging and appearance. As new products or packages are introduced, compare them with existing packaging.

2. Storage

a) Use Tall Man lettering to emphasise differences in medications with sound-alike names.

b) Use additional warning labels for look-alike medicines. Warning labels should be uniform throughout the respective facility to facilitate identification.

c) For sound-alike medications where Tall Man lettering is not applicable, proprietary (brand or trademarked) names may be added to distinguish between the medications.

d) Store LASA medications separately from their LASA pair. Whenever possible, avoid storing the products in immediate proximity to one another.

3. Prescribing

a) Write legibly. Write clearly whether on an inpatient order or on a prescription.

b) Prescription should clearly specify name of medication, dosage form, dose and complete direction for use.

c) Include the diagnosis or medication's indication for use. This information helps to differentiate possible choices in illegible orders.

d) Whenever possible, drug names in computerised prescriber order entry (CPOE) should incorporate Tall Man lettering.

e) Communicate clearly. Take your time in pronouncing the drug name whenever an oral order has to be made. Ask that the recipient of the oral communication repeat the medication name and dose. Verbal orders should be limited to emergency situations only.

4. Dispensing/ Supply

a) Identify medicines based on its name and strength and not by its appearance or location.

b) Check the appropriateness of dose for the medicines dispensed.

c) READ medication labels carefully at all dispensing stages and perform triangle check. Triangle check is to check actual medicines against the medicines' labels and against the prescription.

d) Double checking should be conducted during the dispensing and supply process.

e) Highlight changes in medication appearances to patients upon dispensing.

5. Administration

a) READ medication labels carefully during the administration process and perform triangle check. Triangle check is to check actual medicines against the medication labels and against the prescription.

b) Emphasize the need to read labels rather than relying on visual recognition or location.

c) Make read back clarification of verbal orders a requirement. The staff receiving the verbal order must repeat the orders and ensure that they are verified.

6. Monitoring

a) All facilities need to identify medications that look alike or sound alike in its organisation. The LASA list need to be reviewed and updated periodically at least once a year.

b) Implement feedback mechanism to inform on look-alike medications.

7. Information

a) All relevant personnel have access to the LASA list.

b) Staff are informed on new medications listed as LASA in the hospital or clinics. Example: Displaying information on LASA in the facility's website.

8. Patient Education

a) Inform patients on changes in medication appearances.

b) Educate patients and their caregivers to alert healthcare providers whenever a medication appears to vary from what is usually taken or administered.

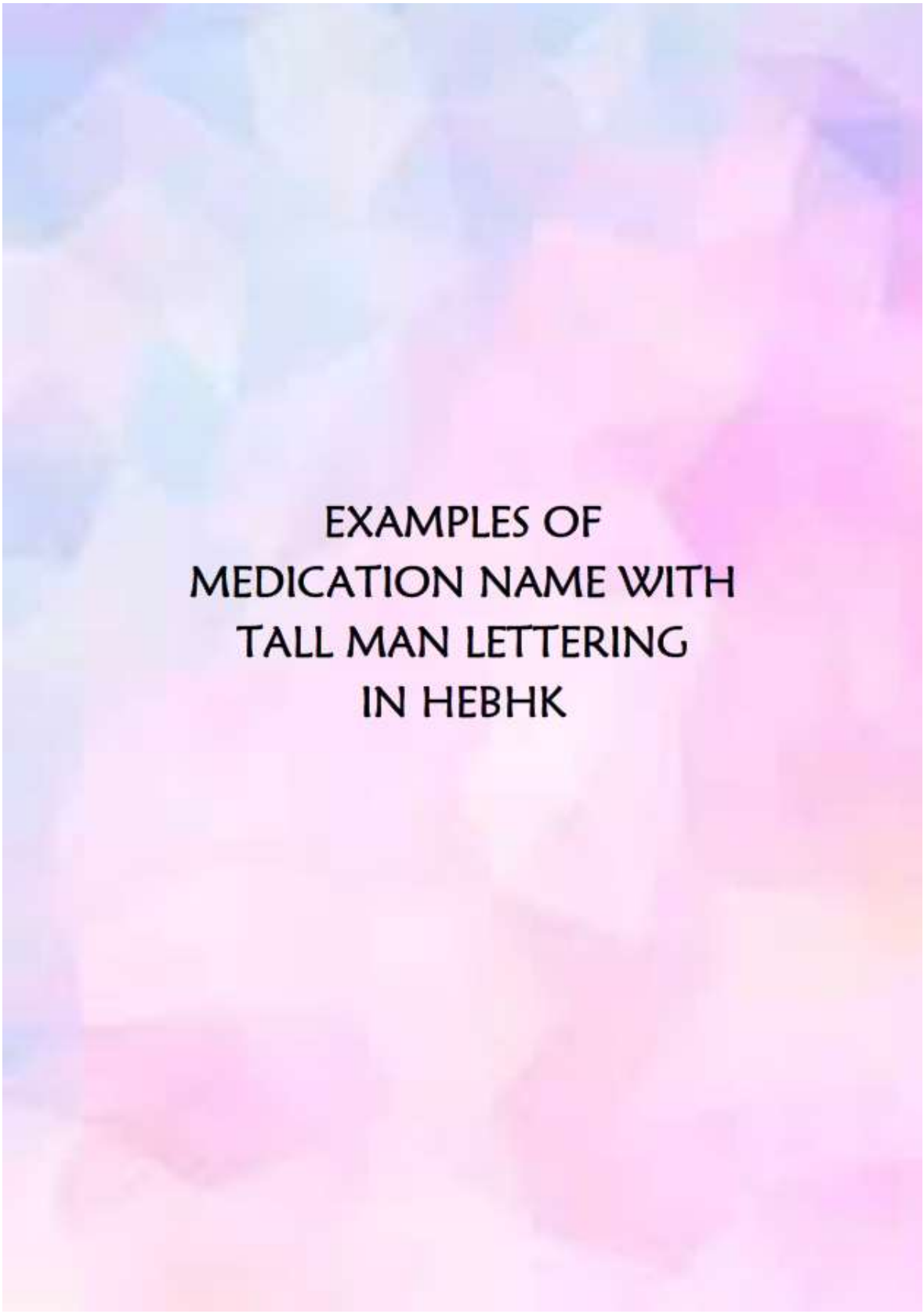
c) Encourage patients and their caregivers to learn the names of their medications.

9. Evaluation

Evaluate medication errors related to LASA medications.

