National Pharmaceutical Regulatory Agency
Ministry of Health, Malaysia

Summary Report on Adverse Events Following Immunisation (AEFI) of COVID-19 Vaccines in Malaysia

(Data as of 31st December 2022)[1-3]

#6

Introduction

The COVID-19 vaccines have been proven to be highly effective in preventing severe illnesses and deaths from COVID-19 infection.[4] In an effort to stall the spread of the infection and end the pandemic, a mass vaccination roll-out was initiated on 24th February 2021 under the **National Immunisation Program for COVID-19 (PICK)** in Malaysia.

Similar to any medicines, vaccines may cause side-effects commonly known as adverse event following immunisation (AEFIs). An AEFI is defined as ***any untoward medical occurrence that follows the administration of a vaccine and may not necessarily be causally related to the vaccine itself.***[5]

It is inaccurate to assume that all AEFIs reported in this summary report are directly caused by the vaccine.

When millions of vaccines are administered in a short period of time, it is expected to see a surge in the number of adverse events being reported including serious ones. However, reviews of these individual reports (details about the process are described below) often reveal that vaccine does not play a role in the vast majority of these events.

The reported adverse events can also occur due to ***fear of injections or the immunisation process, previously undiagnosed illnesses, underlying diseases, or medications being taken concurrently by the vaccine recipients. These events may also happen coincidentally, shortly after a vaccine was administered.***

How does NPRA collect adverse event reports?

Similar to other regulatory agencies, NPRA monitors drugs and vaccines safety through passive surveillance. AEFI reports are collected via the existing **NPRA Adverse Drug Reaction (ADR)/AEFI Reporting System.**

In addition to the current reporting system, during PICK, **notifications of documented minor AEFIs** from the vaccine recipients are also collected through the **MySejahtera Application** in their smartphones.

Documented *AEFIs are* ***known*** *adverse events that already described in the product leaflet and are based on global safety data from clinical trials and/or post-marketing safety monitoring.*

NPRA receives all medicines adverse event reports including AEFIs from pharmaceutical companies, healthcare professionals in government and private health institutions as well as consumers in Malaysia.

NPRA has issued the Malaysian ADR/AEFI Reporting Manual for Healthcare Providers to guide reporters on how to report adverse events.[5] NPRA also continuously highlights the importance of ADR/AEFI reporting and how to report them through periodic communications, several trainings, and awareness campaigns.

How does NPRA process AEFI reports and monitor safety of COVID-19 vaccines?

As with any medicine and vaccine, NPRA closely monitors the safety of COVID-19 vaccines. Every adverse event report received at the national centre is carefully processed and assessed by trained pharmacists. When clinically important information is missing from a report, utmost efforts will be made to obtain additional information.

NPRA requires healthcare providers to report all suspected AEFIs including any death after COVID-19 vaccination, **even if it is unclear whether the vaccine was the cause**. AEFIs are initially categorised into **serious** and **non-serious**. **Serious** AEFIs include those that require hospitalisation, prolonged existing hospitalisation, are life-threatening, cause persistent or significant disability/incapacity, a congenital anomaly/birth defect, or suspected to cause death**. While these events may happen after vaccination, they are rarely caused by the vaccine.** Serious AEFIs are investigated thoroughly by the healthcare facility involved. The investigation report will then be reviewed by a committee of experts, the **COVID-19 Vaccines Pharmacovigilance Special Committee (JFK)** to determine if the events are causally linked to the vaccine.

All reports will be subsequently presented to the **Malaysian Adverse Drug Reactions Advisory Committee (MADRAC)** before they are submitted to the **World Health Organisation (WHO) global database**.

*Reports help to identity **signals** that **alert** scientists of possible cause-and-effect relationships that **need to be investigated.***

Reports recorded in the databases are constantly reviewed and monitored to identify unexpected adverse events or potential safety **signals** for further evaluation. In addition to monitoring local AEFI reports, NPRA also collaborates with Product Registration Holders to monitor and detect any emerging safety issues. NPRA also network with other regulatory agencies to keep abreast with new safety concerns raised globally. This allows rapid detection and assessment of all available safety information on the vaccines to ensure the overall benefit–risk profile of the vaccines remains positive. Any emerging risks of the vaccines will be communicated promptly to healthcare professionals and the public so that suitable actions can be taken accordingly.

