Medicines Adverse Reactions Committee

Meeting date	8/06/2023	Agenda item	3.2.4
Title	**Pericarditis following mpox vaccination**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For information
Active ingredient Modified vaccinia Ankara-Barvarian Nordic live virus	**Product name** [redacted]	**Sponsor**	
Funding	Mpox vaccine is funded by Te Whatu Ora/Ministry of Health		
Previous MARC meetings	193rd MARC meeting • Matters arising from the New Zealand Pharmacovigilance Centre		
Regulatory action	Medsafe monitoring communication: Reports of pericarditis following mpox vaccination		
Classification	Prescription medicine (Section 29)		
Usage data (up to 1 May 2023)	Vaccines administered dose 1: 2,346 Vaccines administered dose 2: 101 Vaccines administered: 2,447		

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1 PURPOSE

Medsafe were alerted to two suspected adverse drug reaction (ADR) reports of pericarditis following vaccination against monkeypox (mpox). In March 2023, Medsafe published a monitoring communication to encourage reporting of any ADRs following mpox vaccination.

The purpose of this paper is to provide the MARC with an update on the signal investigation.

2 BACKGROUND

2.1 Mpox disease and vaccines

2.1.1 Mpox disease

Mpox is an infectious disease caused by the monkeypox virus, it is an enveloped double-stranded DNA virus of the *Orthopoxvirus* genus in the *Poxviridae* family. There are two genetic clades of the mpox virus that have been characterised: Central African (clade I) and West African (clade II) [1].

A global mpox outbreak commenced in May 2022 with 110 countries reporting approximately 87,000 cases and 112 deaths. The global outbreak has primarily affected gay, bisexual, and other men who have sex with men [2].

Mpox can be transmitted via physical contact with someone who is infectious (via infected skin lesions), contaminated materials, or with infected animals. Common symptoms of mpox infection include skin rash or mucosal lesions accompanied by fever, headache, muscle aches, back pain, low energy, and swollen lymph nodes. Symptoms typically begin within a week of exposure, but this can range from 1-21 days [1].

Mpox infection is usually self-limiting with symptoms resolving after 2-4 weeks. However, some people will develop complications that include bacterial skin infections, pneumonia, corneal infections, dehydration (from vomiting and diarrhoea), sepsis, and inflammation of different body parts (encephalitis, myocarditis, proctitis, balanitis, urethritis) [2].

Since 12 January 2023 there have been 41 confirmed cases of mpox in New Zealand. Ten cases acquired the infection overseas and 31 were identified as community transmission. The general risk of exposure to mpox in New Zealand is very low [3].

2.1.2 Mpox vaccines

There are two orthopoxvirus vaccines used to prevent mpox: a replication-deficient modified vaccinia Ankara (MVA) vaccine [redacted] and a replication-competent vaccinia virus vaccine (ACAM2000). The vaccinia virus is a large, double stranded DNA virus that is in the same family of the variola virus (the causative agent of smallpox). Immunisation with a vaccine derived from vaccinia virus provides protection against smallpox, mpox, and other diseases caused by members of the orthopoxvirus family [4].

Comments:
ACAM2000 is a replication-competent vaccinia virus vaccine indicated for the prevention of smallpox. During the mpox outbreak several countries, including Australia and the United States, have made ACAM200 available for mpox prevention. It is not being used in New Zealand for this indication.

2.1.2.1 [redacted] MVA vaccine

The vaccine being used in New Zealand is [redacted] it is a highly attenuated, non-replicating MVA strain vaccine. [redacted]

[redacted] vaccine, where approved, is indicated for active immunisation against smallpox, mpox, and diseases caused by vaccina virus in adults aged 18-years and older. It is given as two doses (0.5mL per dose) no less than 28 days apart via subcutaneous injection [5].

The Centers for Disease Control and Prevention (CDC) allowed for an alternative regimen to be used under an Emergency Use Authorisation issued 9 August 2022. This regimen involves an intradermal route of administration with an injection volume of 0.1mL. The decision arose from a clinical trial that found a lower intradermal dose of MVA vaccine to be immunologically non-inferior to the standard subcutaneous dose and route of administration [6, 7].

