National Pharmaceutical Regulatory Agency
Ministry of Health, Malaysia

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

(Data as of 29th October 2021)[1,2,3]

Introduction

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.***[4]

Hence, it is inaccurate to assume that all AEFIs reported in the summary report are directly caused by the vaccine.

In addition to side effects that may directly be caused by the vaccine or its quality, the reported adverse events can also occur due to ***fear of injections, previously undiagnosed illness, underlying diseases, or medications being taken concurrently by the vaccine recipients. These events may also be coincidental that happen to occur shortly after a vaccine was administered.***

How NPRA collects adverse event reports?

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

In addition to the current reporting system, during the National Immunisation Program of COVID-19 vaccines (PICK), **notifications of documented minor AEFIs** are also collected from the vaccine recipients through the **MySejahtera Application** in their smartphones.

*Documented AEFI 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.[4] NPRA also continuously highlights the importance of ADR/AEFI reporting through periodic communications, several trainings, and awareness campaigns.

How NPRA processes AEFI reports and monitors 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 detailed information where available.

AEFIs are initially categorised into **serious** and **non-serious**. **Serious** AEFIs include those that require hospitalisation, prolong hospitalisation, are life-threatening or suspected to cause death. **While these events can happen after vaccination, they are rarely caused by the vaccine**. Any suspected deaths after COVID-19 vaccines were also captured by the NPRA and included in the serious AEFI category. NPRA requires healthcare providers to report any death after COVID-19 vaccination, **even if it's unclear whether the vaccine was the cause**. **Serious** AEFIs are investigated thoroughly by the healthcare facility involved. The investigation report will then be evaluated by the committee of experts, the **Pharmacovigilance Committee of COVID-19 Vaccines (JFK)**, that will determine if the event and the vaccine are causally linked.

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

All reports recorded in the databases are constantly reviewed and monitored for the possible identification of unexpected adverse reactions also known as **signal.** Reports of suspected AEFIs are used alongside other types of safety information to learn more about the vaccines to ensure the overall benefit–risk profile remains positive.

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

NPRA is also working in collaboration with partners in the health system and internationally to rapidly assess all available safety data and communicate any emerging safety issues as needed.

Total Doses of Covid-19 Vaccine Administered[1,2]

The vaccines roll-out under the National Immunisation Program for COVID-19 (PICK) in Malaysia has started in late February 2021.

As of 29th October 2021, a total of **49,779,070 COVID-19 vaccine doses** have been administered (*Figure 1*).

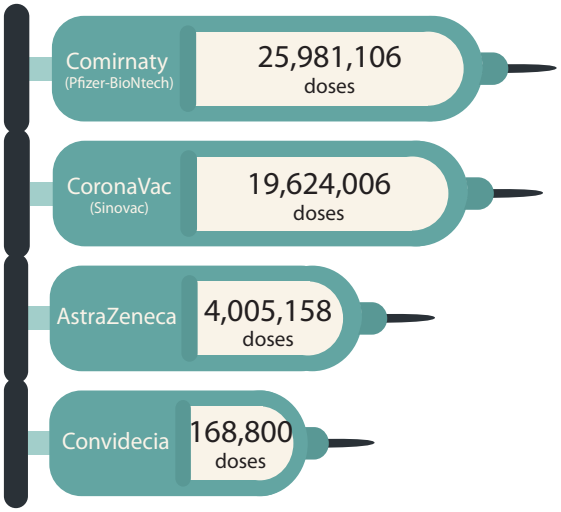

Figure 1: Total COVID-19 vaccine doses administered by brand

Rate of Reported Adverse Events[3]

AEFI responses received via MySejahtera Application

From the start of the vaccine roll-out up up to 29th October 2021, the rate of minor AEFIs recorded via the MySejahtera Application is **19.5 responses* for every 1,000 doses** of vaccines administered.

The most common side effects notified were injection site pain, headache, fatigue, muscle pain and fever, which will usually recover in a few days without treatment.

