HSA's COVID-19 Vaccine Safety Update #13
(30 December 2020 – 31 August 2022)

This is HSA's 13th safety update of the COVID-19 vaccines covering the period from the roll-out of the vaccines on 30 December 2020 to 31 August 2022. It provides an overview of the reports by healthcare professionals of ***suspected adverse events***[1] ***(AEs)*** associated with COVID-19 vaccines to the Health Sciences Authority (HSA) and our current assessment of these AEs.

2 The COVID-19 vaccines* used in Singapore are:

- mRNA vaccines: Pfizer-BioNTech/Comirnaty, Moderna/Spikevax
- Protein subunit vaccine: Nuvaxovid
- Inactivated vaccines: Sinovac-CoronaVac, Sinopharm

3 As of 31 August 2022, a total of 15,802,991 doses of COVID-19 vaccines have been administered. The majority of the doses administered were the mRNA vaccines (95.9%; 15,149,498 doses) as these were the first vaccines that were made available and recommended for use in Singapore. This was followed by the inactivated COVID-19 vaccines (4.0%; 635,420 doses) and Nuvaxovid vaccine (0.1%; 18,073 doses).

4 Vaccination has been demonstrated to be the most effective way to reduce deaths and severe illness from COVID-19 infection and has enabled Singapore to ease most of the safe management measures. **The benefits of the Pfizer-BioNTech/Comirnaty, Moderna/Spikevax, Nuvaxovid and Sinovac-CoronaVac COVID-19 vaccines continue to outweigh the known risks.**

** Pfizer-BioNTech/Comirnaty is registered as a therapeutic product by HSA. Moderna/Spikevax, Nuvaxovid and Sinovac-CoronaVac are authorised under the Pandemic Special Access Route whereas Sinopharm is supplied via HSA's Special Access Route.*

Key updates (as of 31 August 2022)

i) mRNA COVID-19 Vaccines

- A total of 10,289,262 primary doses, 4,420,853 first booster doses and 439,383 second booster doses of the mRNA vaccines have been administered. **The reporting rates of AEs and serious AEs[2] for the mRNA vaccines remained rare. The serious AE reporting rates for the first and second booster doses were at 0.004% (162 reports) and 0.0005% (2 reports), respectively, which were lower compared to the primary doses at 0.009% (916 reports).**

- There were no new safety findings since the previous update published in June 2022 (please refer to the previous HSA's COVID-19 Vaccine Safety Update for details).

[1] An adverse event is any untoward medical occurrence in a patient administered a pharmaceutical product (including vaccines) but does not necessarily have a causal relationship with this treatment/vaccination.

[2] An adverse event is classified as serious when the event resulted in hospitalisation/extended stay in hospital, resulted in a significant reduction in functioning level/disability, resulted in a life-threatening illness (e.g. anaphylaxis) or death, resulted in birth defects or is a medically important event.

Table 1. Overview of vaccination data and no. of suspected AE reports by healthcare professionals for mRNA COVID-19 vaccines

	Pfizer-BioNTech/Comirnaty	Moderna/Spikevax	Total
No. of persons who have received the first dose	4,126,802	1,114,492	**5,241,294**
No. of persons who received two doses*	4,062,588	985,380	**5,047,968**
No. of persons who received booster dose 1	3,195,141	1,225,712	**4,420,853**
No of persons who received booster dose 2	373,385	65,998	**439,383**
Total no. of doses administered	11,757,916	3,391,582	**15,149,498**
No. of suspected AE reports	14,393 (0.12% of doses administered)	3,106 (0.09% of doses administered)	**17,499 (0.12% of doses administered)**
No. of suspected serious[2] AE reports	879 (0.007% of doses administered)	196 (0.006% of doses administered)	**1,075 (0.007% of doses administered)**

*The primary vaccination regimen for Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines comprise 2 doses. The number of persons who received two doses included those who had received the first dose.

ii) Nuvaxovid COVID-19 Vaccine

- The vaccination programme for Nuvaxovid COVID-19 vaccine was rolled out on 18 May 2022, with 18,073 doses being administered as of 31 August 2022.