[redacted] is not an approved vaccine in NZ but available under section 29 of the Medicines Act 1981. Patients must undergo a consultation and informed consent process with a medical practitioner prior to vaccination, it is given as two doses via subcutaneous injection [8].

2.2 Pericarditis

Pericarditis refers to inflammation of the pericardial sac around the heart. There are several sub-types of pericarditis including viral, bacterial, parasitic, fungal, uremic, malignant, and traumatic- pericarditis. Clinical features of pericarditis include [9]:

- Chest pain- typically sharp and pleuritis, improved by sitting up and leaning forward
- Pericardial friction rub
- Electrocardiogram (ECG) changes- new widespread ST elevation and PR depression
- Pericardial effusion

Most cases of acute pericarditis are considered to be a result of viral infections. Viral pericarditis can occur via direct infection of the pericardium (observed with adenoviruses and coxsackievirus infections) or via secondary immune-mediated inflammation of the pericardium [10].

Other causes for pericarditis include injury to the chest, recent cardiac injury (following a heart attack or heart surgery), manifestation of other chronic health conditions including inflammatory autoimmune disorders [9]. Pericarditis is treatable and most people do not require hospitalisation. Goals of therapy include relief of pain and inflammation and prevention of occurrence [11].

Comments:
Rare cases of myo-/pericarditis following vaccination have been reported with ACAM2000 (replication-competent vaccinia virus) vaccine and following mpox infection.

2.2.1 Mpox disease and pericarditis

Several case reports have been published that suggest a rare association between mpox infection and onset of myo-/pericarditis. These cases have been summarised in Table 1. All cases presented with typical signs suggestive of myo-/pericarditis and were reported to have recovered shortly after, there were no fatal outcomes reported.

The exact mechanism of infection-induced acute myo-/pericarditis is unknown but suspected to be related to immune-mediated inflammation [10].

Table 1: Summary of case reports for myo-/pericarditis following mpox infection

Author, date, title	Case details
Dumont et al, 2022. Myocarditis in monkeypox-infected patients: a case series [12].	There were three cases of myocarditis attributable to mpox infection in France 2022. Patient 1: a 21-year-old male developed fever and anal pain and mpox diagnosis was confirmed by PCR. Two days later he presented with acute chest pain radiating to the arms and jaw. Testing revealed ECG ST segment elevation, troponin T levels of 4040pg/mL, creatine kinase (CK) 418U/L and C-reactive protein (CRP) 27mg/L. Transthoracic echocardiography (TTE) showed a nondilated, nonhypertrophied left ventricle. Cardioprotective treatment was initiated and there was no recurrence of pain. Laboratory values were normalised. No other causes of myocarditis were found. Patient 2: a 25-year-old male with no medical history reported skin pustules a few days following unprotected sexual intercourse. Five days later he reported constant chest pain and palpitations. ECG showed a discrete ST segment elevation and under-shift of the PQ segment. Blood work noted elevated troponin T 700pg/mL, CK 318U/L and CRP 39mg/L. TTE noted impaired left ventricular ejection fraction (45%) and inferolateral akinesia. Symptoms resolved following cardioprotective treatment., No other infection or cause of myocarditis was found after medical examination and biological assessment. Patient 3: a 32-year-old male developed erosive cutaneous lesions one week after unprotected sexual intercourse. Three days later he presented with retrosternal chest pain and fever. Blood tests noted troponin T levels of 2035pg/mL, CK 2295U/L and CRP 115mg/L. His ECG and TTE were normal. Cardioprotective treatment and tecovirimat were initiated, no other causes of myocarditis were found. Authors considered that all three cases of myocarditis were attributable to mpox infection. The outcome was rapidly favourable in all patients after cardioprotective treatment, regardless of the use of antiviral treatment.
Brouillard et al, 2022. Monkeypox associated myocarditis [13].	Authors describe a case where a 34-year-old male presented to ED with chest pain (constant, sharp, pleuritic, non-radiating). ECG testing noted sinus tachycardia with antero-lateral concave ST elevation compatible with pericarditis. Blood tests revealed elevated CRP 154.5mg/L, white blood cell count 13.9*109/L and troponin 211ng/L. The patient was diagnosed with myopericarditis of unknown eitology and a concurrent chlamydia infection. He was treated for mpox and chlamydia and was reported to have recovered. The authors outline a case report of a possible association between mpox infection and myopericarditis.

