REPORTING ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) GUIDELINE

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CONTENT

PREFACE

This document is intended to provide guidance on the requirements and procedures for submission of adverse event following immunisation (AEFI) reports to the Brunei Darussalam Medicines Control Authority (BDMCA) and/ or relevant technical committees relating to vaccines/ vaccination. This guideline does not cover the entire scope of vaccine pharmacovigilance which is defined as the science and activities relating to the detection, assessment, understanding and communication of AEFIs and other vaccine- or immunisation-related issues, and to the prevention of untoward effects of the vaccine or immunisation[1]. Whilst every effort is made to ensure the information contained in this document is accurate, the authors cannot guarantee its full accuracy nor its completeness. The BDMCA accepts no liability for any errors or omissions in this document, or for any action/ decision taken or not taken as a result of using this document.

ABBREVIATIONS

AEFI	Adverse Event Following Immunisation
BDMCA	Brunei Darussalam Medicines Control Authority
BDPAC	Brunei Darussalam Pharmacovigilance Advisory Committee
Bru-HIMS	Brunei Darussalam Health Information Management System
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th revision
NADRMC	National Adverse Drug Reaction Monitoring Centre
NEC	Not Elsewhere Classified
WHO	World Health Organisation

1.0 INTRODUCTION

1.1 BACKGROUND

An adverse event following immunisation (AEFI) is any untoward medical occurrence which follows immunisation, which does not necessarily have a causal relationship with the usage of the vaccine[1]. An adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease[1]. Immunisation safety surveillance is important for early detection and timely appropriate response to adverse events[2]. This is to lessen the negative impact on the health of individuals[2].

The objectives of immunisation safety surveillance are as follows[2]:

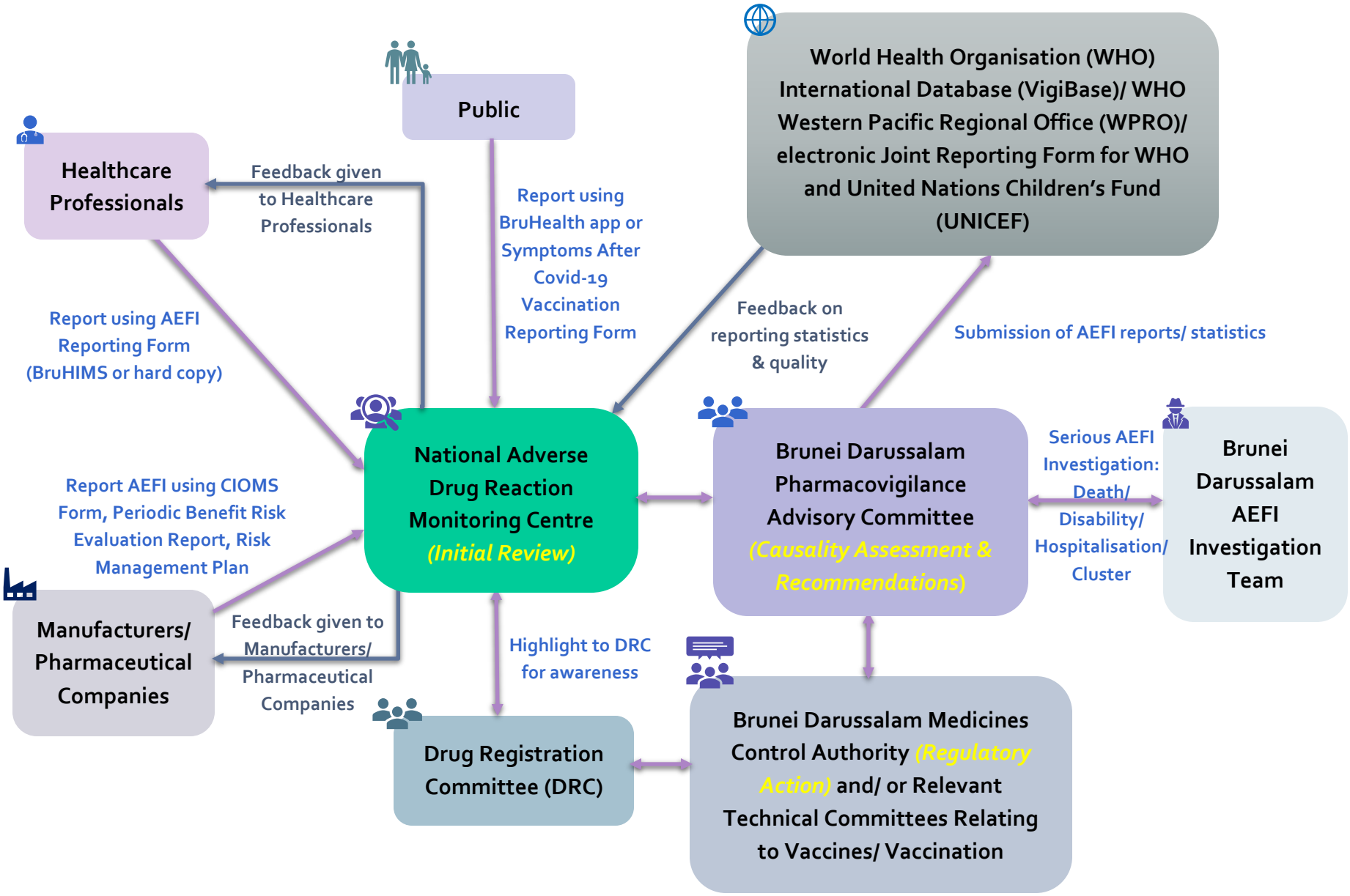
- To detect and identify issues with vaccines in a timely manner[2].
- To identify clustering or unusually high rates of AEFI even if they are considered mild[2].
- To ensure and facilitate causality assessment of serious and unexpected/unusual AEFI reports[2].
- To identify signals of unknown vaccine reactions, generate new hypotheses about vaccine
  reactions that are specific to a given population[2].
- To collaborate and share information with the World Health Organisation (WHO) in order to generate new and additional information on vaccine safety[2]

