Adverse Drug Reaction (ADR) / Adverse Event Following Immunisation (AEFI) Reporting

Manual for Healthcare Providers

National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz),
46200 Petaling Jaya,
Selangor, Malaysia.
Tel: 603-7883 5400
Facsimile: 603-79567075
Email: npra@npra.gov.my
Website: http://www.npra.gov.my

Record of Updates on Pharmacovigilance related Guidelines and Manual Issued by NPRA

Date	Name and Version	Summary of the Edition/Changes
March 2002	Malaysian Guidelines for the Reporting & Monitoring	This is the first guideline developed to outline the requirements and procedures to be followed for **submission of reports of adverse drug reactions** (ADR) to the Drug Control Authority (DCA).
October 2010	*Garispanduan Farmakovigilans Vaksin untuk Anggota Kesihatan* *Edisi Pertama 2010*	This is the first guideline developed to outline the requirements and procedures to be followed for **submission of reports and investigation of adverse drug reactions following immunisation (AEFI).**
August 2016	*Garispanduan Farmakovigilans Vaksin untuk Anggota Kesihatan* *Edisi Kedua 2016*	This edition incorporates the updated requirements and procedures to be followed for **submission of reports and investigation of adverse drug reactions following immunisation (AEFI).**
September 2016	Malaysian Pharmacovigilance Guidelines Second Edition 2016	This edition incorporates the requirements and procedures for **submission of ADR reports by healthcare providers as well as submission of other information regarding product safety by product registration holders (PRHs) to the DCA (e.g Risk Management Plan (RMP), Periodic Benefit Risk Evaluation Report (PBRER)).**
August 2021	Adverse Drug Reaction (ADR) /Adverse Event Following Immunisation (AEFI) Reporting Manual for Healthcare Providers First Edition, August 2021	This manual outlines the requirements and procedures of reporting for ADR as well as reporting and investigation of AEFI. It has also included the new causality assessment for AEFI.

PREAMBLE

This guideline has been developed to outline the requirements and procedures for submission of adverse drug reaction (ADR) and adverse event following immunisation (AEFI) reports to the Drug Control Authority (DCA) for healthcare providers.

The Drug Control Authority (DCA) established under the Control of Drugs and Cosmetics Regulations 1984 is tasked to ensure the safety, quality and efficacy of medicinal products registered in Malaysia.

Under the current arrangement, the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) acts as the advisory body to DCA on local and international drug safety issues. The National Adverse Drug Reaction Monitoring Centre, located within the National Pharmaceutical Regulatory Agency (NPRA) serves as the secretariat to MADRAC, and has been a member of the World Health Organisation (WHO) Programme for International Drug Safety Monitoring since 1990.

The requirement outline in this manual will help to improve the quality and standard of ADR/AEFI reporting in Malaysia.

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Advisor:

Dr. Roshayati Mohamad Sani
Director
National Pharmaceutical Regulatory Agency

Co-Advisor :

Dr Noraida Mohamad Zainoor
Deputy Director
Centre of Compliance and Quality Control

Prepared and Edited by:

Dr. Azuana Ramli
Norleen Mohamed Ali
Noor'ain Shamsuddin
Wang Khee Ing
Nafiza Mohd Ismail
Ng Chiew Seng

With contributions from:

Bavahrni a/p Subramaniam
Choo Sim Mei
Dr. Vidhya Hariraj
Farah Faridah Jamaludin
Jeevenraj Rajagopal
Lee Sing Chet
Lim Sze Gee
Ng Jia Mean
Ng Wan Ning
Nora Ashikin Mohd Ali
Norshazareen Abd. Manab
Nur Ayuni Ahmad
Nurul Aimi Mohd Reduzan
Rema Panickar a/p Sugunan @ Vasanthan
Soon Vi Vian
Syifa' Izzati Mohd Zainul Arifien
Wan Noor Ardila Wan Abhar
Wo Wee Kee
Yeoh Hee Sheong
Yu Yong King

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GLOSSARY

Adverse event (AE); synonym: Adverse experience
Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this.

An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Adverse event following immunisation (AEFI)
Any untoward medical occurrence which follows immunisation 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.

Adverse reaction; synonyms: Adverse drug reaction (ADR), Suspected adverse (drug) reaction, Adverse effect, Undesirable effect
A response which is noxious or unintended to a medicinal product that is administered in standard doses by the proper route for the purpose of prophylaxis, diagnosis, or treatment.

The response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

Adverse reactions may arise from use of the product within or outside the terms of the registered indication or from occupational exposure. Conditions of use outside the registered indication include off-label use, overdose, misuse, abuse and medication errors.

Authority
Drug Control Authority/*Pihak Berkuasa Kawalan Dadah*

Biologics
Biologic/Biological product refers to a product whose active substance is made by or derived from a living organism (plant, human, animal or microorganism) and may be produced by biotechnological methods and other cutting-edge technologies. This product imitates the natural biological substances in our bodies such as hormones, enzymes or antibodies [please refer to the current Drug Registration Guidance Document (DRGD)].

Biosimilars
A new biological medicinal product developed to be similar in terms of quality, safety and efficacy to an already registered, well-established, medicinal product [please refer to the current Drug Registration Guidance Document (DRGD)].

Clinical trial
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal

product(s) with the objective of ascertaining its (their) safety and/or efficacy. This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one country.

Cluster case
Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered.

AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines.

Compassionate use of a medicinal product
Making a medicinal product available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by registered medicinal product.

Consumer
For the purpose of reporting cases of suspected adverse reactions, a person who is not a healthcare professional.

Consumer medication information leaflet/*Risalah maklumat ubat untuk pengguna* (RiMUP)
A leaflet containing information for the consumer on how to use the medicinal product safely and effectively.

Generic medicinal product
A medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the innovator medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Healthcare providers
For the purposes of reporting suspected adverse reactions, healthcare provider are defined as medically qualified persons, such as physicians, dentists, pharmacists, nurses and other allied healthcare professionals.

Medicinal product
A drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose;

or

A drug to be used as an ingredient of a preparation for a medicinal purpose.

Minimum criteria for reporting
For the purpose of reporting cases of suspected adverse reactions, the minimum data elements for a case are: an identifiable reporter, an identifiable patient, an adverse reaction and a suspect medicinal product.

Misuse of a medicinal product
Situations where the medicinal product is intentionally and inappropriately used not in accordance with the registered information.

Non-serious AEFI
An event that is not 'serious' and does not pose a potential risk to the health of the recipient. Non-serious AEFIs should be carefully monitored because they may signal a potentially larger problem with the vaccine or immunisation, or have an impact on the acceptability of immunisation in general.

Off-label use
Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the registered indication or information.

Overdose
Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose. Clinical judgement should always be applied.

Package insert
An insert containing information for the user which accompanies the medicinal product.

Pharmacovigilance
Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.

Safety concern
An important identified risk, important potential risk or missing information.

Serious adverse reaction
An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.

Medical and scientific judgement should be exercised in deciding whether other situations should be considered serious reactions, such as important medical events that might not be immediately life-threatening or result in death or hospitalisation but might jeopardise the patient or might require intervention to prevent one of the other outcomes listed above.