Rodriguez-Nava et al, 2022. Myocarditis attributable to monkeypox virus infection in 2 patients [14].	Patient 1: 32-year-old male (with no history of mpox vaccination) sough hospital care for his diagnosis of mpox. Whilst hospitalised the patient complained of chest pain and dyspnoea. He had elevated troponin and B-type natriuretic peptide of at 165ng/L and 1,258pg/mL respectively. Other tests were unremarkable, and the patient was admitted for suspected myocarditis. He received no specific treatment for myocarditis and had rapid resolution of symptoms and normalisation of troponin levels. Patient 2: a 37-year-old male was evaluated in hospital for rash, fever, dyspnoea and decreased exercise tolerance. He had a history of treated syphilis and was taking HIV preexposure prophylaxis. Laboratory findings noted an elevated serum troponin I of 0.35ng/mL and B-type natriuretic peptide was 49pg/mL. ECG demonstrated normal sinus rhythm with T wave inversion in the inferior and anterolateral leads. The patient remained hospitalized for 4 days. Dyspnoea improved on day 3 to be resolved by day 4 and cardiac enzymes normalized. The patient received supportive care without directed therapy for mpox or myocarditis. Mpox-associated myocarditis was considered the most likely eitology for both patients. However, given the temporal relationship, authors could not completely confirm the diagnosis with histopathologic tests or exclude other potential causes. The pathophysiology of orthopox-induced myocarditis remains unknown.
Shaik et al, 2022. Monkeypox associated pericarditis [15].	A 51-year-old male with a one-week history of mpox infection presented to hospital with retrosternal chest pain radiating to the left arm. His laboratory results showed elevated CRP and Erythrocyte sedimentation rate of 65.5mg/L and 34mm/hr respectively and ECG noted widespread ST-elevation. Other causes of pericarditis were ruled out and mpox-associated pericarditis was determined to be the most likely cause. The authors state that cardiac involvement could be one of the more unusual symptoms of mpox infection. This case report highlights the emergence of mpox infection as a primary cause of viral pericarditis with mild pericardial effusion.
El-Qushayri et al 2023. Cardiovascular manifestations of monkeypox virus outbreak: an overview of reported cases [16].	Authors conducted a literature search aiming to identify relevant papers on the cardiovascular manifestations of mpox infections. They identified 6 case reports of myocarditis, one report of pericarditis, one report of myopericarditis, and one report of atrial fibrillation. Only 6 case reports contained complete data for assessment., Of those involved patients, 5 had abnormal ECG results and troponin levels, and 3 had abnormal echocardiogram and cardiac MRI results. No deaths were reported and all patients in the review recovered from their cardiovascular manifestations. The authors concluded that the way mpox infection affects the cardiovascular system is unknown and given cardiac manifestations have been reported this remains an area for further investigation.

2.2.2 Mpox vaccines and pericarditis

2.2.2.1 Replication-competent vaccinia virus vaccines

Cohort studies have identified cases of myo-/pericarditis following vaccination with replicating smallpox vaccines (ACAM2000, Dryvax), these are summarised below. As a result, the data sheet/prescribing information for ACAM2000 vaccine was updated to include myo-/pericarditis as an ADR [4, 17].
The authors of the studies note that the clinical presentation of the events were similar to that seen with other aetiologies however, the intensity of symptoms usually less. Fatalities are generally rare, and histopathologic examination of fatal cases did not find evidence of viral invasion of the myocardium or pericardium [18].

Engler et al, 2015. A prospective study of the incidence of myocarditis/pericarditis and new onset cardiac symptoms following smallpox and influenza vaccination [19]
Purpose: To determine the prospective incidence of new onset cardiac symptoms, clinical and possible subclinical myocarditis/pericarditis in temporal association with immunization.

Methods: New onset cardiac symptoms, clinical myo-/pericarditis symptoms and cardiac specific troponin T (cTnT) elevations following smallpox vaccination (above individual baseline values) were measured in a multi-center prospective, active surveillance cohort study of healthy subjects receiving either smallpox vaccine or trivalent influenza vaccine (TIV).