List of Look Alike, Sound Alike Medications in HEBHK can be downloaded from HEBHK official portal https://hklg.moh.gov.my/#garis-panduan-farmasi

Examples of Medication Name with Tall Man Lettering in HEBHK can be downloaded from HEBHK official portal https://hklg.moh.gov.my/#garis-panduan-farmasi



REFERENCES

1. Guide on Handling Look Alike, Sound Alike Medications, 2012. Pharmaceutical Services Division, Ministry of Health Malaysia.

Drug Allergy

World Allergy Organization (WAO) defined drug allergy as an immunologically mediated drug hypersensitivity reactions. Meanwhile, the Joint Task Force on Practice Parameters defined drug allergy as an immunologically mediated response to a pharmaceutical and/or formulation (excipient) agent in a sensitized person.

Allergic reaction can happen immediately or after a few days after the administration of medicines. Examples of allergic reactions are:

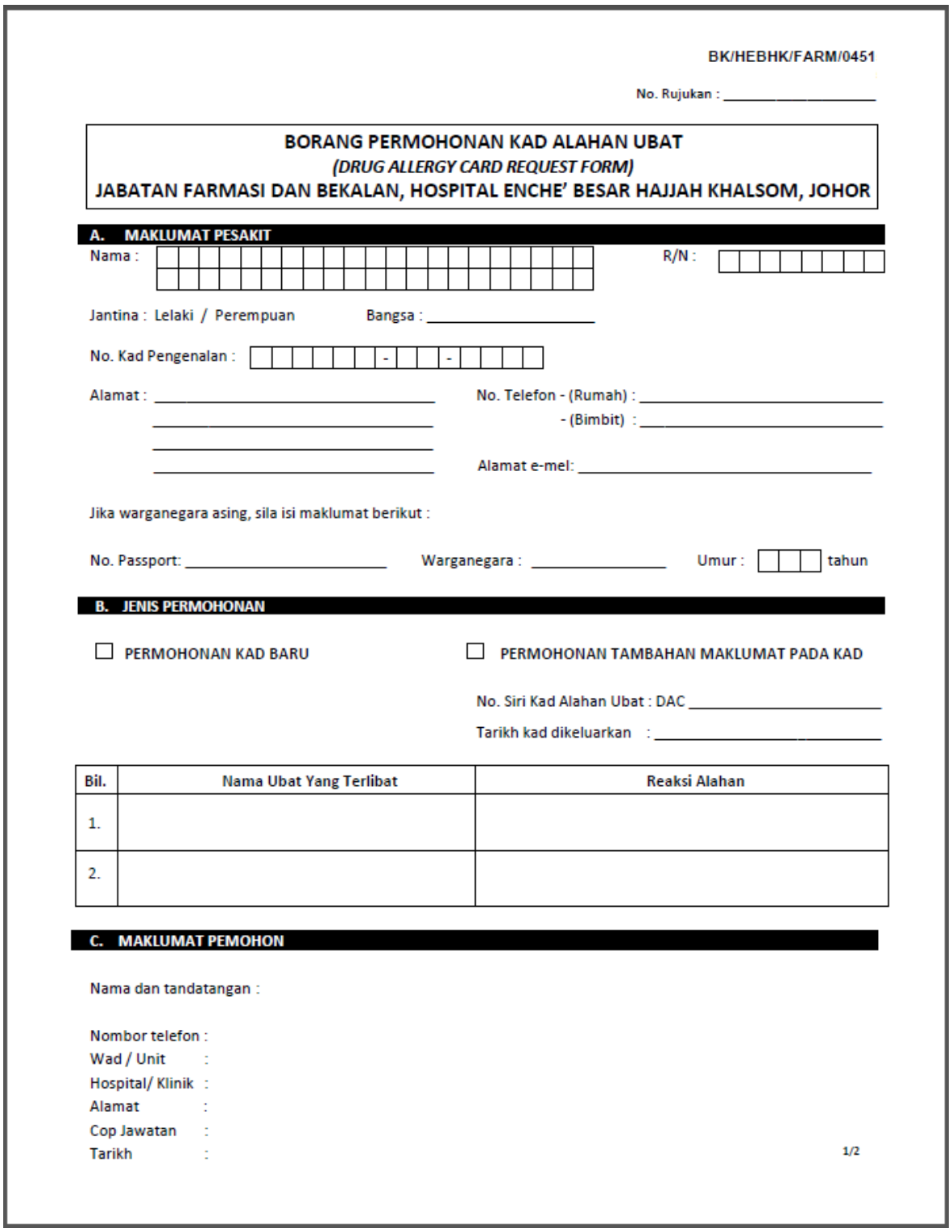
- Cutaneous reactions such as urticaria, eczema, if severe can be Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)
- Lips, eyes, tongue or face swelling
- Anaphylaxis

IMMEDIATE VERSUS DELAYED DRUG HYPERSENSITIVITY REACTIONS

Type	Onset	Clinical features	Examples
Immediate drug hypersensitivity reactions	Onset usually occurs within one hour after drug exposure. Symptoms resolve rapidly with treatment. Previous exposure not always confirmed.	• Generalised pruritus • Ocular pruritus and tearing • Sneezing and rhinorrhea • Urticaria, angioedema • Shortness of breath, dyspnoea, wheezing, rhonchi • Abdominal pain (which is usually accompanied by the other cutaneous manifestations listed above) • Anaphylaxis	Beta-lactam antibiotics, nonsteroidal anti-inflammatory drugs, biological agents, iodinated contrast media, neuromuscular blocking agents
Delayed drug hypersensitivity reactions	Onset usually 7-14 days after first drug exposure, but certain reactions (e.g. drug-induced hypersensitivity syndrome, Stevens-Johnson Syndrome, or Toxic Epidermal Necrolysis) may occur even up to 6 weeks after first drug exposure. Onset usually within 3 days of second exposure.	• Maculopapular eruption • Fixed drug eruptions • Drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug induced hypersensitivity syndrome (DIHS). This is characterised by macules/ papules with systemic features, including: ➢ Fever ➢ Lymphadenopathy ➢ Eosinophilia ➢ Hepatitis ➢ Interstitial nephritis ➢ Rarely, arthritis, cardiac or pulmonary involvement • Stevens-Johnson Syndrome (SJS); Toxic Epidermal Necrolysis (TEN) or SJS-TEN overlap, characterised by: ➢ Target lesions or Erythema multiforme ➢ Mucosal or cutaneous erosions ➢ Vesicles, blistering, or epidermal detachment • In SJS, epidermal detachment is between 1-10% body surface area (BSA); SJS-TEN overlap 10-30% and TEN >30% BSA • Acute generalised exanthematous pustulosis (AGEP) • Drug-induced vasculitis • Bullous drug eruptions	Beta-lactam antibiotics, sulphur drugs, anti-epileptics, allopurinol, nonsteroidal anti-inflammatory drugs, iodinated contrast media

DRUG ALLERGY CARD REQUEST FORM

Drug allergy card request form need to be filled by prescriber and submit to Drug Information Unit, Pharmacy Department.