Total Doses of COVID-19 Vaccines Administered[1-2]

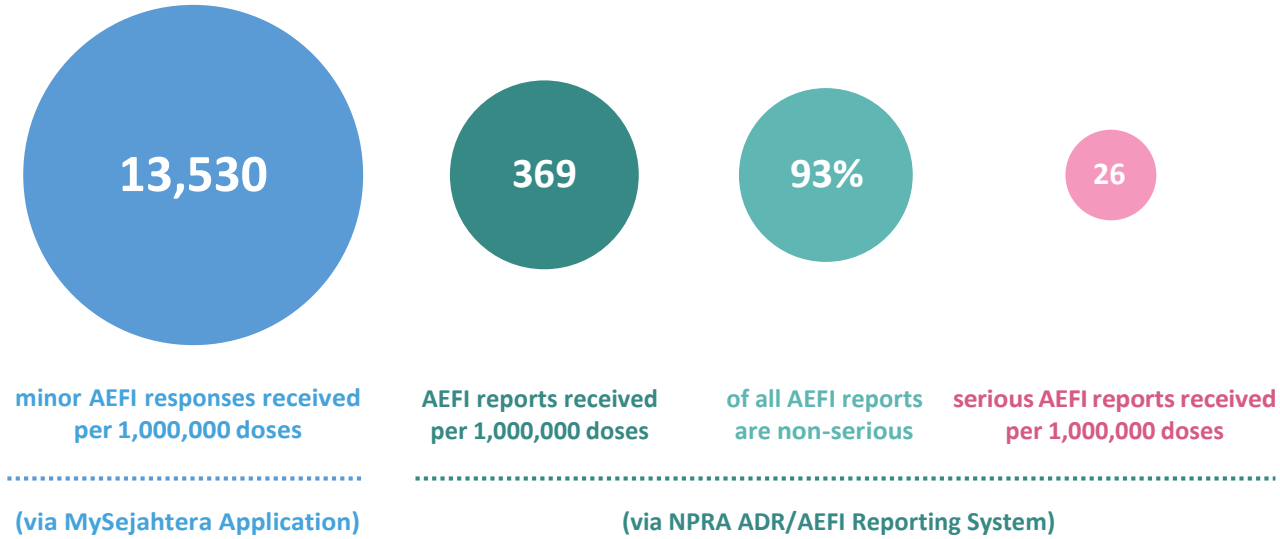
In Malaysia, there are currently eight (8) types of COVID-19 vaccines that have been conditionally registered with the Drug Control Authority (DCA). These vaccines have met NPRA's high standards for quality, safety and efficacy. They are Comirnaty (Pfizer), CoronaVac (Sinovac), Vaxzevria (AstraZeneca), Convidecia (Cansino), Covilo (Sinopharm), Spikevax (Moderna), Jcovden (Janssen), and Covaxin (Bharat).

To date, only Comirnaty, CoronaVac, Vaxzevria, Convidecia, and Covilo vaccines are being used in the National COVID-19 Immunisation Programme (PICK). As of 31st December 2022, a total of 72,326,604 COVID-19 vaccine doses have been administered.

Table 1: The number of COVID-19 vaccine doses administered by product (as of 31st December *2022)*

Comirnaty (Pfizer)	44,826,965 doses
CoronaVac (Sinovac)	21,531,578 doses
Vaxzevria (AstraZeneca)	5,697,765 doses
Convidecia (Cansino)	227,957 doses
Covilo (Sinopharm)	42,339 doses

Rate of Reported Adverse Events[2-3]



AEFI responses received via MySejahtera Application

From the start of the vaccine roll-out up to 31st December 2022, the total of minor and documented AEFIs recorded via the MySejahtera Application was 978,569 which is equivalent to 13,530 responses* for every 1,000,000 doses of vaccines administered.

The most common side effects notified were consistent with those typically observed following vaccination. These include injection site pain, headache, fatigue, muscle or joint pain, lethargy, and fever, which will usually recover in a few days with or without treatment. The reporting trend of these common side-effects were also consistent throughout the monitoring period.

> *Important note: *The total number of responses collected may not accurately represent the total number of individuals who experience an adverse event, as each individual may notify more than one response.*

AEFI reports received via the NPRA ADR/AEFI Reporting System

While through the existing NPRA ADR/AEFI Reporting System, the total of AEFI reports received was 26,676 which is equivalent to **369 reports per 1,000,000 doses** administered. The majority of reports received, at **93%, were non-serious**, short-term, and did not pose any potential risk to the health of the vaccine recipients.