Spontaneous report, synonym: Spontaneous notification
An unsolicited communication by a healthcare professional or consumer to a product registration holder or the Authority.

Unexpected adverse reaction
An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

ABBREVIATIONS

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
DCA	Drug Control Authority
NPRA	National Pharmaceutical Regulatory Agency
OTC	Over-The-Counter
PI	Package Insert
PRH	Product Registration Holder
PV	Pharmacovigilance
RiMUP	*Risalah Maklumat Ubat untuk Pengguna*
SOC	System Organ Class
TMHS	Traditional Medicines and Health Supplements
WHO	World Health Organisation

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PART 1: INTRODUCTION TO PHARMACOVIGILANCE

Before a product is marketed, experience of its safety and efficacy are limited to its use in clinical trials. The conditions under which patients are studied pre-marketing do not necessarily reflect the way the product will be used in hospitals or in general practice once it is marketed.

No matter how extensive the pre-clinical work in animals and the clinical trials in patients, certain adverse effects may not be detected until a very large number of people have used the medicinal product.

The National ADR Monitoring Centre, National Pharmaceutical Regulatory Agency (NPRA) is responsible for product safety monitoring including ADR/AEFI Reporting.

P1.1 PHARMACOVIGILANCE

P1.1.1 Definition of Pharmacovigilance

i. Pharmacovigilance is defined by the World Health Organisation (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.

ii. In line with this definition, the objectives of pharmacovigilance are:

a) To identify previously unrecognised adverse reactions or changes in the patterns of adverse effects;

b) To prevent harm from adverse reactions arising from the use of medicinal products;

c) To assess the risks and benefits of products in order to determine what actions, if any, are necessary to improve their safe use;

d) To promote the safe and effective use of medicinal products, through providing timely information about the safety of medicinal products to patients, healthcare providers and the public as well as to monitor the impact of any action taken.

P1.1.2 Scope of Pharmacovigilance

The scope of pharmacovigilance in Malaysia includes (but is not limited to):

a) ADR/AEFI Reporting and Monitoring
- Reporting by healthcare providers, consumers and Product Registration Holder (PRH), collection of reports and monitoring by PRH and the Authority.

b) Safety Profile Monitoring
- Through preparation and evaluation of Periodic Benefit Risk Evaluation Report (PBRER) and Risk Management Plan (RMP), as well as signal detection activities.

c) Risk Management
   - Evaluation of safety issues to determine risk minimisation measures.

d) Safety Communication
   - Communication via Direct Healthcare Providers Communication (DHPC), Consumer Medication Information Leaflet (RiMUP), Product Insert (PI), websites and publications; ensure PI and RiMUP are updated with latest safety information according to NPRA Directives and circulars.

P1.2 LEGAL BASIS

In accordance with 'Regulation 28: Reporting adverse reaction' under the Control of Drugs and Cosmetics Regulations 1984, Sale of Drugs Act 1952 (amendment 2006), product registration holders or any person who possesses any registered product shall inform immediately the Director of Pharmaceutical Services of any adverse reaction arising from the use of the registered product.

P1.3 CONFIDENTIALITY

All reports submitted to NPRA are treated as being confidential and reporters are not required to divulge the identity of the patients involved as the sole purpose of collecting the reports are for monitoring the safety profile of products and for formulating regulatory actions to minimise risks to consumers.
However, the reporter must be able to identify the patient and provide additional information when required.

P1.4 REPORTING ADVERSE DRUG REACTION (ADR) AND ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI)

i. Reporting of adverse drug reactions (ADRs) and adverse event following immunisation (AEFI) is the main activity in pharmacovigilance, to improve the safety profile of medicinal products.

ii. The WHO encourages reporting of ALL suspected ADR/AEFI. NPRA is committed to this scheme in order to ensure the safe use of medicinal products throughout the country.

P1.5 OBJECTIVES OF ADR/AEFI MONITORING

The primary objectives of ADR/AEFI monitoring are as follows:

i. To detect ADR/AEFIs 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 ADR/AEFIs in this country.

P1.6 IMPACT OF ADR/AEFI MONITORING

P1.6.1 Analysis and the Possible Outcomes of ADR/AEFI Reports

When an ADR/AEFI report is analysed at the National ADR Monitoring Centre, NPRA and compared with other evidence, one of the following outcomes may be found:

i. The drug and the event probably were associated, and that this is a new finding. In such case, the report is an element in a new discovery.

ii. An association between the drug and the event is well known from the literature, even though it may be rare. In this case, the fact that the reporter did not know this will indicate the need for thorough information to be given.

iii. No conclusion can be drawn and further data on other cases must be sought.

iv. The drug and the event were probably not associated.

P1.6.2 Achievement of the Primary Objectives

The primary objectives (See Section P1.5 will allow the following actions to be taken by:

i. The Authority

a) Appropriate regulatory action in the interest of public health to minimise risk of ADR/AEFIs for consumers;

b) Make data available for drug analysis locally, to reduce the dependency on other countries;

c) Promote rational drug usage;

d) Promote the development of knowledge in this field, by sharing information with other countries via WHO.

ii. Product Registration Holders

a) Initiate steps to make changes to the product dossier/information leaflets/labels;

b) Make changes to product formulations or implement other product research and/or development strategies as necessary;

c) Take measures to increase awareness of these findings.

The knowledge gained from ADR/AEFI monitoring will also allow healthcare professionals to prescribe drugs rationally, while the public will be able to use medicinal products in an appropriate manner.

PART 2: ADVERSE DRUG REACTION (ADR) REPORTING

Reporting of ADR and AEFI are the main activities in pharmacovigilance. Through monitoring and analysis of ADR and AEFI reports, signals related to safety profile of medicines such as unexpected ADR/AEFI, unusual presentation of a known ADR/AEFI, or a susceptible patient group may be identified. These findings will initiate further evaluation to establish the possible role of a medicine in causing the reaction and provide important information for the NPRA to conduct necessary actions such as changes in the product safety information and profiles or providing early warnings to healthcare providers.

P2.1 SCOPE OF ADR REPORTING

i. Suspected ADRs encountered should be reported for all products registered with DCA, i.e. pharmaceutical products, Over–The-Counter (OTC) products, health i. supplements, and natural/traditional products.

ii. A reaction is suspected if the reporting healthcare providers (i.e doctor, pharmacist, dentist, nurse and medical assistant) believes that there is a possible causal relationship between the reaction and the product in question. If so, all available relevant clinical information must be provided.

iii. All adverse reactions should be reported even though it is not used in accordance to the approved posology.

iv. Reactions to non-registrable products **should not** be reported as these products are beyond the jurisdiction of the Authority. In accordance with the Drug Registration Guidance Document (DRGD), non-registrable products include:

a) Diagnostic agents and test kits for laboratory/in-vitro use
b) Medical devices
c) Food
d) Sports nutrition, such as body-building products
e) Raw herbs used in extemporaneous preparations, including those that are dried and cut into pieces, without dosage instructions and indications.
f) Insect repellents, insecticides, pesticides and parasiticides.
g) Detergents/disinfectants for domestic use.

v. In ADR reporting, priority should be given in the following categories:

a) Serious ADRs

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- Results in death;
- Life-threatening;

- Requires inpatient hospitalisation or prolongation of existing hospitalisation;
- Causes significant disability/incapacity;
- Causes congenital anomaly/birth defects;
- Is a medically important event or reaction.