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

Minor AEFI responses per 1,000 doses

AEFI reports received via NPRA Reporting System

While through the existing NPRA Reporting System, the overall rate of AEFI reports received is **0.45 reports per 1,000 doses** administered, of which the majority of reports, at **93.3% of total doses, or 0.42 reports per 1,000 dose,** are **non-serious**, short-term, and do not pose a potential risk to the health of the recipient.

Only 0.03 per 1,000 doses were categorised as **serious AEFIs**. The **ACTUAL reporting rate of serious AEFIs is much lower**, as the relatively higher number of minor AEFI responses received via the Mysejahtera Application should be accounted for in the background.[3]

The majority of these serious cases require only **short-term hospitalisation for treatment and observation.** Anaphylaxis, one of the more commonly reported AEFI in serious cases, for example usually occurs 15 minutes after vaccination. As all vaccine recipients are required to be observed for 15-30 minutes as part of risk management[5], any anaphylaxis reaction can be treated immediately and effectively.

However, it should be noted that the causal link of the event to the vaccination in these reports has not been ascertained meaning ***the vaccine does not necessarily caused the fatal outcome***, as explained in the Introduction section.

To date, **none of the fatal outcome reported among the vaccine recipents could be directly linked to the vaccination.**

Overall AEFI reports per 1,000 doses

AEFI reports are non-serious

Serious AEFI reports per 1,000 doses

Summary

Similar to global scenario[6], **the vast majority** of the reported AEFIs in Malaysia are **non-serious.**[3] The most common reactions included injection site pain, headache, fatigue, muscle pain, fever, chills, and acute stress reactions (e.g. anxiety and tremor).

The rate of **serious** AEFIs reported via the NPRA Reporting System is **small** at **0.03 per 1,000 doses,** most requiring **short-term hospitalisation for observation and treatment.**[3]

Based on the current situation, the **benefit-to-risk-ratio** of COVID-19 vaccines registered in Malaysia **remains very favourable** i.e. **the benefits clearly outweigh the risks.**

The NPRA is continuously monitoring the safety of COVID-19 vaccines in the Malaysian population. The NPRA encourages all healthcare professionals and patients to report any suspected AEFIs so that possible new risks can be identified, and appropriate safety measures and regulatory actions can be taken to mitigate the risk, if deemed necessary.

References

1. Ministry of Health, Malaysia. COVIDNOW in Malaysia [Internet]. [cited 2021 Oct 29]. Available from: https://covidnow.moh.gov.my/vaccinations/
2. Ministry of Health, Malaysia. covid19-public [Internet]. Github. 2021 [cited 2021 Oct 29]. Available from: https://github.com/MoH-Malaysia/covid19-public/tree/main/epidemic
3. National Pharmaceutical Regulatory Agency (NPRA). The Malaysian National ADR database [Internet]. [cited 2021 Oct 29]. Available from: https://www.npra.gov.my (access restricted).
4. National Pharmaceutical Regulatory Agency (NPRA). The Malaysian Adverse Drug Reaction (ADR)/Adverse Event Following Immunisation (AEFI) Reporting Manual for Healthcare Providers [Internet]. 2021 [cited 2021 Oct 29]. Available from: https://www.npra.gov.my/easyarticles/images/users/1047/Adverse-Drug-Reaction-ADR--Adverse-Event-Following-Immunisation-AEFI-Reporting-Manual-For-Healthcare-Providers.pdf
5. Ministry of Health, Malaysia. ANNEX 48: Clinical Guidelines on COVID-19 Vaccination in Malaysia. 3rd ed. [Internet]. 2021 [cited 2021 Oct 29]. Available from: https://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm/ANNEX_48_CLINICAL_GUIDELINES_FOR_COVID_IN_MALAYSIA_3rd_EDITION_12072021.pdf
6. Uppsala Monitoring Centre (UMC). COVID-19 vaccine reporting in VigiBase. Report 9, data extraction date: 2021-09-26.

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/fax/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 via mail/fax/email

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