Serious adverse events after COVID-19 vaccination occurred but very rarely. During this monitoring period, only 1,867 or 7% of the total AEFI reports received were categorised as **serious AEFIs.** Note that the **ACTUAL proportion of serious AEFIs could be much smaller**, when the relatively high number of minor AEFI responses received via the MySejahtera Application are taken into account. **The reporting rate of serious AEFIs was recorded at 0.0026% of total doses administered,** or **26 reports per 1,000,000 doses**.

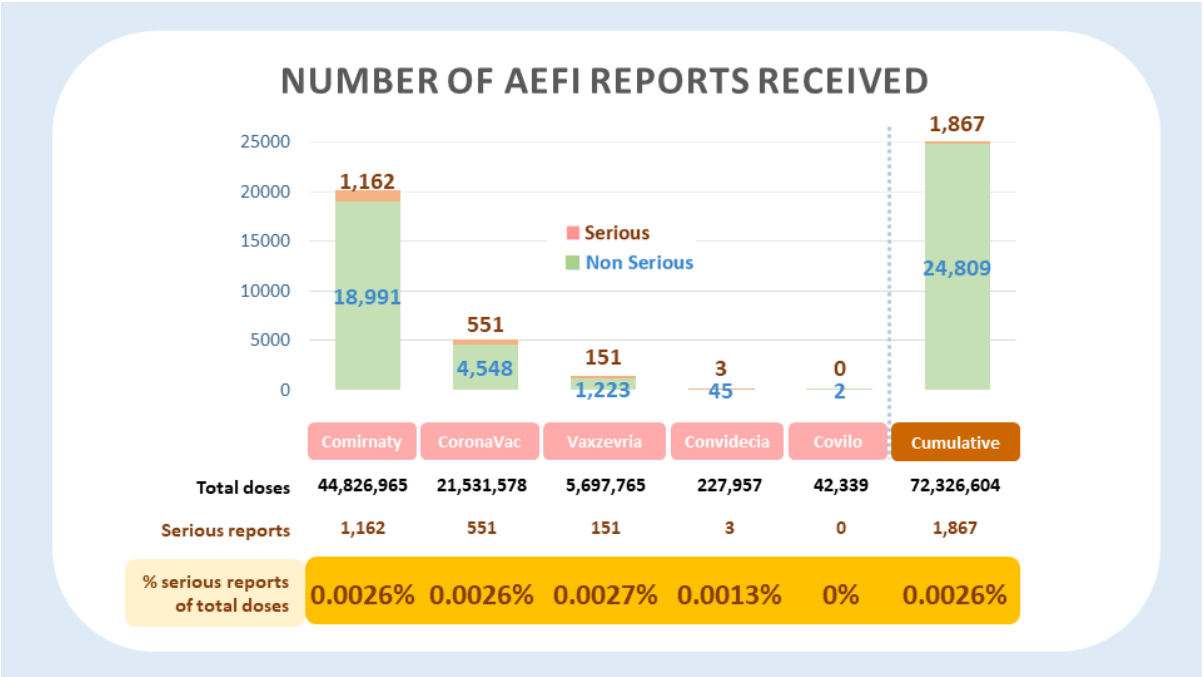


Figure 1: Number of AEFI reports received via NPRA ADR/AEFI Reporting System

It should be noted that the number of reports received for different COVID-19 vaccines are not directly comparable as the total number of doses used for each vaccine differs as they were rolled out at different times during the vaccination programme.

The **most frequently reported serious AEFIs** were shortness of breath, chest pain, palpitations and anaphylactic reaction. The majority of these serious cases require only **short-term hospitalisation for treatment or further observation and at the time of AEFI reporting, the affected recipients had mostly recovered or in the state of recovering from the reported event.**

It should be stressed that the causal links of the event to the vaccination in these reports have not been ascertained meaning that the vaccines do not necessarily cause the serious events, as explained in the Introduction Section.

Out of **1,867 serious AEFI reports received**, 612 were reports for death cases. As of 31st December 2022, the investigation reports received for 520 cases have been evaluated by the JFK expert committee, and concluded that three (3) cases were likely to be related to the vaccination: two (2) cases involving the Comirnaty vaccine and one (1) case involving the Vaxzevria vaccine.