BK/HEBHK/FARM/0451

No. Rujukan : _____

BORANG PERMOHONAN KAD ALAHAN UBAT
(DRUG ALLERGY CARD REQUEST FORM)
JABATAN FARMASI DAN BEKALAN, HOSPITAL ENCHE' BESAR HAJJAH KHALSOM, JOHOR

A. MAKLUMAT PESAKIT

Nama : R/N :

Jantina : Lelaki / Perempuan Bangsa : _____

No. Kad Pengenalan : - -

Alamat : _____ No. Telefon - (Rumah) : _____
_____ - (Bimbit) : _____
_____
_____ Alamat e-mel: _____

Jika warganegara asing, sila isi maklumat berikut :

No. Passport: _____ Warganegara : _____ Umur : tahun

B. JENIS PERMOHONAN

☐ PERMOHONAN KAD BARU ☐ PERMOHONAN TAMBAHAN MAKLUMAT PADA KAD

No. Siri Kad Alahan Ubat : DAC _____

Tarikh kad dikeluarkan : _____

Bil.	Nama Ubat Yang Terlibat	Reaksi Alahan
1.		
2.		

C. MAKLUMAT PEMOHON

Nama dan tandatangan :

Nombor telefon :
Wad / Unit :
Hospital/ Klinik :
Alamat :
Cop Jawatan :
Tarikh :

1/2

D. UNTUK KEGUNAAN FARMASI

No. Siri Kad : DAC-11-01030012-_____

Tarikh kad dikeluarkan : _____

Nama dan tandatangan :
Pegawai Farmasi

Cop Jawatan :

Tarikh :

☐ LULUS

☐ TOLAK

Nyatakan sebab: _____

_____

_____

E. PENGESAHAN PENERIMAAN OLEH PESAKIT

Saya _____ pesakit / penjaga nombor kad pengenalan | | | | | | | - | | | - | | | | dengan ini telah menerima kad alahan dan telah diberi penerangan sewajarnya berkaitan keperluan memaklumkan atau menunjukkan kad alahan tersebut apabila berjumpa pegawai perubatan, pegawai farmasi, pegawai pergigian atau anggota kesihatan lain.

Tandatangan Pesakit / Penjaga : Tarikh :	Tandatangan dan cop Pegawai Farmasi : Tarikh :

2/2

DRUG ALLERGY CARD

Drug allergy card with a serial number will be issued out to patient. The format of serial number for HEBHK is shown below:

DAC – code of facility type – code of state / district / facility – serial number

DAC – 11 – 01030012 – xxxx

The card will have the necessary information on the patient's drug allergies to enable healthcare practitioners select the appropriate medicine for the patient.

Information on allergy includes:

- Drug which causes allergic reaction
- Type of allergic reaction occurred

Patients are advised to bring and show their drug allergy cards to healthcare practitioners when seeking treatment or getting medicines.

DRUG ALLERGY WARNING STICKER

Drug allergy warning sticker will be pasted on patient's file.

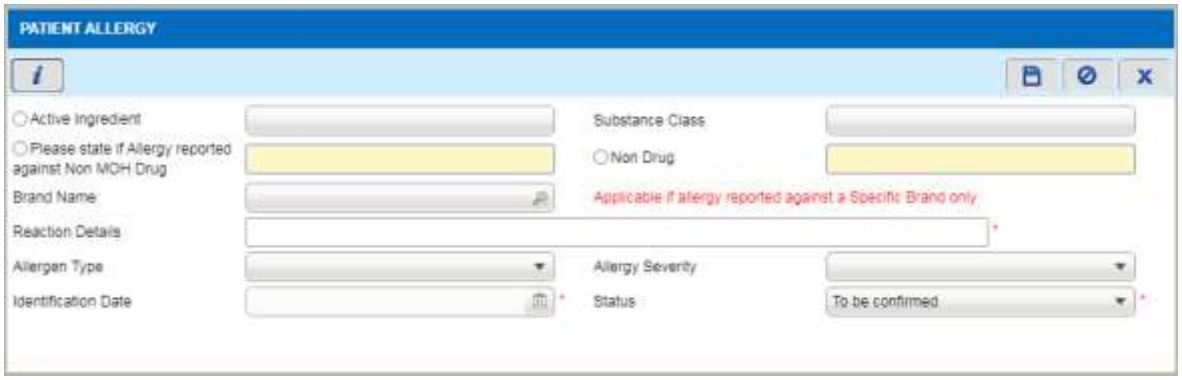
DRUG ALLERGY CARD DATABASE

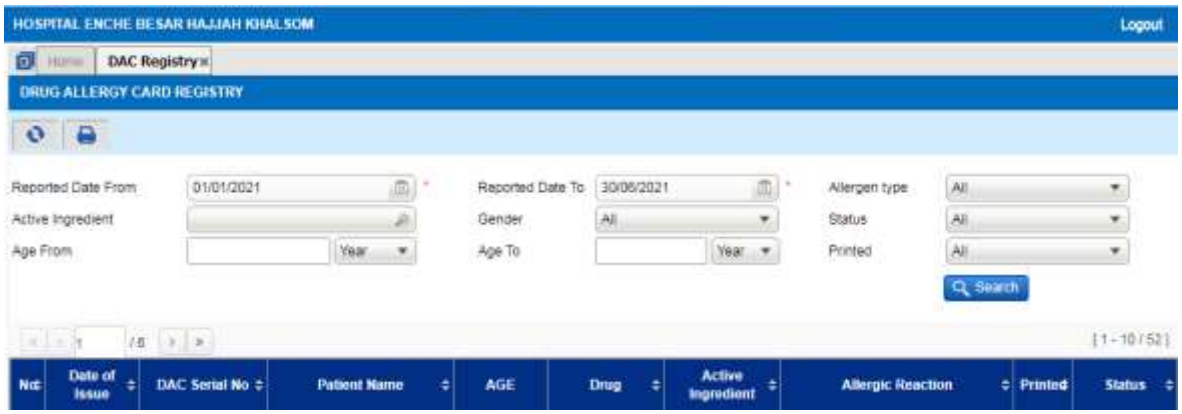
The information of patients who experienced drug allergy need to be recorded in the drug allergy database as shown below:

DRUG INFORMATION UNIT, HOSPITAL ENCHE' BESAR HAJJAH KHALSOM, KLUANG (DAC-11-01090012-_____)

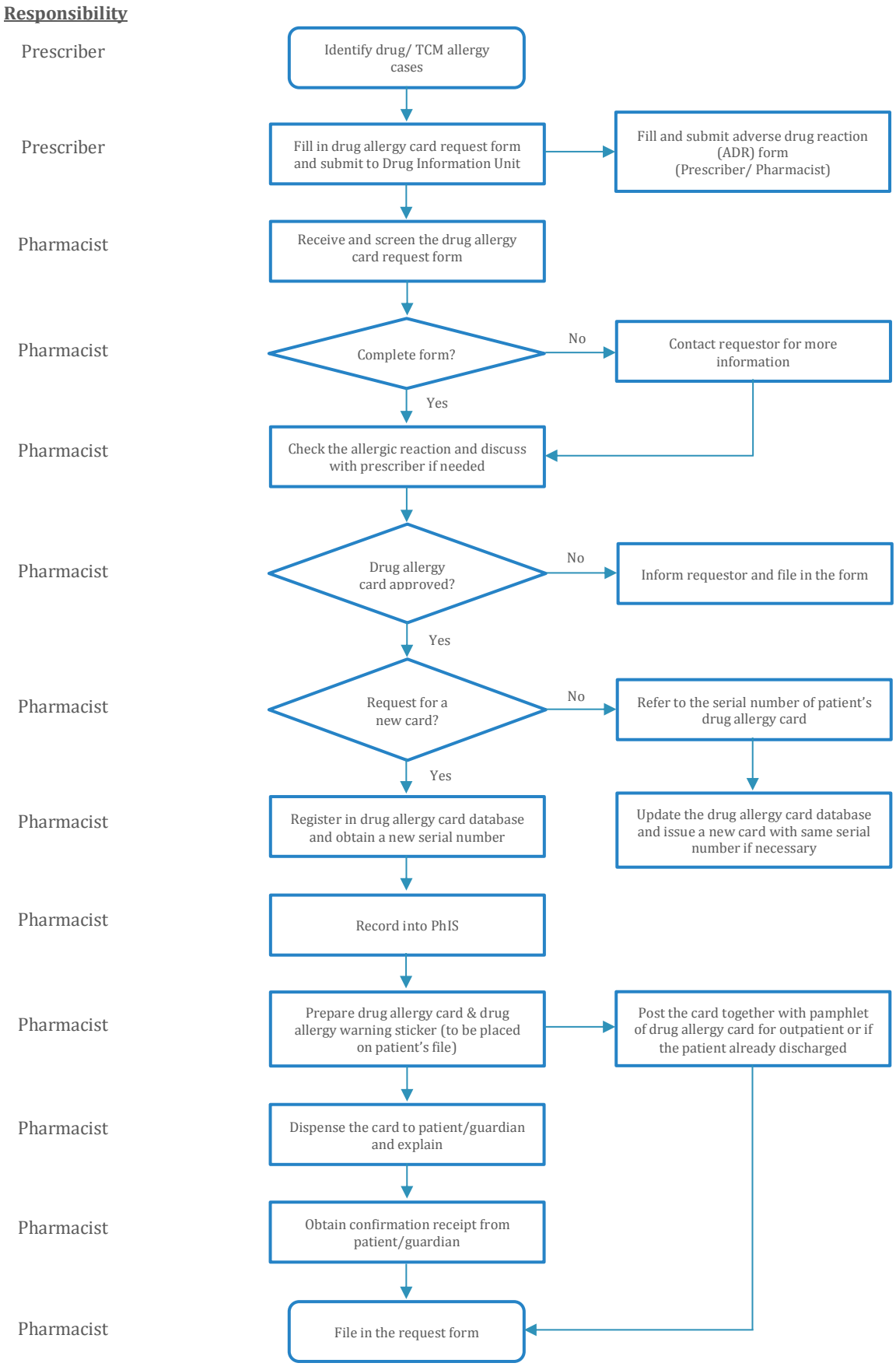
No. Rujukan Fail	Tarikh Kad Dikeluarkan	No. Siri Kad Alahan	Butiran Pesakit						Nama Ubat	Reaksi Alahan	Butiran Pemohon		Pelekat Alahan dikenpal (Ya/Tidak)
			Nama Penuh Pesakit	No K/Pasport (xxxxxx-xx-xxxx)	Umur (tahun)	Institusi	Bangsa	Warganegara			Kategori Pemohon (Doktor, Pegawai Farmasi, dll)	Fasiliti/Unit	

Besides, the information will also be recorded into Pharmacy Information System (PhIS).





FLOW CHART OF DRUG ALLERGY CARD REQUEST IN HEBHK



REFERENCES

1. The National Drug Allergy Reporting Guidelines, 2018. Ministry of Health Singapore.
2. Garis Panduan Pengesanan Pesakit dengan Alahan Ubat, 2011. Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
3. Joint Task Force of Practice Parameters; representing the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology. Drug Allergy: An Updated Practice Parameter. Annals of Allergy: Asthma & Immunology. 2010 Oct; 105(4):259-273.

Adverse Drug Reaction (ADR)

DEFINITION OF ADVERSE DRUG REACTION BY WHO, 1972

A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

OBJECTIVES OF ADR REPORTING

i. To detect ADRs as early as possible especially serious, unknown and rare reactions;
ii. To establish the frequency and incidence of adverse reactions, both the well recognised and newly discovered reactions;
iii. To identify risk factors that may predispose/induce/influence the development, severity and incidence of adverse reactions e.g. genetic/racial factors, drug interactions, underlying conditions, and
iv. To maintain a database for sharing of information with regards to ADRs in this country.

MINIMUM DATA ELEMENTS FOR ADR REPORTING

i. A named suspected drug
ii. A suspected reaction
iii. An identifiable patient
iv. An identifiable reporter

DIFFERENCE BETWEEN ADVERSE DRUG REACTION AND DRUG ALLERGY

***Adverse Drug Reaction**

Definition by WHO, 1972:

'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.'