  Note: Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

b) Suspected ADR(s) to medicinal products (including minor/common ADRs).

c) Unexpected/unlabelled ADRs for all new and generic products.

d) ADR(s) related to suspected drug-drug or drug-food interactions.

e) Change in frequency of a known ADR(s).

f) ADR(s) involving special patient populations, e.g. pregnant, breastfeeding, elderly or paediatric patients.

P2.2 PRINCIPLES OF ADR REPORTING

i. Report the event soon after it occurs (spontaneous reporting). A recent event is easier to report upon and the report is more likely to be accurate.

ii. If possible, take the decision to report whilst the patient is still with you, so that he/she can easily be questioned about the event and the details filled in at once on the report form.

iii. All reports of suspected ADR should have these four (4) minimum information:

a) One or More Suspected Substance/Medicinal Product
"Product" means: -
- A drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings for a medicinal purpose; or
- A drug to be used as an ingredient of a preparation for a medicinal purpose.

b) One or More Suspected Adverse Reaction
A valid report should contain at least one specific ADR

c) One Single Identifiable Patient
Charaterised by initials, patient identification number, date of birth, age, age group and/or gender. The information should be as complete as possible.

d) Identifiable Reporter
- Characterised by qualification (e.g. physician, pharmacist or other healthcare providers), name, initials, address or contact details so that follow-up activities can be performed
- Consumer

iv. If any of these minimum criteria remain unknown, a report on the incident **should not** be submitted. Reports without this essential information cannot be assessed objectively and will not be entered into the Malaysian ADR database.

v. Nevertheless, where possible, the specific brand name and the product registration number (MAL number) of the suspected product should be used. If it is not known, the generic name should be provided.

vi. Reports that involved **biologic products** (e.g. insulin, low molecular weight heparin, erythropoietin), reporters need to clearly specify the brand name, active ingredient, MAL number and batch number to ensure the traceability.

vii. Standard medical terminology should be used to describe the ADR. The use of vague or non-standardise terms should be avoided.

viii. Every healthcare facility may decide for itself how the ADR reporting systems should be operated and by whom. The arrangements will depend on the facilities' own organisation.

P2.3 REPORTING REQUIREMENTS IN SPECIAL PATIENT POPULATIONS

P2.3.1 Use of a Medicinal Product during Pregnancy or Breastfeeding

ADR related to pregnancy and breastfeeding regardless of whether the product is contraindicated in this situation must be reported

i. Pregnancy

a) Reports of exposure to medicinal products during pregnancy should contain as many detailed information as possible (e.g. gestational age during exposure, length of exposure) in order to assess the relationships between reported adverse events and the suspected medicinal product.

b) Individual cases with an abnormal outcome associated with a medicinal product following exposure during pregnancy are classified as serious reports and should be reported. This especially refers to:

- Reports of congenital anomalies or developmental delay in the foetus or the child;

- Reports of foetal death and spontaneous abortion;
- Reports of suspected ADR involving neonates.

c) In such cases, transmission via semen following paternal exposure should also be considered.

d) Medicinal products taken before the gestational period should be considered as suspected drug when an active substance or one of its metabolites has a long half-life.

e) Unintended pregnancy following the use of contraceptive medication should also be reported.

ii. Breastfeeding

Suspected ADR/AEFI(s), which occur in infants following exposure to a medicinal product from breast milk, should be reported.

P2.3.2 Use of a Medicinal Product in Paediatric or Elderly Population

The collection of safety information in the paediatric or elderly population is important, therefore whenever possible age of the patient should be reported.

P2.4 REPORTING REQUIREMENTS IN SPECIAL SITUATIONS

P2.4.1 Director General of Health Approved Product

The prescriber of the registered medicinal product used as approved by the Director General of Health, must report all adverse drug reaction occurring with the use of the product, in the specified patients.

P2.4.2 Compassionate Use/Named Patient Use

Where an organisation or a healthcare provider, supplying a registered medicinal product under compassionate use or named patient use, is notified or becomes aware of an ADR, it should be reported to the Authority within the stipulated timeline as in Appendix 2.

P2.4.3 Reports of Overdose, Abuse, Off-Label Use, Misuse, Medication Error or Occupational Exposure

Reports of overdose (accidental or intentional), abuse, off-label use, misuse, medication error or occupational exposure, which lead to an ADR, should be reported to NPRA.

P2.5 FOLLOW UP REPORTS

i. Reporters can submit additional relevant information that was not available at the time of initial reporting in the form of follow-up reports (if necessary).

ii. Any follow-up reports should be cross-referenced with ADR number of the initial report (e.g. electronic ADR number). This is to minimise the duplication of reports submitted to NPRA.

iii. NPRA may also request additional information on a case-by-case basis.

P2.6 ADR REPORTING FORMS

The following are the ADR Reporting Form

i. Online Reporting Form available via

https://npra.gov.my/index.php/en/health-professionals/reporting-adr.html

ii. Prepaid reporting blue form

iii. Consumer Side Effect Reporting Form (ConSERF) – for consumer/patient that wish to report directly to NPRA

P2.7 ADR REPORTING ROUTES

ADR reports can be submitted to NPRA via the following routes:

i. Online reporting
   a. NPRA website - http:/npra.moh.gov.my
   b. Pharmacy Hospital Information System (PhIS) for government facilities.

ii. Reporting blue form
Post to:
The National Adverse Drug Reaction Monitoring Centre
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz)
46200 Petaling Jaya
Selangor.

iii. Fax to: 603-79567075

iv. Email: fv@npra.gov.my

PART 3: ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI)

Monitoring of AEFI is an effective way to monitor immunisation safety and contributes to the credibility of National Immunisation Programme (NIP). Vaccines used in national immunization programmes are extremely safe and effective. Nevertheless, no vaccine is perfectly safe and adverse reactions can occur following immunization. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events.

P3.1 SCOPE OF AEFI REPORTING

i. WHO defined adverse event following immunisation (AEFI) as any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccines. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

ii. Case detection is the most important first step in AEFI monitoring. The reporter (physician, pharmacist or other healthcare provider) who detects an AEFI may report on suspicion ground alone. Reporter do not need to assess the causal relationship between event and vaccine.

iii. Suspected AEFIs arising following the use of vaccines registered with DCA, be it coincidental or truly caused by the vaccine should be reported.

iv. **ALL** adverse event following immunisation should be reported.

a) Serious AEFI – AEFI will be considered serious if it results in:
- death
- life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalization
- persistent or significant disability or incapacity, or is a congenital anomaly/birth defect
- Any medical event that requires intervention to prevent one of the outcomes listed above may also considered as serious.

b) Non-serious AEFI - An AEFI that is not ‘serious’ and does not pose a potential risk to the health of the recipient. Example:
- injection site reactions (erythema, swelling, pain)
- fever
- irritability

c) Events associated with a newly introduced vaccine

d) AEFIs that may have been caused by immunization error or anxiety related reaction

e) Significant events of unexplained cause occurring within 30 days after vaccination.

f) Events causing significant parental concern. Example: Unresolved fever, injection site swelling more than 5 cm and inconsolable crying (>3 hours).

iii. Non-serious AEFI should also be reported because they may signal a potentially larger problem with the vaccine or immunization or have an impact on the acceptability of immunization in general.