1.2 OBJECTIVE

This guideline provides healthcare professionals with guidance on reporting adverse event following immunisation (AEFI) of vaccines to the Brunei Darussalam Medicines Control Authority (BDMCA) and/ or relevant technical committees relating to vaccines/ vaccination *via* the National Adverse Drug Reaction Monitoring Centre (NADRMC), Ministry of Health, Brunei Darussalam [Figure 1. Flowchart of AEFI Reporting & Processing of AEFI (Covid-19]. The healthcare professionals in this guideline are defined as doctors, dentists, pharmacists, nurses, vaccinators and pharmacy technicians that uses vaccines in their practice. The AEFI reports received by NADRMC are submitted to the Brunei Darussalam Pharmacovigilance Advisory Committee (BDPAC) which plays a vital role in conducting causality assessments of AEFI cases particularly serious cases and of public concern.

The purposes of healthcare professionals reporting AEFIs are to safeguard the public, monitor the safety profile of vaccines and for formulating regulatory actions to minimise risks to consumers.

Figure 1. Flowchart of AEFI Reporting & Processing of AEFI Reports



2.0BASIC PRINCIPLES OF REPORTING AEFI

2.1 WHICH EVENTS SHOULD BE REPORTED?

Any AEFI that is of concern should be reported which include[2]:

- serious AEFIs, hospitalisation/ death following immunisation[2];
- signals and events associated with a newly introduced vaccine[2];
- AEFIs that may have been caused by immunisation error[2];
- significant events of unexplained cause occurring after vaccination[2];
- events causing significant parental or community concern and[2];
- increasing frequency of minor reactions, even if not severe (markers for immunisation errors or problems with specific vaccine lots)[2].

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose[3]:

- results in death[3];
- is life-threatening[3];
- is a congenital abnormality[3];
- requires hospitalisation[3];
- results in disability[3];
- is medically significant[3]

All minor AEFI reactions such as high fever and minor local reactions are encouraged to be reported as it is helpful to monitor and record crude numbers/ rates for minor reactions as comparison with background rates[2]. This could identify product quality defects or immunisation errors, or even increased susceptibility of vaccine reaction among a particular population[2].