It includes all unintended pharmacologic effects of a drug except therapeutic failures, intentional overdosage, abuse of the drug, or errors in administration.

Type A Reaction (Common and Predictable)

This reaction is usually dose dependent, are related to the known pharmacologic actions of the drug and occur in otherwise healthy individuals. They are estimated to comprise approximately 85% to 90 % of all ADRs.

- Overdose
- Drug interactions
- Side effects
- Secondary or indirect effects

Type B Reaction (Rare and Mostly Unpredictable)

This reaction is generally dose independent, are unrelated to the pharmacologic actions of the drug, and occur only in susceptible individuals. They are estimated to comprise approximately 10% to 15% of all ADRs.

- Drug intolerance
- Drug idiosyncrasy
- ***Drug allergy** An immunologically mediated response to a pharmaceutical and/or formulation (excipient) agent in a sensitized person.

In conclusion, drug allergy is subset of adverse drug reaction.

CLASSIFICATION OF ADVERSE DRUG REACTIONS

Drug Reaction	Examples
Type A: Reactions occurring in most normal patients, given sufficient dose and duration of therapy: Common and predictable	
Overdose	Hepatic failure (acetaminophen) Metabolic acidosis (aspirin)
Side effects	Nausea, headache (with methylxanthines) Oral thrush or vaginal candidiasis (with glucocorticoids) Nephrotoxicity (with aminoglycosides)
Secondary or indirect effects	Diarrhea due to alteration in GI bacteria after antibiotics Phototoxicity (with doxycycline or thiazide diuretics)
Drug interactions	Macrolide antibiotics increasing theophylline, digoxin, or statin blood levels
Type B: Drug hypersensitivity reactions restricted to a small subset of the general population: Rare and mostly unpredictable	
*Intolerance**	Tinnitus after a single aspirin tablet
Idiosyncrasy¶ (pharmacogenetics)	G6PD deficiency: Hemolytic anemia after antioxidant drugs (eg, dapsone)Δ TPMT deficiency: Toxicity during azathioprine therapyΔ Pseudoallergic reaction (with NSAIDs)
Immunologic drug reactions (allergy)	Anaphylaxis from beta-lactam antibiotics Photoallergy with quinidine Immune-mediated thrombocytopenia (with heparin) Serum sickness (with antivenom preparations) Vasculitis (with phenytoin) Stevens-Johnson syndrome (with trimethoprim-sulfamethoxazole) Drug-induced hypersensitivity syndrome (with allopurinol in HLA-B*58:01 individuals)Δ

GI: gastrointestinal; G6PD: glucose-6-phosphate dehydrogenase; TPMT: thiopurine methyltransferase; NSAIDs: nonsteroidal anti-inflammatory drugs.

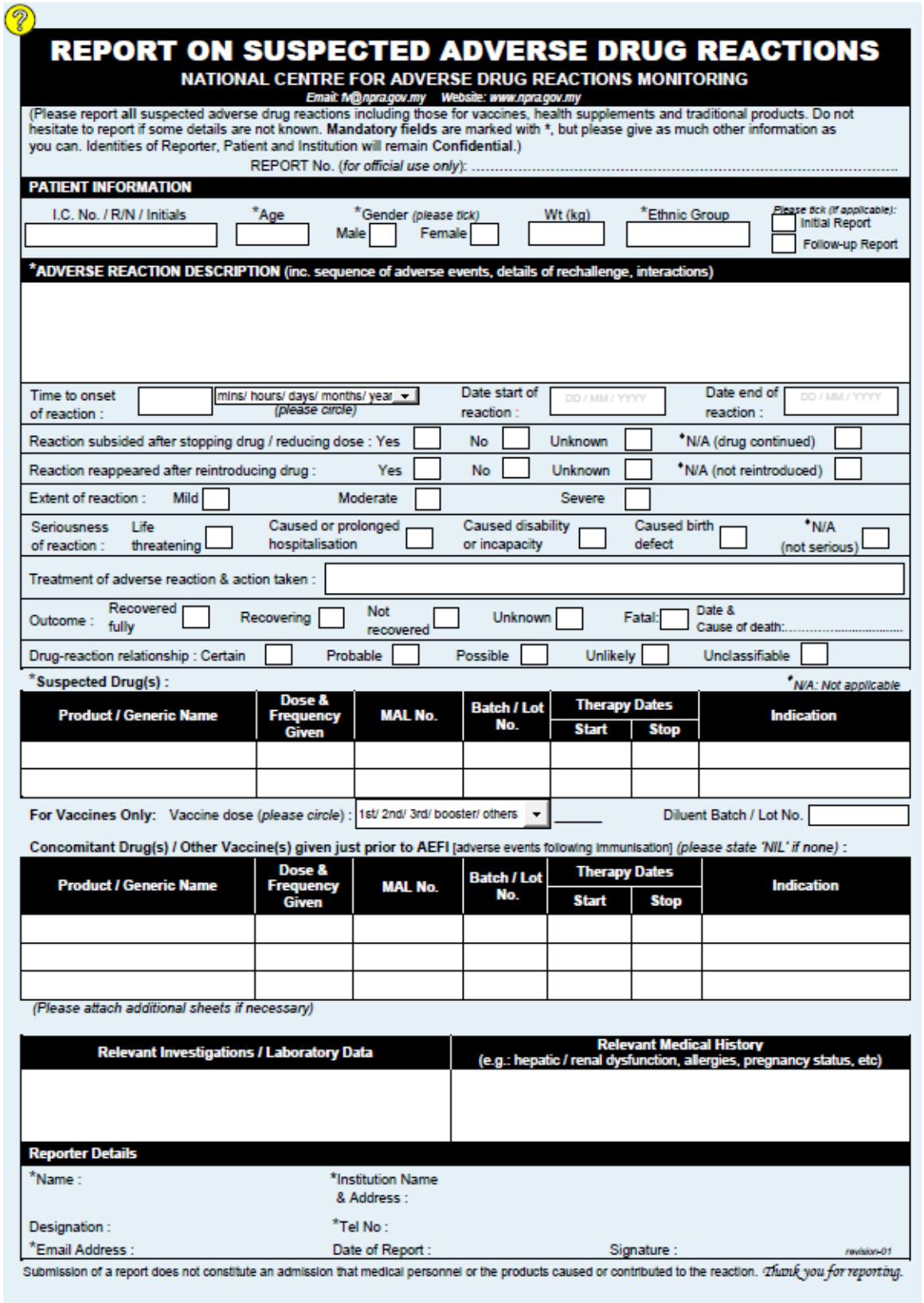
* Side effects at subtherapeutic doses.