P3.2 PRINCIPLES OF AEFI REPORTING

i. Case detection is the most important first step in AEFI monitoring. The reporter (physician, pharmacist or other healthcare provider) who detects an AEFI may report on suspicion ground alone. Reporter do not need to assess the causal relationship between event and vaccine.

ii. Report the event soon after it occurs (spontaneous reporting). A recent event is easier to report upon and the report is more likely to be accurate. Please refer to Appendix 2 for ADR reporting time frame.

iii. If possible, take the decision to report whilst the patient/guardian is still with you, so that he/she can easily be questioned about the event and the details filled in at once on the report form.

iv. All reports of suspected AEFI should have these four (4) minimum information:

a. One or More Suspected Vaccine

b. One or More Suspected Adverse Event

c. One Single Identifiable Vacinee/Patient
Charaterised by initials, patient identification number, date of birth, age, age group and/or gender. The information should be as complete as possible.

d. Identifiable Reporter
- Characterised by qualification (e.g. physician, pharmacist or other healthcare providers), name, initials, address or contact details so that follow-up activities can be performed
- Consumer

v. If any of these minimum criteria remain unknown, a report on the incident **should not** be submitted. Reports without this essential information cannot be assessed objectively and will not be entered into the Malaysian ADR database.

vi. Nevertheless, where possible, reporters need to clearly specify the brand name, active ingredient, MAL number and batch number for antigen as well as diluent to ensure traceability.

vii. Standard medical terminology should be used to describe the AEFI.

viii. Every healthcare facility may decide for itself how the AEFI reporting systems should be operated and by whom. The arrangements will depend on the facilities' own organisation.

P3.3 FOLLOW UP REPORTS

i. Reporters can submit additional relevant information that was not available at the time of initial reporting in the form of follow-up reports (if necessary).

ii. Any follow-up reports should be cross-referenced with AEFI number of the initial report (e.g. electronic ADR number). This is to minimise the duplication of reports submitted to NPRA.

iii. NPRA may also request additional information on a case-by-case basis.

P3.4 CAUSE-SPECIFIC CATEGORIZATION OF AEFI

i. The Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO) has revised the existing classifications for cause-specific categorization of AEFIs in 2012. The new categorizations are set out in Table 1:

Table 1: Cause-specific categorization of AEFI

No.	Cause-specific categorization of AEFI	Definition	Example
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.	Injection site reactions, Fever
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.	A batch of inactivated vaccine contained live virus. E.g. Cutter Incidence (1955)
3	Immunisation Error - Related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.	Injection site sterile abscess due to subcutaneous administration.
4	Immunisation Anxiety - Related Reaction	An AEFI arising from anxiety about the immunisation.	Vomiting, fainting, hyperventilation
5	Coincidental Event	An AEFI that is caused by something other than the vaccine product, immunisation error or immunisation anxiety.	Dengue fever

P3.4.1 Vaccine-Product and Quality Defect Related Reaction

i. A vaccine product-related reaction refers to reaction due to individual's response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly.

ii. A vaccine quality defect- related reaction refers to reaction due to a defect in a vaccine that occurred during the manufacturing process. Such defects may impact on an individual's response and thus increase the risk of adverse vaccine reactions. However, since the introduction of improved Good Manufacturing Practices (GMP), such quality defects are now rare.

iii. Vaccine reactions may be classified into:

a. Common, minor vaccine reactions

- Most vaccine reactions are minor and do not requires special treatment.
- Injection site reactions, fever and systemic symptoms (e.g. irritability, malaise, loss of appetite) can result as part of the immune response.
- In addition, excipients (e.g. adjuvant, stabilizers or preservatives) contained in vaccines may, rarely, cause reactions.
- The occurrence of local and systemic reactions varies by the type of antigen.

b. Rare, serious vaccine reactions

- 'Serious' and 'severe' are often used as though they were interchangeable terms, but they are not.
- Severe is used to describe the intensity of a specific event (as in mild, moderate or severe). The event itself, however, may be relatively minor medical significant. For example, fever is a minor medical event, but it can be graded as mild or moderate fever according to its severity.
- An AEFI will be considered serious if it fulfills criteria as described in P3.1(iv)(a).
- Anaphylaxis, for example, is always a serious and life-threatening event however treatable. Most of the rare and serious vaccine reactions (e.g. seizures, thrombocytopenia, hypotonic-hyporesponsive episodes (HHE), persistent inconsolable screaming) do not lead to long-term problems.

P3.4.2 Immunisation error-related reactions

i. An immunisation error-related reaction may occur as part of a cluster of AEFIs. These clusters are usually associated with a particular health facility, or one or more vials of vaccine that has been inappropriately prepared or become contaminated. It may also affect a large number of vials (e.g. freezing vaccine during transport may lead to an increase in local reactions).

ii. To avoid/minimize immunisation-error related reactions:

a. It is essential to maintain the cold chain at every stage

b. Vaccines must only be reconstituted with the diluent supplied by the manufacturer.

c. Reconstituted vaccine should be used within the recommended time frame by the manufacturer

d. No other drugs or substances should be stored in the same refrigerator with vaccines.

e. Healthcare professionals must be adequately trained and supervised to ensure that proper procedures are being followed.

P3.4.3 Immunisation stress related response

i. This reaction arises around the immunisation that are related to anxiety and not to the vaccine product, a defect in the quality of the vaccine or the immunisation error.

ii. These reactions are described as AEFI that arising about immunisation which include :
1. Vasovagal-mediated reaction
2. Hyperventilation-mediated reaction
3. Stress-related psychiatric reaction or disorder

iii. Individuals and groups may react to vaccine administration either before, during or immediately after injection. Such reactions have no relation to the content of the vaccine but more of psychogenic effect (e.g. fainting due to needle phobia). The reactions are usually transient and resolved spontaneously.

iv. Examples of anxiety related reaction:
- Light-headedness
- Dizziness
- Tingling around the mouth and in the hands
- Pale
- Vomiting

- Fainting

v. It is important to note that faintish attack (syncope) can be misdiagnosed as anaphylaxis. Healthcare professionals need to differentiate between the two statuses (see Table 2) with very careful observation and clinical judgment.