Booster doses (PICK-B)

The Comirnaty, CoronaVac and Vaxzevria vaccines have been approved for use as boosters in adults under the PICK-Booster (PICK-B) which began on 13th October 2021 based on the results of clinical trials and observations in other countries where booster doses have been rolled out earlier. It was not expected that the type of side effects and the safety profiles would be different to the first and second vaccine doses.[6-12]

As of 31st December 2022, a total of 16,891,837 booster doses of the Comirnaty, CoronaVac and Vaxzevria vaccines had been administered. To date, NPRA had received 1,746 reports (103 reports per 1,000,000 doses administered) following the use of boosters, of which 170 of the reports (**10 reports per 1,000,000 doses administered, or 9.7% of total AEFI reports received**) were categorised as **serious**. This was **lower** than the AEFI reporting rate for COVID-19 vaccines for all vaccine doses combined.

The types of reactions experienced after a booster dose were also found to be similar to those experienced after primary doses, including in heterologous* vaccination. The most common side effects reported were fever, headache, acute stress reaction, injection site pain and muscle pain, dizziness, and shortness of breath.

Review of booster dose AEFI reports at this point of time does not raise any new safety concerns. NPRA will continue to closely monitor AEFI data following the use of boosters.

**Heterologous booster refers to the administration of a vaccine product that differs from the product(s) previously used for primary vaccine series (e.g., a vectored vaccine followed by an mRNA vaccine), once an initially sufficient immune response rate in a vaccinated population has waned over time.[13]*

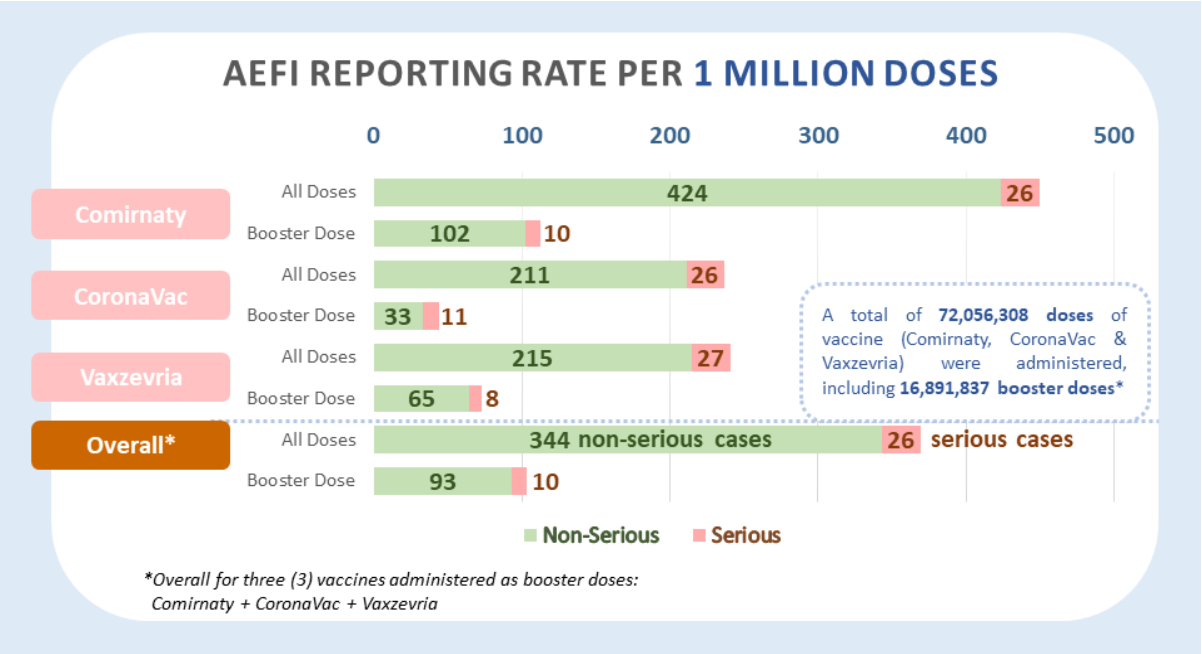


Figure 2: AEFI reporting rate per 1,000,000 doses (all doses versus booster doses)

COVID-19 vaccination in children aged 5 to 11 years

The National COVID-19 Immunisation Programme for children aged 5 to 11 years (PICKids) in Malaysia has been launched on the 3rd February 2022 following the conditional approval of Comirnaty 10 mcg Concentrate for Dispersion for Injection (Pfizer-BioNTech). This special COVID-19 vaccine formulation has a lower dose compared to those for aged 12 years and above (30 mcg). Subsequently, CoronaVac Injection Suspension COVID-19 Vaccine (Vero Cell), Inactivated, the second COVID-19 vaccine conditionally approved for children aged 5 to 11 years in Malaysia, has been made available to PICKids on 7th March 2022.