¶ Drug effect not attributable to known pharmacologic properties of drug and not immune-mediated.

Δ This is an example of a type B reaction that is predictable.

METHODS OF ADR REPORTING

Completed ADR form must be dispatched to Drug Information Unit, Pharmacy Department.



REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: M@npra.gov.my Website: www.npra.gov.my

(Please report **all** suspected adverse drug reactions including those for vaccines, health supplements and traditional products. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No. (*for official use only*): .....

PATIENT INFORMATION

I.C. No. / R/N / Initials | *Age | *Gender (*please tick*) Male ☐ Female ☐ | Wt (kg) | *Ethnic Group | *Please tick (if applicable):* ☐ Initial Report ☐ Follow-up Report

***ADVERSE REACTION DESCRIPTION** (inc. sequence of adverse events, details of rechallenge, interactions)*

Time to onset of reaction : ☐ mins/ hours/ days/ months/ year (*please circle*) | Date start of reaction : DD / MM / YYYY | Date end of reaction : DD / MM / YYYY

Reaction subsided after stopping drug / reducing dose : Yes ☐ No ☐ Unknown ☐ *N/A (drug continued) ☐

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Unknown ☐ *N/A (not reintroduced) ☐

Extent of reaction : Mild ☐ Moderate ☐ Severe ☐

Seriousness of reaction : Life threatening ☐ | Caused or prolonged hospitalisation ☐ | Caused disability or incapacity ☐ | Caused birth defect ☐ | *N/A (not serious) ☐

Treatment of adverse reaction & action taken :

Outcome : Recovered fully ☐ | Recovering ☐ | Not recovered ☐ | Unknown ☐ | Fatal: ☐ | Date & Cause of death:.....

Drug-reaction relationship : Certain ☐ | Probable ☐ | Possible ☐ | Unlikely ☐ | Unclassifiable ☐

***Suspected Drug(s) :** *N/A: Not applicable*

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

For Vaccines Only: Vaccine dose (*please circle*) : 1st/ 2nd/ 3rd/ booster/ others _____ Diluent Batch / Lot No.

Concomitant Drug(s) / Other Vaccine(s) given just prior to AEFI [adverse events following immunisation] *(please state 'NIL' if none)* :

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

(Please attach additional sheets if necessary)

Relevant Investigations / Laboratory Data	Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc)

Reporter Details

*Name : | *Institution Name & Address :

Designation : | *Tel No :

*Email Address : | Date of Report : | Signature :

revision-01

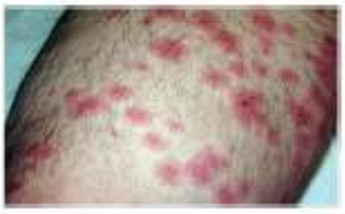
Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

GLOSSARY AND PICTURES OF CLINICAL MENIFESTATION OF CUTANEOUS ADVERSE DRUG REACTIONS

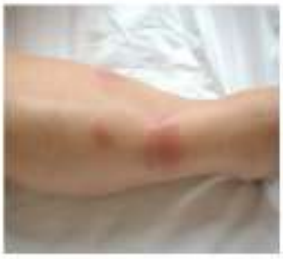
Acneiform Eruption
Rash resembling acne

Alopecia
Excessive hair loss

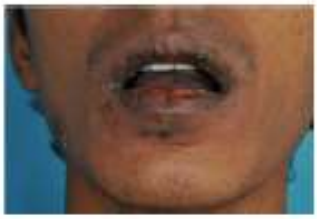
Erythema multiforme
Target lesions comprising of a dark central spot surrounded by a pale halo which is then surrounded by a red ring, occasionally blister at the centre.



Erythema nodosum
Painful deep red nodules over the legs



Fixed drug eruption (FDE)
A few, round erythematous patch, blisters or erosions over the lips, face, hands, feet and genitalia. FDE recurs at the same sites and may extend to other areas if the drug is taken again.



Maculo-papular rash (exanthem)
Generalised small red macules and papules

Photosensitivity
Erythema or rash over sun exposed areas.

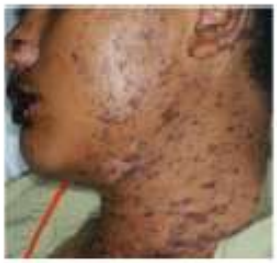
Pigmentary changes
Colour changes of skin, hair, nails and mucous membranes.

Pruritus
Itch of the skin without rash

Purpura
Non-blanching, dark red macules or bruises due to bleeding from small blood vessels.

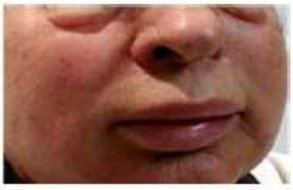
Toxic epidermal necrolysis
Life-threatening variant of Stevens-Johnson Syndrome with large areas of denuded skin

Stevens-Johnson Syndrome
Serious variant of erythema multiforme with involvement of more than 2 mucous membranes (oral/ eye/ genitalia)

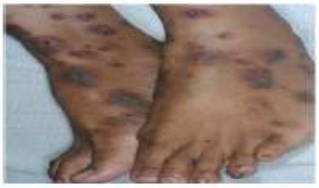


Urticaria
Eruption of wheals/ hives lasting less than 24 hours

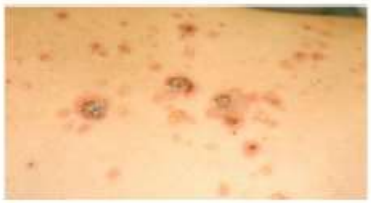
Angioedema
Swelling of the mucous membrane (oral/ eye/ genitalia). May be associated with laryngeal oedema if severe.