Table 2 : Differences between a fainting attack and anaphylaxis

Clinical features	**Fainting**	**Anaphylaxis**
Timing	Before, during or few minutes after injection	A short time, up to few hours
Skin	Generalised pallor, cold clammy skin	Itching, generalised erythema, urticaria, swelling of lips & face, tingling around lips
Respiratory system	Normal breathing, shallow breathing	Tachypnoea, dyspnoea, wheezing, stridor, hoarseness, cyanosis, recession of intercostal spaces
Cardiovascular	Bradycardia, weak pulse, carotid pulse felt, hypotension may occur – reversed by supine position	Tachycardia, weak pulse, carotid pulse may be weak, hypotension – not reversed by supine position
Gastrointestinal	Vomiting	Vomiting, diarrhoea, abdominal cramps
Central Nervous System	Feeling faint, light-headedness, relieved by supine position	Anxiety and distress, loss of consciousness, not relieved by supine position

vi. These reactions can be anticipated when immunising children in groups (e.g. school immunisation programme). Steps such as reducing waiting time, comfortable room temperature, preparation of vaccine out of recipient's view can be taken to minimise the stress.

P3.4.4 Coincidental events

i. An event may occur coincidentally with immunisation and may sometimes be falsely attributed as being a result of the vaccine.

ii. An event happening after immunisation may happen purely by chance and not related to the vaccine. The event that occurred is just a temporal association but not causal.

iii. Vaccines are normally scheduled early in life when infections and other illness are common, including manifestations of an underlying congenital or

neurological condition. It is, therefore, possible to encounter many events, which may be falsely attributed to vaccine through chance association.

iv. For example: incidence of sudden infant death syndrome (SIDS) peaks around the age of early child immunisation. Hence, many SIDS cases will be seen in children who has been recently immunised. However, controlled studies have shown that the association of SIDS and immunisation is coincidental, not causal.

v. Even though coincidental events are not related to immunisation, an investigation may be still necessary. This is to prevent false accusation upon the vaccine and maintain confidence on the immunisation.

P3.5 AEFI REPORTING FORMS

The following are AEFI reporting forms:

i. Non-serious reaction AEFI :-
Online reporting form (www.npra.gov.my) or *Borang Pemantauan Kesan Sampingan Ringan Susulan Imunisasi*

ii. Serious AEFI :
Online reporting form or Report on Suspected Adverse Drug Reaction (blue form)

P3.6 AEFI REPORTING ROUTES

AEFI reports can be submitted to NPRA via the following routes:

i. Online reporting
   a. NPRA website - http://npra.moh.gov.my
   b. Pharmacy Hospital Information System (PhIS) for government facilities.

ii. Reporting blue form
Post to:
The National Adverse Drug Reaction Monitoring Centre
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz)
46200 Petaling Jaya
Selangor.

iii. Fax to: +603-79567075

iv. Email: fv@npra.gov.my

P3.7 AEFI INVESTIGATION BY FACILITY

P3.7.1 The purpose of AEFI investigation

a) To confirm the reported diagnosis or propose other possible diagnoses, and clarify the outcome of the medical incident;

b) To identify the details of the vaccine(s) administered to the affected recipient and determines any vaccine-related link to the AEFI.

c) To identify the cause of the AEFI

d) To examine the operational aspects of the immunisation programme (even if an event seems to be vaccine-induced or coincidental, immunisation errors may have increased its severity).

e) To determine whether a reported event is a single incident or one of a cluster.

P3.7.2 Reported AEFI that requires investigation

a) Suspected AEFI-Related Death Events

i. A death case should be notified to all respective parties without delay (within 24 hours). Set up an investigation team and follow the investigation steps of an AEFI.

ii. It is recommended to request for an autopsy following all death events in order to identify the cause of death. Autopsy reports together with the final investigation report should be sent to NPRA once it is available.

iii. Submit to NPRA the report of Under 5 Mortality Meeting once it is available.

iv. All reports will be evaluated, and causality assessments will be conducted based on the information provided.

b) Serious event such as anaphylaxis, hypotonic-hyporesponsive episode, injection site abscess etc. However, not all serious event needs investigation. Some adverse event (e.g. generalised rash, fever, vomiting) that results in hospitalisation do not require an investigation.

c) Cluster AEFI

i. WHO defined cluster AEFIs as two or more cases of the same adverse event related in time, place or by vaccine administered. Apart from checking on these factors (e.g. checking vaccine batch), the investigator should also check for AEFIs occurring in similar age of groups and populations with genetic predisposition or disease.

ii. A cluster investigation begins by establishing the case definition and identifying all cases that meet the case definition. This can be achieved by collecting detailed information on:

- Data on each patient
- Programmed-related data (storage and handling, etc.)
- Immunisation practices and the associated healthcare professionals' practices.
- Data on vaccines
- Data on other people in the area (including non-exposed)

iii. Once an AEFI cluster has been identified, the cause-specific definitions provide a framework for investigation and causality assessment. Usually, the key considerations will be to investigate the possibility of a vaccine quality defect as well as whether the events may have been immunisation error-related.

d) AEFI that may have been caused by immunization error

e) Any AEFI detected by the health facility & deemed necessary to be investigated.

f) Upon assessment and request by NPRA.

P3.7.3 AEFI investigation process

a) Facility Role

i. In the event that the reporting facility is different from the facility that provided the vaccination, a copy of the ADR form is required to be submitted to the facility that provided the vaccination. This should be handled by the respective pharmacist in-charge in the reporting facility.

ii. If the vaccination provided by a non-MOH facility, the district health office may be requested to initiate the investigation.

iii. Initiation of investigation team. The investigation team consist of (not limited to):

- Hospital Director/ Head of Department/ District Health Officer
- Peadiatrician/ Family Medicine Specialist
- Chief Pharmacist/Pharmacist in-charge
- Matron/Sister in-charge

iv. Quarantine suspected vaccine (same batch number). The person in charge of that facility must ensure that the immunisation programme is not affected. The facility may use:

- Vaccine of a different batch number
- Vaccine of same batch number from neighbouring health facility

v. The facility which provide immunisation or District Health Office which oversee that facility should investigate and collect data on:

- **Patient**: Immunisation history & any related AEFI, previous medical history including prior history of similar reaction, history of hospitalisation in last 30 days, allergies, family history and similar events.

- **Event**: History, clinical description, any relevant laboratory results about the AEFI and diagnosis of event. The diagnosis should meet a standard case definition. Case definition can be adopted from local clinical practise guideline (CPG).
  However, it is best to adopt the Brighton Collaboration case definition (https://www.brightoncollaboration.org/case-definitions) or medical literature.

- **Vaccine**: Its present storage condition, state of vaccine vial monitors (VVM), temperature record of refrigerator, and temperature record during transportation (schools, outreach program).

- **Other vaccinees**: Any similar events reported within a time period similar to, when the AEFI occurred, with the same vaccine and in the same locality.