Results: New onset chest pain, dyspnoea, and/or palpitations occurred in 10.6% of smallpox vaccinees and 2.6% of TIV-vaccinees within 30 days of immunization (relative risk (RR) 4.0, 95% CI: 1.7-9.3). Among the 1081 smallpox vaccinees with complete follow-up, 4 Caucasian males were diagnosed with probable myocarditis and 1 female with suspected pericarditis. This indicates a post smallpox vaccination incidence rate more than 200-times higher than the pre-smallpox vaccination background population surveillance rate of myocarditis/pericarditis (RR 214, 95% CI 65-558).

Halsell et al, 2003. Myopericarditis following smallpox vaccination among vaccina-naïve US military personnel [20]
Purpose: To describe a series of probable cases of myopericarditis following smallpox vaccination among US military service members reported since the reintroduction of vaccina virus.

Method: Surveillance case definitions are presented. The cases were identified either through sentinel reporting to US military headquarters surveillance using the Defense Medical Surveillance System or reports to the Vaccine Adverse Event Reporting System using *International Classification of Diseases, Ninth Revision*.
Outcomes measured: elevated serum levels of creatine kinase (MB isoenzyme), troponin I, and troponin T, usually in the presence of ST-segment elevation on electrocardiogram and wall motion abnormalities on echocardiogram.

Results: Among 230 734 primary vaccinees, 18 cases of probable myopericarditis after smallpox vaccination were reported (an incidence of 7.8 per 100 000 over 30 days). No cases of myopericarditis following smallpox vaccination were reported among 95 622 vaccinees who were previously vaccinated. Among US military personnel vaccinated against smallpox, myopericarditis occurred at a rate of 1 per 12 819 primary vaccinees. Myo/pericarditis should be considered an expected adverse event associated with smallpox vaccination.

Morgan et al, 2003. Myocarditis, pericarditis, and dilated cardiomyopathy after smallpox vaccination among civilians in the United States, January-October 2003 [21].
Purpose: To conduct surveillance to describe and determine the frequency of myocarditis and/or pericarditis (myo/pericarditis) among civilians vaccinated during the US smallpox vaccination program between January and October 2003.

Methods: Active and passive surveillance systems were used to detect smallpox vaccination—associated adverse events among civilian vaccinees. The term "myo/pericarditis" referred to cases with symptom onset within 6 weeks after smallpox vaccination that meet the case definitions for smallpox adverse event surveillance for myocarditis, pericarditis, or both. Authors classified all cases of myo/pericarditis as "suspected," "probable," or "confirmed." Active surveillance included a 21–28-day follow-up of vaccinees and

telephone surveys conducted among a sample of vaccinees at days 10 and 21 after vaccination. Passive surveillance involved health care workers, hospital and local health department personnel who cared for vaccinees, and adverse event coordinators (state health department staff involved in smallpox vaccination programs) who submitted adverse event reports to the Vaccine Adverse Event Reporting System (VAERS).

Results: Authors identified 21 myo/pericarditis cases among 37,901 vaccinees (5.5 per 10,000); 18 (86%) were revacinees, 14 (67%) were women, and the median age was 48 years (range, 25–70 years). The median time from vaccination to onset of symptoms was 11 days (range, 2–42 days). Myo/pericarditis severity was mild, with no fatalities, although 9 patients (43%) were hospitalised. Three additional vaccinees were found to have dilated cardiomyopathy, recognized within 3 months after vaccination. Authors describe an association between smallpox vaccination and myo-/pericarditis among civilians.