2.2 WHEN TO REPORT?

A report should always be made as early as possible usually within **three days** of the event so that a timely decision can be made on the need for action and investigation. For **novel vaccines,** any suspected event that occurred within **ninety days** (subject to change per recommendations of relevant organisations) of vaccination should be reported.

2.3 HOW TO REPORT FOR HEALTHCARE PROFESSIONALS?

2.3.1 Reports by healthcare professionals should be made using the **'AEFI Reporting Form' (Annex I)**. It is important that all of the minimum required information is entered into the reporting form, as this is the basis for decisions regarding the need for further investigation. World Health Organisation recommended 22 core variables, with 10 identified as critical (minimum information) that should be collected for any AEFI surveillance[3].

Table 1: Core variables – minimum information required for reporting in AEFI surveillance[3]

No.	Category	Core variable	
1.	**Identity**	Date AEFI report first received at national centre	*Location (address) Worldwide unique number
		Country where this AEFI was reported	
2.	**Case**	*Patient identifier	Gender
		*Date of birth (or) age at time of onset (or) age group at onset	*Medical history
3.	**Vaccine**	*Primary suspect vaccine name (generic)	*Batch number and expiry date
		Other vaccines given just prior to AEFI	Vaccine dose number for this particular vaccine
4.	**Event**	*Date and time of vaccination	*Adverse event
		*Date and time of AEFI onset	*Outcome of AEFI
5.	**Reporter**	Name of first reporter of AEFI	Email
		Institution/location	Telephone number
		Position/department	

*The ten critical (mandatory) core variables

Source: Immunization Safety Surveillance, 3rd Edition, WHO Western Pacific Region

2.3.2 It is preferable and encouraged to report an AEFI whilst the patient is still easily accessible (e.g. if patient is still warded) to the reporter so that s/he can easily be questioned about the event and the details entered promptly in the **'AEFI Reporting Form' (Annex I)** as completely as possible[4,5].

2.3.3 Enquire specifically whether the patient had also taken any other medicinal or healthcare products which may have contributed towards the event, e.g. other concomitant drugs, traditional medicines, health supplements or exposed to or consumed other known triggering factors[5].

2.3.4 A follow-up report should be submitted if any additional data becomes available later, e.g. if the same patient develops the effect again or if something happens which increases your suspicions or seems to exclude the effect[4,5].

2.3.5 In cases where the patient who sustained the AEFI is a foetus or breastfed infant, information on both the mother and the child/ foetus should be provided[5].

2.3.6 AEFI reports of patients must be treated with utmost confidentiality[4,5].

2.3.7 Submission of AEFI reports *via* Bru-HIMS is available only for doctors with Bru-HIMS access **(Annex II: Bru-HIMS - AEFI Reporting Form Quick Guide).** If the symptoms are suspected to be related to the vaccines, doctors need to enter in the Bru-HIMS, the most up to date and appropriate International Statistical Classification of Diseases and Related Health Problems (ICD) coding of the **adverse effect in therapeutic use according to the relevant vaccine** (Table 2). ICD-10 (10th revision) is currently in use. Doctors also need to enter the **ICD coding of the actual adverse event**.

For example: If patient has acute myocardial infarction with Covid-19 vaccine, the doctor has to enter one ICD-10 coding for the vaccine (Covid-19 - U12.9) and one ICD-coding for the adverse event (Acute myocardial infarction, unspecified - I21.9).

Table 2: ICD-10 coding[6,7]

No.	Vaccine[6,7]	ICD-10 coding - Adverse effect in therapeutic use[6,7]
1	Vaccine NEC*	Y59.9
2	Antineoplastic	Y59.8
3	Bacterial NEC*	Y58.9
4	Mixed NEC*	Y58.8
5	BCG	Y58.0
6	Cholera	Y58.2
7	Covid-19	U12.9
8	Diphtheria	Y58.5
9	Diphtheria with tetanus	Y58.8
10	Diphtheria with tetanus and pertussis	Y58.6
11	Influenza	Y59.0
12	Measles	Y59.0
13	Measles with mumps and rubella	Y59.0
14	Mixed, viral-rickettsial	Y59.8
15	Mumps	Y59.0
16	Pertussis	Y58.6
17	Pertussis with diphtheria	Y58.6
18	Pertussis with Diphtheria and tetanus	Y58.6
19	Plague	Y58.3
20	Poliomyelitis	Y59.0
21	Protozoal	Y59.2
22	Rabies	Y59.0
23	Rickettsial NEC*	Y59.1
24	Rocky Mountain spotted fever	Y59.1
25	Rubella	Y59.0
26	Smallpox	Y59.0
27	TAB (Thypoid-paratyphoid A and B)	Y58.1
28	Tetanus	Y58.4
29	Typhoid	Y58.1
30	Typhus	Y59.1
31	Viral Vaccine NEC*	Y59.0
32	Yellow Fever	Y59.0