- **Service**: Vaccine and diluents storage and distribution, immunisation practices such as reconstitution process, aseptic technique.

vi. Fill up investigation form and submit to NPRA.

b) NPRA Role

i. NPRA will evaluate the investigation reports received from facilities as well as manufacturing reports received from PRH.

ii. If the vaccine involved does not conform with the product specification and/or there is a need of nationwide quarantine:

a) NPRA will issue a quarantine notification to State Health Director and the product registration holder with copies to Director General

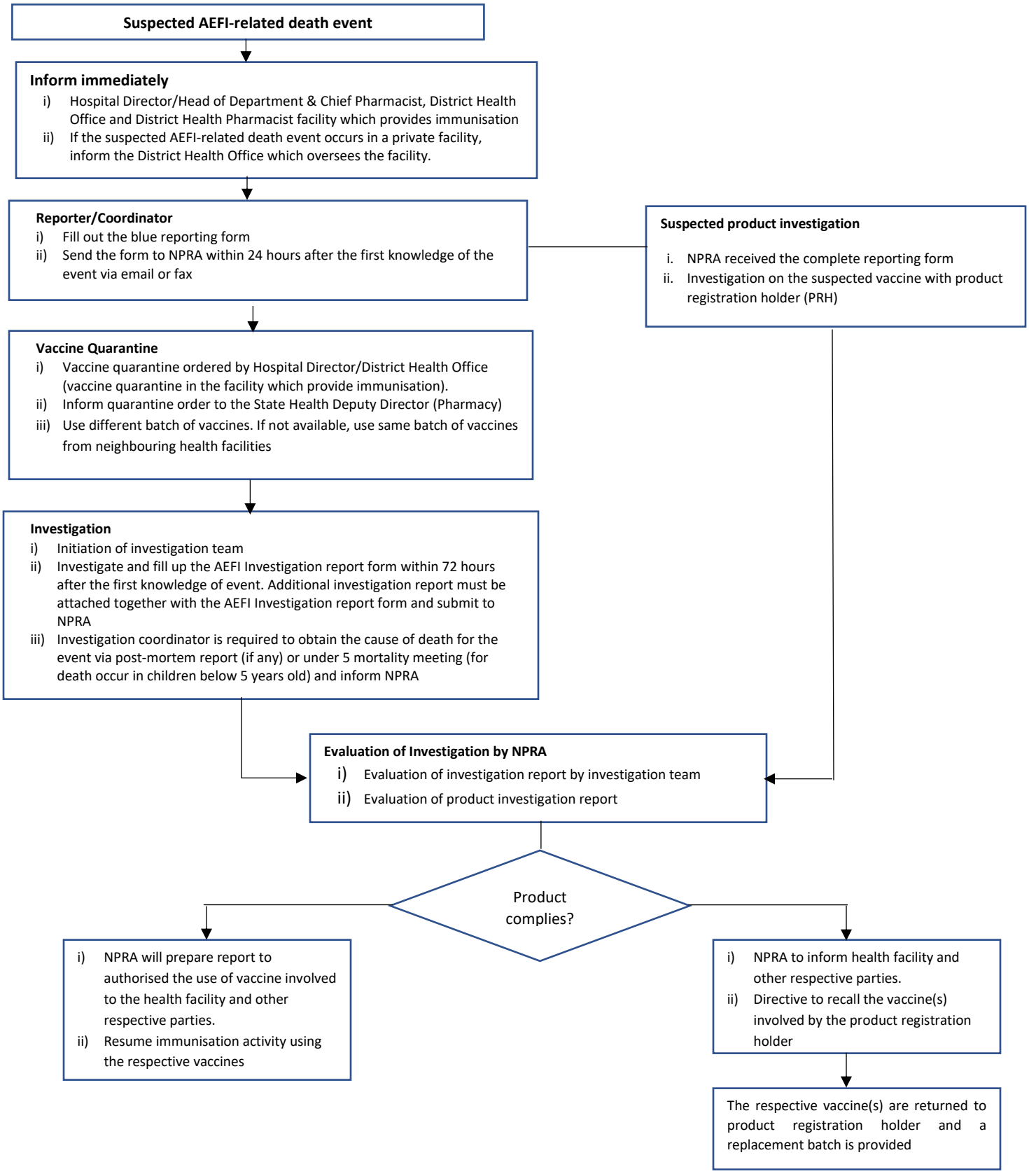
of Health, Deputy Director General (Public Health) and Senior Director of Pharmaceutical Services.

b) State Health Director will distribute the quarantine notification to all health facilities. Meanwhile product registration holder will distribute it to the private health facilities.

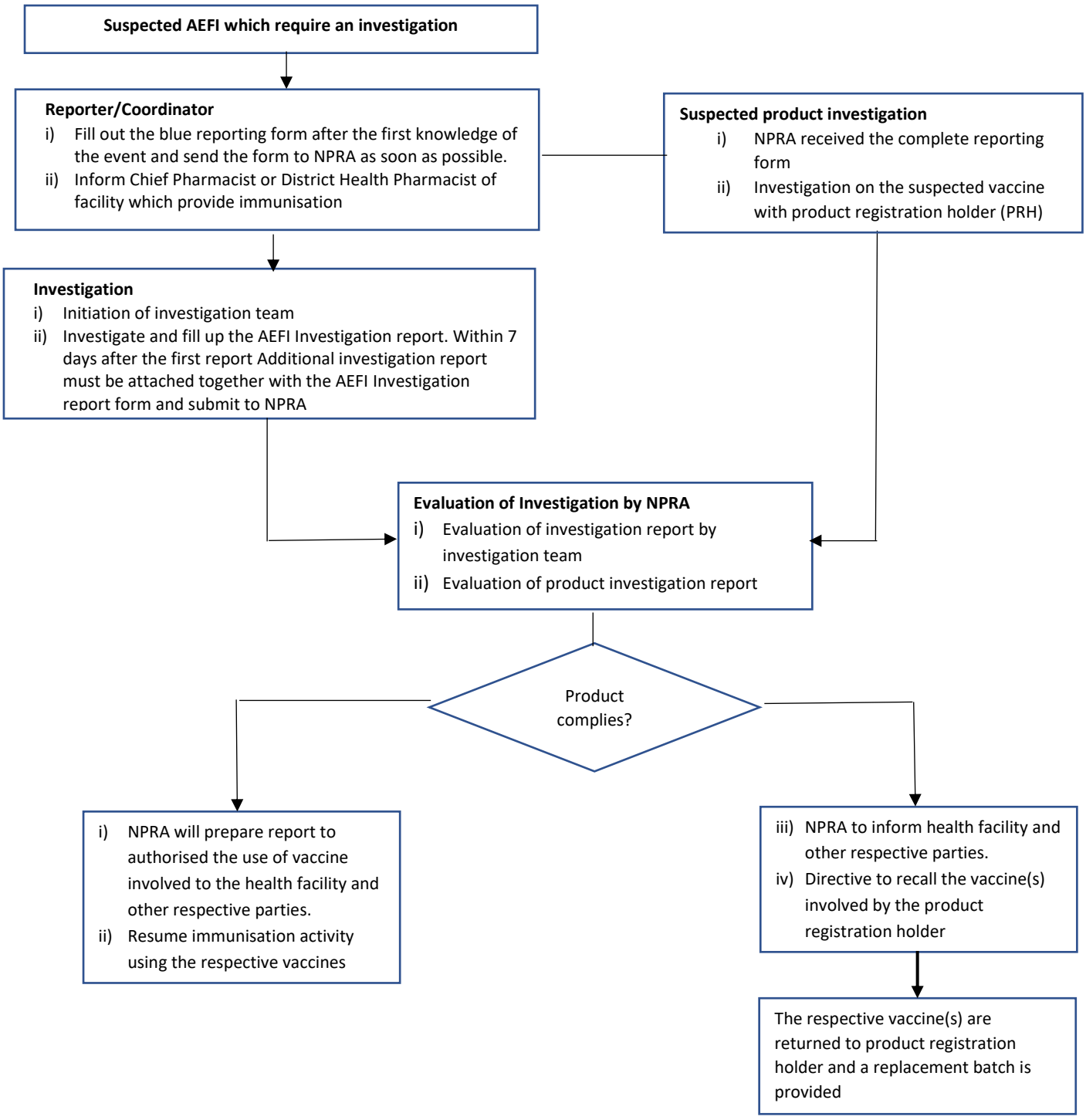
c) In situation where it warrants regulatory action (i.e product recall, product suspension), the vaccines will be returned to the product registration holder and eplacements should be sent to the affected facilities.

iii. If the vaccine involved conforms to the product specification, NPRA will issue a report to authorise the use of vaccine.