The NPRA is closely monitoring the AEFI reported in these 5 to 11-years-old children. As of 31st December 2022, a total of 3,312,886 doses of the Comirnaty and CoronaVac vaccines have been administered to children aged 5 to 11 years. There have been 523 AEFI reports received for this age group, equating to a rate of **158 reports per 1,000,000 doses administered**. The AEFI reporting rate for children aged 5 to 11 years is **lower than the overall AEFI reporting rate** thus far (369 for per 1,000,000 doses administered).

Of these, the **vast majority (94%)** were non-serious effects. The most frequently reported side effects for PICKids were fever, immunisation stress-related response (ISSR), skin itchiness or redness, dizziness, and headache. From the total of 523 AEFI reports received for children aged 5 to 11 years, there were 34 reports involving serious AEFIs such as exacerbations of asthma, acute facial paralyses (Bell's palsy), and seizures.

The AEFI reporting rate among vaccine recipients aged 5 to 11 years old in Malaysia (158 reports per 1,000,000 doses) was comparable to global scenario, for instances, in Canada (223 reports per 1,000,000 doses) and in Australia (722 reports per 1,000,000 doses). These countries also reported lower AEFI reporting rates among children aged 5 to 11 years compared to adult vaccine recipients.[8-

[9] Similarly, the most frequently reported adverse effects were mild side effects, such as pain, swelling, injection site itchiness or redness, headache and fatigue.

To date, no safety issues have been identified locally and globally following COVID-19 vaccine use in this age group.[7-9,14-16] NPRA will continue to monitor the safety of COVID-19 vaccines used in children aged 5 to 11 years, including for the CoronaVac vaccine.

Adverse Events of Special Interest

NPRA is also closely monitoring the occurrences and outcome of specific adverse events known as 'adverse events of special interest', including anaphylaxis, acute facial paralysis, myocarditis/pericarditis, and vaccine-induced immune thrombocytopenia and thrombosis (VITT). These events have mainly been reported in the vaccines clinical trials and post-marketing surveillance globally or observed previously with the use of other vaccines. [6-12]

Anaphylaxis is a well-known adverse reaction and the most commonly reported serious AEFI associated with vaccines in general. It usually occurs 15-30 minutes after vaccination. Acknowledging this risk, as part of the risk management plan, PICK requires all vaccine recipients to be observed for 15-30 minutes post vaccination at the vaccination centres. In rare instances should anaphylaxis reaction occurs, the affected recipient can be treated immediately and effectively.[17]

- During the monitoring period, NPRA had received a total of **108 reports** for anaphylaxis (Brighton level 1-3) with COVID-19 vaccines equivalent to 1.5 reports per million doses administered. Comirnaty, the mRNA vaccines recorded the highest number of cases at 72 reports or 1.6 per million doses administered. This locally observed rate of anaphylaxis was similar to those reported overseas.[6-10] All anaphylaxis cases were treated accordingly and had recovered or were recovering at the time of reporting.

Acute facial paralysis, also known as Bell's palsy, is a condition that causes temporary weakness on one side of the face. It typically develops gradually and most people recover within a few months. Acute facial paralysis can strike at any age and has been linked to a number of infectious diseases, including the SARS-CoV-2 virus.[6,18] Acute facial paralyses had been reported in clinical trials of mRNA vaccines, including Comirnaty vaccine. Recent findings also showed an overall increased risk of Bell's palsy after immunisation with CoronaVac, the inactivated virus vaccine.[19]

- NPRA had received a total of **157 reports** of acute facial paralysis associated with COVID-19 vaccines during the monitoring period, equating to 2.2 reports per million doses administered. Comirnaty vaccine was associated with 90 reports or 2 per million doses administered, CoronaVac vaccine with 47 reports or 2.2 per million doses administered, and Vaxzevria vaccine with 20 reports or 3.5 per million doses administered. All acute facial paralysis cases had recovered or were recovering at the time of reporting.