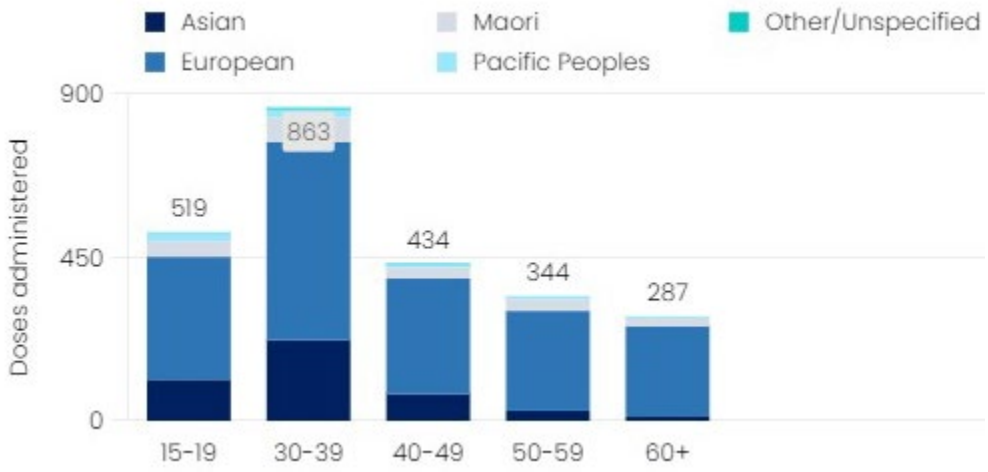
2.3 Usage

Vaccine uptake is relatively low, which is to be expected given the very low risk of infection/community transmission. Vaccination against mpox began 16 January 2023. Up to 1 May, there have been 2,447 mpox vaccines administered, most of these being dose 1 (Figure 1). Most vaccines are in the 30–39-year age group and are of European ethnicity (Figure 2).

Figure 1: Number of mpox vaccines administered, up to 1 May 2023. Source: Qlik App. Mpox vaccinations (accessed 3 May 2023)

Vaccines administered dose 1	Vaccines administered dose 2	Vaccines administered
2,346	101	2,447

Figure 2: Number of mpox vaccinations administered by age group and priority ethnicity, up to 1 May 2023. Source: Qlik App. Mpox vaccinations (accessed 3 May 2023)



2.4 Data sheets

The EU [redacted] SmPC and FDA [redacted] Prescribing Information does not list myo-/pericarditis as an ADR. However, the EU Risk Management Plan (RMP) includes myo-/pericarditis as an important potential risk that continues to be monitored. Additionally, the FDA have mandated reporting of all serious ADRs and administration errors of [redacted] vaccine to the vaccine adverse event reporting system (VAERS) [5, 22].

The Canadian Product Monograph (section 9) for [redacted] states that 'cardiac adverse events were noted in some [redacted] recipients. However, despite close cardiac monitoring there were no confirmed cases of myocarditis, pericarditis, endocarditis, or any other type of cardiac inflammatory disease of related syndromes recorded' [23].

Comments:

[redacted] vaccine is not an approved vaccine in New Zealand or Australia however, it is available under Section 29 of the Medicines Act 1981 (NZ) and under an emergency use exemption Section 18A of the Therapeutic Goods Act 1989 (Australia). Because the vaccine is not approved, there is no country specific data sheet available.

2.5 Safety information for mpox vaccination

2.5.1 New Zealand information

An information leaflet on adverse reactions following mpox vaccination is to be given to vaccinees [24]. The leaflet contains information on common injection site and systemic adverse reactions, it also contains information on myocarditis and pericarditis (Figure 3). It is made by Te Whatu Ora.

Figure 3. After the monkeypox (mpox) vaccination (accessed 21 March 2023).

Myocarditis and pericarditis: Heart and breathing changes Tightness, heaviness, discomfort, pressure or pain in your chest or neck difficulty breathing or catching your breath Feeling faint, dizzy, or lightheaded Fluttering, racing, or pounding heart, or feeling like it's 'skipping beats'	Myocarditis is inflammation of the heart muscle, while pericarditis is inflammation of the tissue forming a sac around the heart. These conditions are usually caused by viral infections, but they are also a very rare potential side effect of the mpox vaccine. Symptoms of myocarditis and pericarditis linked to the vaccine generally appear within a few days, and mostly within the first few weeks of having the vaccine. Talk to your family doctor or practice nurse, or call **Healthline** on **0800 611 116** anytime to get advice. If you have an **immediate concern about your safety, call 111** and make sure you tell them you have had a mpox vaccination.

2.5.2 Australian information

In Australia, both ACAM2000 and [redacted] vaccines are available for people who meet the criteria for mpox vaccination. [redacted] is the preferred vaccine based on its safety profile. The TGA have published the following statement on mpox vaccines and myo-/pericarditis [25]

> Mpox and COVID-19 vaccines
>
> ACAM2000 and mRNA COVID-19 vaccines are each associated with a rare risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining of the heart). The risk is highest in young adults, particularly males.
>
> It is uncertain whether [redacted]S® is associated with a risk of myocarditis or pericarditis.
>
> ATAGI recommends that people at higher risk of myocarditis and pericarditis should consider separating their mpox vaccine dose and their mRNA COVID-19 vaccine dose by several weeks.