Appendix 1 : Suspected AEFI-related death event investigation workflow



Appendix 2 : AEFI Investigation (other than death related cases) workflow*



*Serious case (other than death related case), cluster events, immunisation error and case deemed necessary to be investigated

Appendix 3 : Reporting Form

REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@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/ years *(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.*

ConSERF

CONSUMER SIDE EFFECT REPORTING FORM

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Help us make medicines safer

*Please fill in all sections marked with * and give as much other information as you can.*
*All personal data will remain **confidential**.*

Report No. *(for official use)*:

Information about the person who had the side effect

Name :
*Gender: □ Male □ Female
*Age :

Nationality: □Malaysian □Other:_____
*Ethnicity: □ Malay □ Chinese □ Indian □ Other:_____

*Any health problems / allergies / pregnancy? *(please specify)*:

E.g.: Diabetes, high blood pressure, asthma, allergy to painkiller, or 16 weeks pregnant

Reporter details

Date of report:
Reporter's name:
*Tel. Number :
Email address:

Information about the medication(s) suspected to cause the side effect, and other medications

Suspected Medicine(s): *(please attach additional sheets if necessary)*

Suspected medicine name *(include MAL number if known)*	Dosage *(e.g. 250mg three times daily)*	Dates: Started	Dates: Stopped	Reason for use
		DD/MM/YY	DD/MM/YY	

Were any other medicines taken at the same time?: □Yes *(please give the details below)* □No

Other medicine(s) name *(include MAL number if known)*	Dosage *(e.g. 250mg three times daily)*	Dates: Started	Dates: Stopped	Reason for use
		DD/MM/YY	DD/MM/YY	

Information on the side effect(s)

1. * **Date** of side effect(s): a) Reaction started on D D M M Y Y b) Reaction subsided on D D M M Y Y
2. * Please **describe the side effect(s)** experienced:

3. * How long was the **medication(s) taken** before the side effect appeared? ____ minutes/hours/days/months/years *(choose)*
4. * Did the side effect subside when the medication(s) was **stopped**? □ Yes □ No □ Did not stop taking the medicine
5. * Did the side effect reappear when the medication(s) was **taken again**? □ Yes □ No □ Did not take again
6. * How **serious** was the side effect? *(select all that apply below)*
   □ Mild or slightly uncomfortable □ Had to seek medical advice □ Admitted to the hospital
   □ Uncomfortable but could carry out daily activities □ Bad, interferes with daily activities □ Other:_____
7. * Was any **treatment given**/ medication taken to overcome the side effect? □ Yes *(please specify)* □ No
8. * What is the **current outcome** of the side effect?
   □ Fully recovered □ Getting better □ Side effects continuing □ Caused death

Thank you for reporting

Ver.1.1 (2016)

BORANG PEMANTAUAN KESAN ADVERS RINGAN SUSULAN IMUNISASI

Pindaan-5

Sekiranya anda atau orang yang berada di bawah jagaan anda mengalami kesan advers susulan imunisasi, sila isi borang ini dan kembalikan kepada kakitangan institusi kesihatan tempat vaksin diterima atau yang berdekatan.

Nama klinik/sekolah/lain-lain tempat di mana vaksin diterima: .....

1. Maklumat penerima vaksin:-
   a) Nama: .....
   b) Umur: ..... c) Jantina: ☐ Lelaki ☐ Perempuan
   d) No. telefon: .....
   e) Bangsa: ☐ Melayu ☐ India ☐ Cina ☐ Lain-lain (nyatakan) .....
2. Tarikh vaksin diterima: .....
3. Masa vaksin diterima: .....
4. Kesan advers yang dialami:-

(Tempoh masa berlakunya kesan advers selepas menerima vaksin adalah penting untuk diisi)

Kesan advers (*potong yang tidak berkaitan)	Tandakan √ jika berkaitan	Tempoh masa berlakunya kesan advers selepas menerima vaksin (*potong yang tidak berkaitan)
a. Kesan pada tempat suntikan:		
i) Bengkak	☐	.....minit/jam/hari*
ii) Sakit	☐	.....minit/jam/hari*
iii) Kegatalan	☐	.....minit/jam/hari*
iv) Merah pada tempat suntikan	☐	.....minit/jam/hari*
v) Lain-lain (nyatakan)	☐	.....minit/jam/hari*
b. Demam	☐	.....minit/jam/hari*
c. Ruam/gatal*	☐	.....minit/jam/hari*
d. Kerengsaan (irritability)	☐	.....minit/jam/hari*
e. Kurang selera makan	☐	.....minit/jam/hari*
f. Sakit kepala/pening kepala*	☐	.....minit/jam/hari*
g. Loya/muntah*	☐	.....minit/jam/hari*
h. Sakit otot/badan*	☐	.....minit/jam/hari*
i. Lemah tangan/kaki*	☐	.....minit/jam/hari/minggu*
j. Lain-lain (nyatakan)	☐	.....minit/jam/hari*

5. Adakah penerima vaksin menerima sebarang rawatan di klinik/hospital untuk kesan advers yang dialami?
   ☐ Ya ☐ Tidak
6. Adakah kesan advers tersebut dapat diatasi atau pulih? ☐ Ya ☐ Tidak
7. Maklumat vaksin yang diterima:-
   a) Jenis vaksin
   - ☐ BCG
   - ☐ Hepatitis B, Dos: pertama/kedua/ketiga*
   - ☐ DTaP-IPV-HepB-Hib Dos: pertama/kedua/ketiga/booster*
   - ☐ Pneumokokal, Dos: pertama/kedua/booster*
   - ☐ Measles
   - ☐ Japanese encephalitis, Dos: pertama/kedua
   - ☐ Lain-lain (nyatakan): .....
   - ☐ MMR, Dos: pertama/kedua
   - ☐ Diphtheria & Tetanus
   - ☐ Measles & Rubella
   - ☐ Human papillomavirus, Dos: pertama/kedua*
   - ☐ Tetanus
   - ☐ Polio, oral/suntikan*

   b) Perihal vaksin

Vaksin 1		Vaksin 2	
Jenama vaksin:	.....	Jenama vaksin:	.....
No. kelompok:	.....	No. kelompok:	.....
Tarikh luput:	.....	Tarikh luput:	.....
Bahagian badan yang disuntik: (jika berkaitan)	☐ Lengan ☐ Paha ☐ Kanan ☐ Kiri	Bahagian badan yang disuntik: (jika berkaitan)	☐ Lengan ☐ Paha ☐ Kanan ☐ Kiri

9. Maklumat pelapor:- ☐ Ibubapa/penjaga ☐ Penerima vaksin ☐ Anggota kesihatan
   a) Nama: .....
   b) No. telefon: .....
   c) Tarikh laporan: .....