- Locally, 28 AE reports were received of which 82% (23 reports) were non-serious ones which included allergic reactions such as rash and eyelid swelling, numbness, vasculitis (inflammation of blood vessels), dizziness and chest pain. These were largely consistent with what were reported in the clinical studies or with other COVID-19 vaccines. There were 5 serious AE reports (0.03% of administered doses) which included 4 cases of anaphylaxis and 1 case of serious allergic reaction. These occurred in susceptible individuals who had previous allergic reactions or adverse effects to Pfizer/Comirnaty and Sinovac-CoronaVac COVID-19 vaccines, as well as a history of drug or food allergies. All the patients have recovered from the serious adverse reactions.

- Anaphylaxis is a rare and potentially life-threatening allergic reaction that can occur following vaccination in certain susceptible individuals. As with the mRNA vaccines, safeguards such as pre-vaccination screening, post-vaccination observation period and ensuring that all vaccination centres are medically equipped and staffed by qualified medical professionals are in-place to mitigate this risk.

- HSA is also monitoring myocarditis and pericarditis AEs closely. To date, no local AE reports of myocarditis or pericarditis have been received with the Nuvaxovid COVID-19 vaccine. A small number of reports of myocarditis and pericarditis following vaccination have been reported overseas where exposure to Nuvaxovid COVID-19 vaccine is higher.

As a precautionary measure, persons who are vaccinated with the Nuvaxovid COVID-19 vaccine should avoid strenuous physical activity or exercise for two weeks after vaccination to mitigate the potential risk of myocarditis. It is important to note that COVID-19 infection is known to be associated with myocarditis. Based on published literature, 40 extra myocarditis events per million persons were observed following COVID-19 infection.[3]

iii) Sinovac-CoronaVac and Sinopharm COVID-19 Vaccines

- A total of 635,420 doses of the inactivated vaccines have been administered as of 31 August 2022. The serious AE reporting rate remained rare at 0.006% (39 reports).

- As with the case of mRNA vaccines, there were no new safety findings for the inactivated vaccines since the last update published in June 2022 (please refer to the previous HSA's COVID-19 Vaccine Safety Update for details).

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Interpretation of the data

HSA reviews the submitted AE reports, in consultation with our expert panels.[4] AEs are reported by healthcare professionals to HSA when they suspect that the AEs may be associated with the vaccine. This does not necessarily mean that the vaccine has caused the AEs. In some instances, these AEs are related to an underlying or undiagnosed disease or the natural progression of an underlying disease. It may be coincidental that the event occurred around the same time when the vaccine was given but is not caused by the vaccine. The causality based on isolated cases of individual events usually cannot be established as many illnesses cause the same symptoms and signs, and there are generally no confirmatory tests for diagnosing an AE. Hence, AEs are assessed and interpreted in the context of background incidence rates of such occurrences (i.e., historical rates in our general population unexposed to the COVID-19 vaccines). While each individual report is carefully reviewed, the totality of data from all sources (e.g., mechanistic actions, clinical assessments of local AE reports from healthcare professionals, public self-reported AEs, epidemiological studies, literature and overseas reports) has to be considered before drawing any evidence-based conclusions on the safety of the vaccine.

The type and number of reports received for the different COVID-19 vaccines are not directly comparable as the vaccines may have been used in the vaccination programme for different lengths of time, and may have been administered to different numbers of people with different underlying medical conditions and across different settings. Similarly, the AE numbers or rates between countries should not be directly compared as the usage of the vaccines may be different and the AE reporting systems are often also different.

The description of suspected AEs in this update reflects the available information known at the time by HSA. These data may undergo changes as more information on individual reports becomes available through follow-up, and as more data are reported and evaluated.

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[3] Patone, M., Mei, X.W., Handunnetthi, L. et al. Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. Nat Med (2021)

[4] HSA has appointed seven Expert Panels to review neurological AEs, cardiac AEs, thromboembolic and haematological AEs, renal AEs, ear AEs, immunological AEs and severe hypersensitivity reactions such as anaphylaxis