An information leaflet following [redacted] vaccine states the risk of myo-/pericarditis is unknown, but people should seek medical attention if they develop chest pain (Figure 4) [26].

Figure 4. Australian information on [redacted] vaccine (accessed 28 March 2023).

It is not known if [redacted] is associated with a risk of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining of the heart). Spacing [redacted] and a COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis after mRNA COVID-19 vaccine, such as young adult males.

You should seek medical attention after vaccination if you:

- **Think you are having an allergic reaction. Call 000 if you experience severe symptoms, such as difficulty breathing, wheezing, or collapsing.**
- **Have chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, or shortness of breath**
- **Are worried about a potential side effect or have new or unexpected symptoms**

2.5.3 United States of America information

The Centers for Disease Control and Prevention (CDC) have published safety information and guidance for mpox vaccines during the 2022 mpox outbreak. This page was last updated 12 January 2023 and according to the CDC, several studies have assessed the cardiac safety of people who received the [redacted] vaccine. In one study, there were three cases of heart palpitations, two cases of tachycardia and no cases of myocarditis or pericarditis detected. Overall, data did not suggest an increased risk of myocarditis or pericarditis after vaccination with [redacted] compared with placebo controls [27]. Reporting of serious adverse events from mpox vaccination including myo-/pericarditis is mandatory.

3 SCIENTIFIC INFORMATION

3.1 Published literature

There is very little published literature on the topic of cardiac events (including pericarditis) following [redacted] vaccination. There is one retrospective cohort study that uses electronic health records to evaluate cardiac adverse events following [redacted] vaccination, this study is discussed below and the full text attached as an annex.

3.1.1 Sharff et al, 2023, Cardiac events following [redacted] vaccination for prevention of Mpox [28].

Purpose: To describe the incidence of cardiac adverse events of special interest (AESI) in the Kaiser Permanente Northwest population who received at least one dose of [redacted] vaccine for prevention of mpox.

Method: Authors conducted a retrospective cohort study of 2,126 patients aged 12 or older who were vaccinated with at least one dose of [redacted] vaccine between 14 July 2022, and 10 October 2022. Authors searched the Kaiser Permanente Northwest databases, including the electronic health records, to evaluate for cardiac adverse events of special interest (AESI) that occurred within a 21-day follow up period. Search terms included diagnoses of elevated troponins, chest pain, myocarditis, pericarditis, myopericarditis, acute myocardial infarction, cardiac dysrhythmia, cardiac arrest, or ventricular fibrillation.

Results: 2,126 people received 3,235 [redacted] vaccine doses in the review time period, 1033 people received one dose (48.6%); 1,077 received two doses (50.7%); 16 patients received three doses (0.75%). Of the 2,126 members, 1,811 (85.2%) were male, 290 (13.6%) were female and 25 (1.2%) were non-binary or unknown. Ages ranged from 12 to 82 years. Encounter ICD-10-CM diagnosis codes and troponin values identified 24 possible cardiac AESI events.

Physician adjudication confirmed 10 cardiac AESI events for an incidence of 3.1 per 1000 doses (95% CI 1.5-5.7). The 10 AESI cases are presented on Table 2. Of the patients who suffered a cardiac AESI event, 9 of the 10 patients (90%) had a history of at least one cardiac risk factor. There were 8 patients who had a cardiac AESI following their first dose of [redacted] of these, 5 patients received a second dose at least 4 weeks later without any further adverse events.

[redacted]

Discussion: Cardiac AESIs have been reported following [redacted] vaccination, in this cohort review the most common presenting symptoms were chest pain and palpitations. Of the ten patients who experienced a cardiac AESI, seven were seen in an outpatient setting and three presented to the emergency department, no patients were hospitalised because of the event and all cases were self-limiting with no attributable death.