Maklumat tambahan bagi anggota kesihatan
d) Jawatan & tempat bertugas: .....
.....
e) Jenis imunisasi: ☐ Rutin ☐ Kempen

Segala maklumat yang dikemukakan adalah sulit dan hanya akan digunakan untuk tujuan memantau kesan advers ringan susulan imunisasi sahaja.

Pindaan-2

Appendix 4 : AEFI Investigation Form
Borang Penyiasatan Kejadian AEFI

1. Maklumat Tempat Suntikan Diberi

Nama Klinik/ Hospital : ……..

Alamat: .....

.....

Tarikh terima notifikasi : .....

Tarikh siasatan dilakukan: .....

2. Maklumat Penerima Vaksin

Nama : ……

Umur : …… Jantina : Lelaki/Perempuan

Tarikh lahir: ☐☐ - ☐☐ - ☐☐☐☐ (hari/bulan/tahun)

No.Pendaftaran : …….. Berat : ..... kg

Alamat : ……

……

No. Tel : ……

3. Maklumat Kesihatan Penerima Vaksin sebelum suntikan diberi (sila tandakan √ di ruang yang berkenaan)

☐ Demam >38.5ºC

☐ *Malignancy* yang sedang menjalani rawatan anti neoplastik /radiasi/kemoterapi/ immunosuppresi

☐ Masalah pendarahan (eg: hemofilia)

☐ Mendapat *pneumonia/rash* dalam tempoh seminggu sebelum vaksinasi

☐ Menjalani rawatan kortikosteroid berdos tinggi

☐ Mengalami cirit-birit / muntah

☐ TB aktif yang tidak dirawat

☐ Pernah mendapat sawan (epilepsi) sebelum vaksinansi

☐ Hipersensitiviti /alahan terhadap vaksin atau lain-lain

☐ Imunodefisiensi (contoh: penyakit imunodefisiensi keturunan, *leukaemia*, *lymphoma*, penyakit Hodgkin's, HIV dengan imunosuppresi yang teruk, Hipogammaglobulinaemia, pemindahan sum-sum tulang)

☐ Lain-lain masalah (nyatakan)

4. Perihal reaksi yang dialami

Bil	Jenis Reaksi	Tarikh dan Masa	Keadaan reaksi (sedikit/sederhana/ teruk)	Tempoh diantara reaksi dan suntikan diberi (jam/minit)	Rawatan di beri (ubat/dos/tarikh /regim)	Nama Pegawai yang memberi rawatan	Kes dirujuk (nama hospital)

5. Keadaan kes semasa siasatan dilakukan

……

6. Diagnosa akhir

……

7. Kes kematian

Tarikh	Tempat	Post mortem (Ya/Tidak)	Sebab kematian

8. Keputusan dan tarikh ujian makmal/radiologi yang berkaitan:

Tarikh	Ujian makmal	Keputusan

9. Maklumat Vaksin Yang Disyaki

Jenis vaksin dan jenama	Nama pengeluar	No. Batch	No. Lot Pengeluar	Tarikh luput	Kuantiti dos yang diberi (ml)	Tempat (site) dan cara (route) suntikan	Dos yang ke berapa?	Tarikh dan masa suntikan diberi

10. Maklumat Vaksin Yang Disyaki

Nama vaksin	Keadaan vaksin	Bil. kanak-kanak yang telah diberi batch vaksin yang sama	Bil. aduan AEFI daripada batch vaksin yang sama

11. Maklumat Pengendalian Vaksin (sila tandakan √ di ruang yang berkenaan)

	Ya	Tidak
i. Tempat vaksin disimpan:		
a. Pembeku/freezer	☐	☐
b. Am/general compartment	☐	☐
c. Bercampur dengan ubat-ubat cecair yang lain	☐	☐
ii. Vaksin bertukar warna	☐	☐
iii. Suhu peti sejuk kekal di antara 2oC-8oC dalam tempoh sebulan sebelum kejadian	☐	☐
iv. Peti sejuk diselenggara secara berkala	☐	☐
v. Tarikh penyelenggaraan peti sejuk kali terakhir	...../...../.....	
vi. Terdapat keladak (sediment) di dalam vial vaksin sebelum digunakan	☐	☐
Jika ya, Adakah ia hilang apabila digoncang	☐	☐
Keldak itu mendap dalam tempoh 30 minit dengan cecair jernih di atasnya selepas digoncang	☐	☐

12. Maklumat Pengendalian Dan Pemberian Suntikan (sila tandakan √ di ruang yang berkenaan)

	Ya	Tidak
Teknik/bahagian badan yang betul diberi suntikan	☐	☐
Cara pengendalian (rekonstitusi) vaksin yang Betul	☐	☐
Menggunakan teknik aseptik	☐	☐
Menggunakan peralatan yang steril	☐	☐
Menggunakan pencair (diluents) yang betul	☐	☐
Cara pengendalian vaksin yang betul semasa sesi vaksinasi	☐	☐
Menyemak senarai semak kontraindikasi sebelum vaksinasi	☐	☐
Adakah kanak-kanak yang tidak diberi pelalian mengalami kejadian yang serupa	☐	☐

13. Tindakan yang telah diambil	**14.** Ulasan
15. Cadangan untuk tindakan lanjut	**16.** Ketua Penyiasat:
	Tandatangan:
	Nama & cop:
	Tarikh:

Soalan tambahan bagi borang penyiasatan kejadian AEFI

A. Maklumat kesihatan pesakit sebelum menerima vaksin

Maklumat kesihatan pesakit sebelum menerima vaksin	
1.	Sejarah kejadian sama yang pernah berlaku
2.	Sejarah kejadian kesan advers dengan imunisasi terdahulu
3.	Sejarah alergi
4.	Sejarah perubatan keluarga
5.	Sejarah kemasukan ke hospital (dalam tempoh sebulan yang lalu)

B. Maklumat perubatan pesakit semasa di klinik/hospital

Maklumat perubatan pesakit semasa di klinik/hospital	
1.	Kronologi kejadian kesan advers
2.	Keputusan ujian darah/prosedur
3.	Rawatan yang diberi
4.	Diagnosis akhir

(sila lampirkan kertas bagi maklumat tambahan jika perlu)

Below are the documents referred to when preparing this manual:

1. EMA Guideline on Good Pharmacovigilance Practices (GVP) Module VI – Collection, Management and Submission of Reports of Suspected Adverse Reactions to Medicinal Products (Rev 2) – *July 2017*
2. WHO Western Pacific Region Immunization Safety Surveillance Third Edition - *2015*