Vasculitis
Palpable purpura



Vesiculobullous reaction
Blistering eruption of the skin



CLINICAL MANIFESTATION OF ADVERSE DRUG REACTION

1. Type of cutaneous adverse drug reaction (please √)
   - You are allowed to choose more than one of the following.

1. Acneiform Eruption		9. Pruritus only	
2. Alopecia		10. Purpura	
3. Erythema multiforme		11. Toxic Epidermal Necrolysis	
4. Erythema nodosum		12. Stevens-Johnson Syndrome	
5. Fixed drug eruption		13. Urticaria / Angioedema	
6. Maculo-papular rash (exanthem)		14. Vasculitis	
7. Photosensitivity		15. Vesiculobullous reaction	
8. Pigmentary changes		16. Others :	

2. Please specify part of the body affected

_____

_____

DRUG REACTION RELATIONSHIP

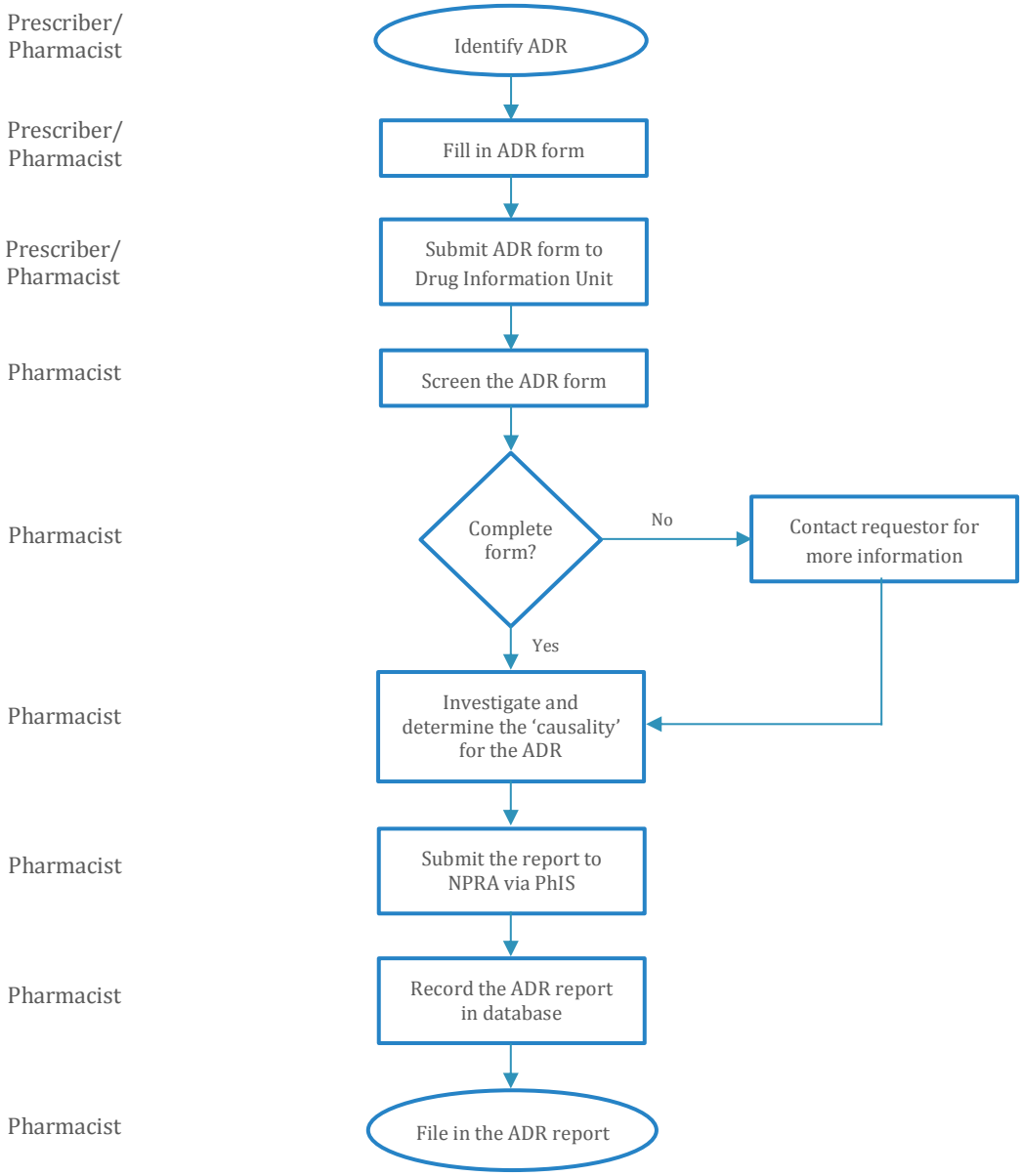
Table 2. WHO-UMC Causality Categories

Causality term	*Assessment criteria**
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

* All points should be reasonably complied with

FLOW CHART OF ADR REPORTING IN HEBHK

Responsibility



REFERENCES

1. Malaysian Pharmacovigilance Guidelines (2nd Edition), September 2016. Ministry of Health Malaysia.
2. The Uppsala Monitoring Centre. The use of the WHO-UMC system for standardized case causality assessment.
3. World Health Organization (2018). Essential Medicines and Health Products Information Portal: Glossary, Adverse Drug Reaction.
4. Solensky, R., & Khan, D. A. (2010). Drug Allergy: An Updated Practice Parameter.
5. Pichler, W. J. (2019). Drug hypersensitivity: Classification and clinical feature.

Adverse Event Following Immunization (AEFI)

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

CLASSIFICATION

NO	CATEGORIES	EXPLAINATION
1	Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product. *Example: Extensive limb swelling following DTP vaccination.*
2	Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer. *Example: Failure by the manufacturer to completely inactivate a lot of inactivated polio vaccine (IPV) leads to cases of paralytic polio.*
3	Immunization error-related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. *Example: Transmission of infection by contaminated multidose vial.*
4	Immunization-anxiety-related reaction	An AEFI arising from anxiety about the immunization. *Example: Vasovagal syncope in an adolescent during/following vaccination.*
5	Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety. *Example: A fever occurs at the time of the vaccination (temporal association) but is in fact caused by malaria.* *Coincidental events reflect the natural occurrence of health problems in the community with common problems being frequently reported.*

TYPES OF AEFI (MINOR REACTIONS)

1. Local Reactions

- Pain
- Swelling
- Redness at the site of injection

2. Systemic Reactions

- Fever
- Malaise
- Muscle pain
- Headache
- Loss of appetite

TYPES OF AEFI (SEVERE REACTIONS)

- Anaphylaxis
- Seizure
- Sepsis
- Thrombocytopenia
- Severe local reaction

METHODS OF AEFI REPORTING

AEFI encountered by healthcare professionals needs to be reported using ADR form and submit to Drug Information Unit, Pharmacy Department.

REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: m@npra.gov.my Website: www.npra.gov.my

(Please report all suspected adverse drug reactions including those for vaccines, health supplements and traditional products. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No. (*for official use only*): .....

PATIENT INFORMATION

I.C. No. / R/N / Initials | *Age | *Gender (*please tick*) Male ☐ Female ☐ | Wt (kg) | *Ethnic Group | *Please tick (if applicable)*: ☐ Initial Report ☐ Follow-up Report

***ADVERSE REACTION DESCRIPTION** (inc. sequence of adverse events, details of rechallenge, interactions)*

Time to onset of reaction : ☐ mins/ hours/ days/ months/ year (*please circle*) | Date start of reaction : DD / MM / YYYY | Date end of reaction : DD / MM / YYYY

Reaction subsided after stopping drug / reducing dose : Yes ☐ No ☐ Unknown ☐ *N/A (drug continued) ☐

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Unknown ☐ *N/A (not reintroduced) ☐

Extent of reaction : Mild ☐ Moderate ☐ Severe ☐

Seriousness of reaction : Life threatening ☐ Caused or prolonged hospitalisation ☐ Caused disability or incapacity ☐ Caused birth defect ☐ *N/A (not serious) ☐

Treatment of adverse reaction & action taken :

Outcome : Recovered fully ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal: ☐ Date & Cause of death:.....

Drug-reaction relationship : Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

*Suspected Drug(s) : *N/A: Not applicable

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

For Vaccines Only: Vaccine dose (*please circle*) : 1st/ 2nd/ 3rd/ booster/ others _____ Diluent Batch / Lot No.

Concomitant Drug(s) / Other Vaccine(s) given just prior to AEFI [adverse events following immunisation] (*please state 'NIL' if none*) :

Product / Generic Name	Dose & Frequency Given	MAL No.	Batch / Lot No.	Therapy Dates		Indication
				Start	Stop	

(Please attach additional sheets if necessary)

Relevant Investigations / Laboratory Data	Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc)

Reporter Details

*Name : | *Institution Name & Address :

Designation : | *Tel No :

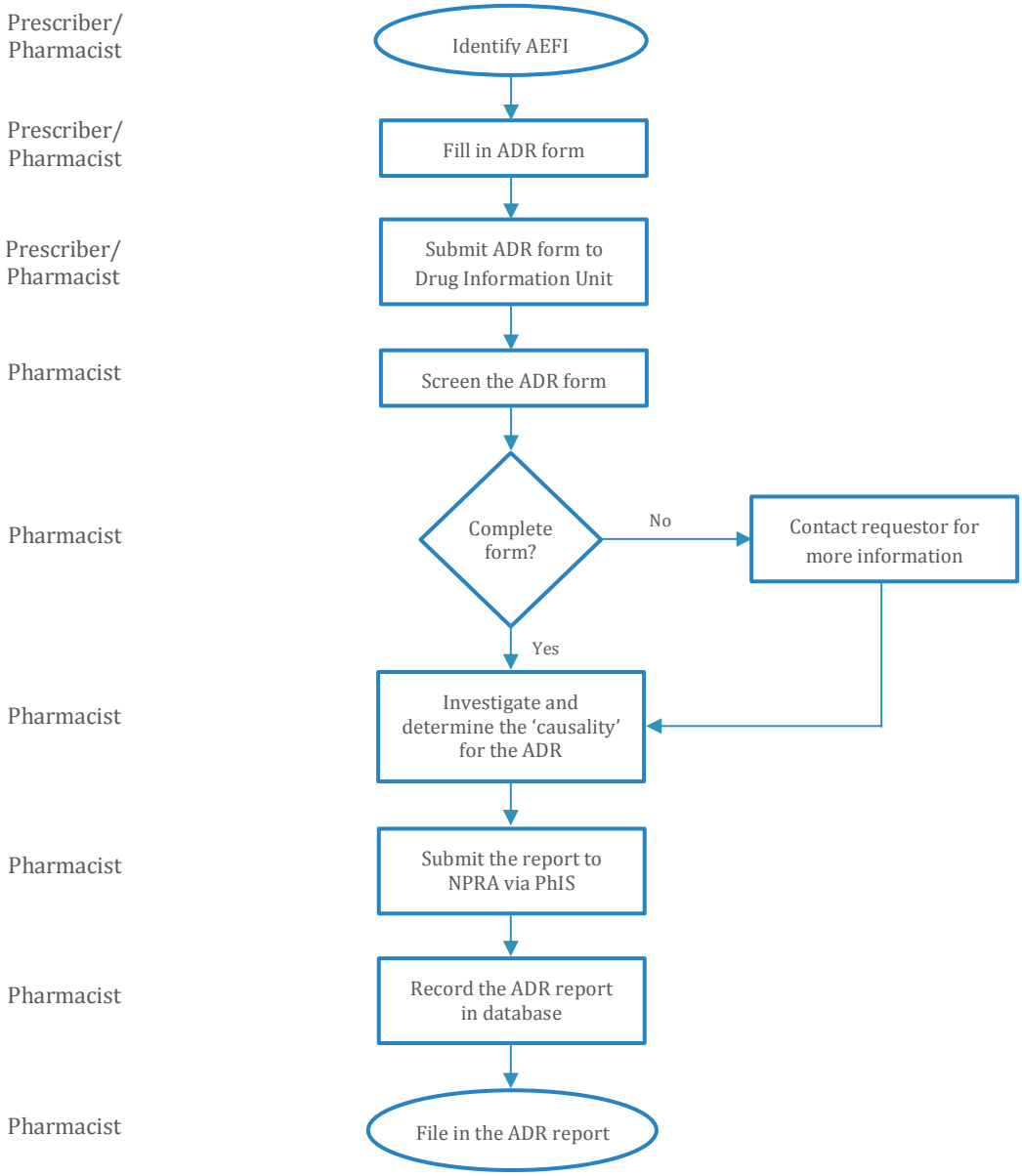
*Email Address : | Date of Report : | Signature :

revision-01

Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

FLOW CHART OF AEFI REPORTING IN HEBHK

Responsibility



REFERENCES

1. Garispanduan Farmakovigilans Vaksin Untuk Anggota Kesihatan (Edisi Kedua), 2016. Ministry of Health Malaysia.
2. WHO Vaccine Safety Basics. https://vaccine-safety-training.org/classification-of-aefis.html