Note: The above ICD-10 coding can be subjected to changes.

** NEC - Not elsewhere classified.*

2.3.8 AEFI reports can also be submitted using the **'AEFI Reporting Form' (Annex I)** which can be downloaded from Ministry of Health website **[http://www.moh.gov.bn/SitePages/Downloads.aspx]** or requested by e-mail to: **nadrmc.dps@moh.gov.bn**

Filled AEFI reports are to be submitted to:

National Adverse Drug Reaction Monitoring Centre (NADRMC)
c/o Pharmacovigilance Section
1st Floor, Department of Pharmaceutical Services Building
Simpang 433, Rimba Highway
Kg Madaras, Bandar Seri Begawan
BB1514
Brunei Darussalam
Telephone Number: +673 2393301/ 2393230 Ext 201, 206, 207
Fax Number: +673 2393037
E-mail: nadrmc.dps@moh.gov.bn

GLOSSARY

Adverse Event Following Immunisation (AEFI)[1]	Any untoward medical occurrence which follows Immunisation and which does not necessarily have a causal relationship with the usage of the vaccine[1]. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease[1].
Causal Association[2]	A cause-and-effect relationship between a causative (risk) factor and an outcome[2]. Causally-associated events are also temporally associated (i.e. they occur after vaccine administration), but events which are temporally associated may not necessarily be causally associated[2].
Causality Assessment[2]	In the context of AEFI surveillance, causality assessment is a systematic review of data about AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received[2].
Cluster[2]	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered[2]. AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines[2].
Immunisation Safety[2]	The process of ensuring the safety of all aspects of immunisation, including vaccine quality, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste, and surveillance of adverse events[2].
Immunisation Safety Surveillance[2]	A system for ensuring immunisation safety through detecting, reporting, investigating, and responding to AEFIs[2].

Non-Serious AEFI[2]	An event that is not 'serious' and does not pose a potential risk to the health of the recipient[2]. 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[2].
Serious AEFI[3]	An event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect[3]. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious[3].
Severe Vaccine Reaction[2]	The severity of a vaccine reaction is a measure of its intensity. A severe reaction is a reaction of high intensity, graded as mild, moderate or severe. Severe reactions may include serious and non-serious reactions[2].
Signal[1]	Information (from one or multiple sources) which suggests a new and potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verificatory action[1].
Surveillance[2]	The continuing, systematic collection of data that are analysed and disseminated to enable decision-making and action to protect the health of populations[2].

Vaccine[2]	A biological preparation that improves immunity to a particular disease. In addition to the antigen, it contains multiple components (excipients); each component may have unique safety implications[2].
Vaccine Pharmacovigilance[1]	The science and activities relating to the detection, assessment, understanding and communication of AEFIs and other vaccine- or Immunisation-related issues, and to the prevention of untoward effects of the vaccine or immunisation[1].
Vaccine Product-Related Reaction[1]	An AEFI that is caused or precipitated by a vaccine that is due to one or more of the inherent properties of the vaccine product, whether the active component or another component of the vaccine (e.g. adjuvant, preservative or stabilizer)[1].
Vaccine Quality Defect Related Reaction[2]	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects with the vaccine product, including its administration device as provided by the manufacturer[2].
Vaccine Reaction[2]	An event caused or precipitated by the active component or one of the other components of the vaccine[2]. It may also relate to a vaccine quality defect[2].
Vaccine Safety[2]	The process that maintains the highest efficacy of and lowest adverse reaction to a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunisation safety[2].

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