Myocarditis/Pericarditis is a known but very rare side effect of mRNA vaccines e.g., Comirnaty, especially in male adolescents and young adults.[6-9,20] Symptoms typically include palpitation, chest pain, arrhythmia and dyspnoea. It is usually mild and temporary, with most people getting better within a few days with minimal treatment.[21]

- As of 31st December 2022, NPRA had received **72 reports** which have been assessed as likely

to be myocarditis/pericarditis following about 44.8 million doses of the Comirnaty vaccine. This is equivalent to 1.6 reported myocarditis/pericarditis cases per million doses of Comirnaty vaccine. Among Comirnaty vaccine recipients, myocarditis/pericarditis was found to be more common in adolescents aged 12 to 17 years (0.9 report per million doses), compared to adults aged 18 years and above (0.8 report per million doses). There had also been **one (1) report** of likely myocarditis/pericarditis following about 5.7 million doses of the Vaxzevria vaccine, equating to 0.2 per million doses. Most of the cases were mild in nature and the vaccine recipients responded well to the treatment and had recovered or were recovering at the time of reporting. Only one (1) case recorded a fatal outcome for which relatedness to myocarditis following vaccination cannot be excluded.

Vaccine-induced immune thrombocytopenia and thrombosis (VITT), which may also be called thrombotic thrombocytopenia syndrome (TTS) following COVID-19 vaccination, is another known but very rare serious side effect of adenoviral vector COVID-19 vaccines such as Vaxzevria vaccine. The exact mechanism of how VITT is triggered is still under investigation, however the majority of cases are associated with the finding of thrombosis (frequently in uncommon locations, such as cerebral venous sinus or splanchnic veins), low platelet count, markedly elevated D-dimer, and positive anti-platelet factor 4 (anti-PF4) antibodies.[22] Individuals with VITT generally present symptoms between 4 and 42 days (most commonly 4-30 days) after vaccination with an adenoviral vector vaccine, which include persistent headaches which do not respond to common pain killers, blurred vision, difficulty with speech, seizures, and bleeding or bruising.

- Up to 31st December 2022, **five (5) cases** of VITT were reported following about 5.7 million doses of Vaxzevria vaccine and **one (1) case** following about 44.8 million doses of Comirnaty vaccine. Of these, two (2) cases recorded fatal outcomes which were likely to be related to VITT following vaccination, while the other four (4) cases had recovered or were recovering with treatment at the time of reporting.

Summary

Similar to global scenario[6-12], **the vast majority (93%)** of the reported AEFIs in Malaysia were **non-serious**. The most common reactions were injection site pain, headache, fatigue, muscle or joint pain, lethargy and fever.

The rate of **serious** AEFIs reported via the NPRA ADR/AEFI Reporting System was **small at 26 reports per 1,000,000 doses**, most requiring **short-term hospitalisation for observation and treatment**. However, following detailed investigations and evaluations, the vast majority of these events were not directly caused by the vaccines given.

The **benefit-to-risk-ratio** of COVID-19 vaccines registered in Malaysia **remains very favourable**.

NPRA is continuously monitoring the safety of COVID-19 vaccines in the Malaysian population. We encourage all healthcare professionals and vaccine recipients to report any suspected AEFIs. This provides valuable data that helps us to identify new risks and appropriate safety measures and regulatory actions can be taken to mitigate the risks.

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How to report adverse events?

For more information, visit www.npra.gov.my

By reporting suspected adverse events to the NPRA, you help us learn more about the benefits and risks of vaccines – so we can all make better informed decisions.

Always report – so we can learn more about that vaccine and improve how it is used.

For healthcare professionals:

Report adverse events to the NPRA (as healthcare professional) through

- Pharmacy hospital information system (PhIS), OR
- Online web form, OR
- Submission of manual form via mail/email

For consumers:

Inform your healthcare providers at your health facility to make a report on your behalf.

Alternatively, report adverse events to the NPRA (as consumer) through

- Online web form (ConSERF), OR
- Submission of manual form (ConSERF) via mail/email

You are encouraged to first discuss with your healthcare providers regarding the adverse events before reporting directly to NPRA.