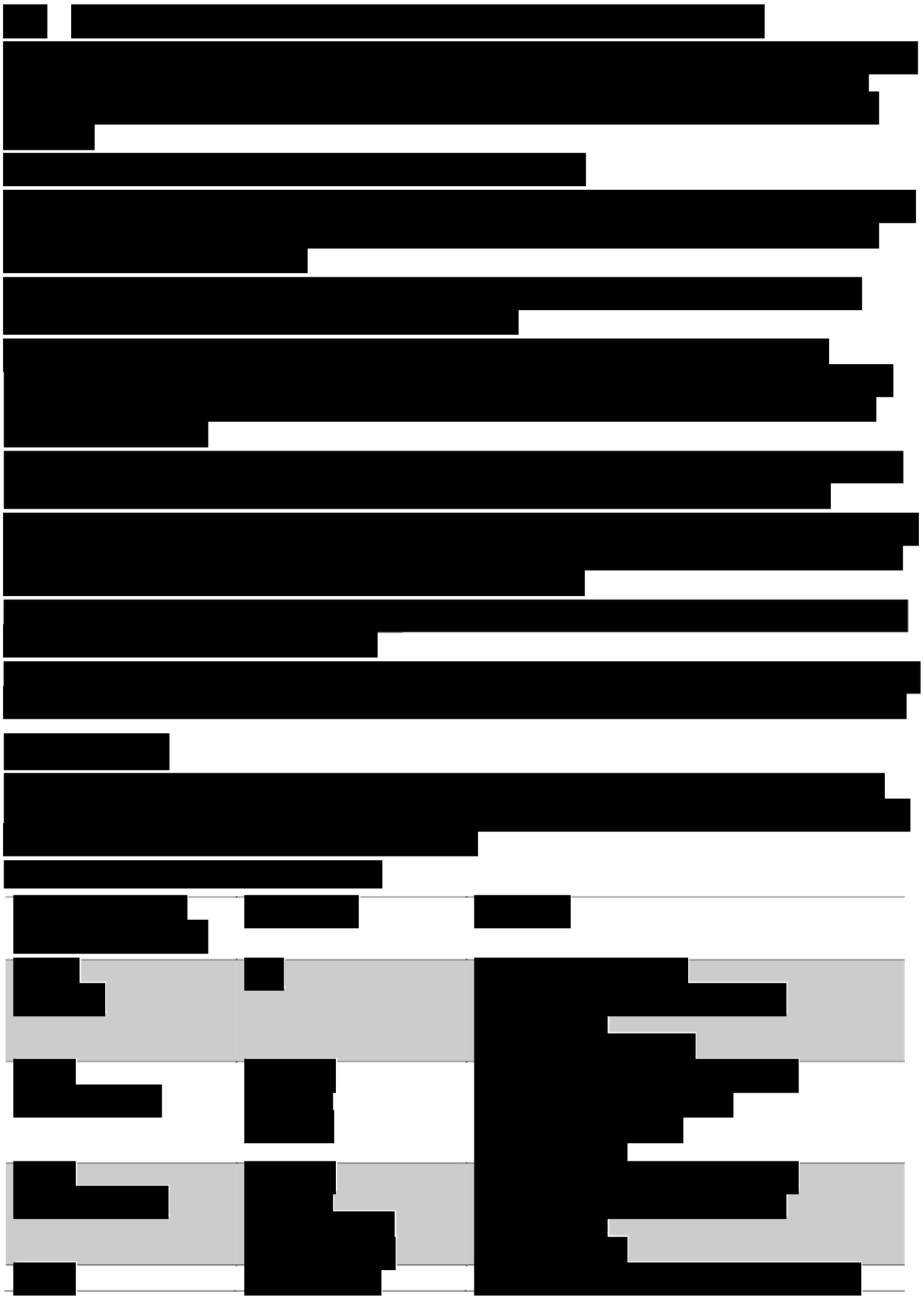
The authors retrospective cohort study of [redacted] vaccination did not find any cases of myo-/pericarditis in their population sample. The 10 cardiac AESI events all had alternative explanations and no hospitalisations or serious adverse outcomes were attributed to vaccination. As only 10 AESI cases were confirmed the authors were unable to measure the incidence of the events and could not stratify the results by dose or patient characteristics.

Overall, the study provides information that the observed risk of cardiac events with [redacted] is low and is consistent with the known cardiac safety profile of the vaccine. The authors conclude that further research is needed to evaluate the incidence of cardiac AESI by dose number and route of administration as well as the contribution of pre-existing conditions to event incidence.

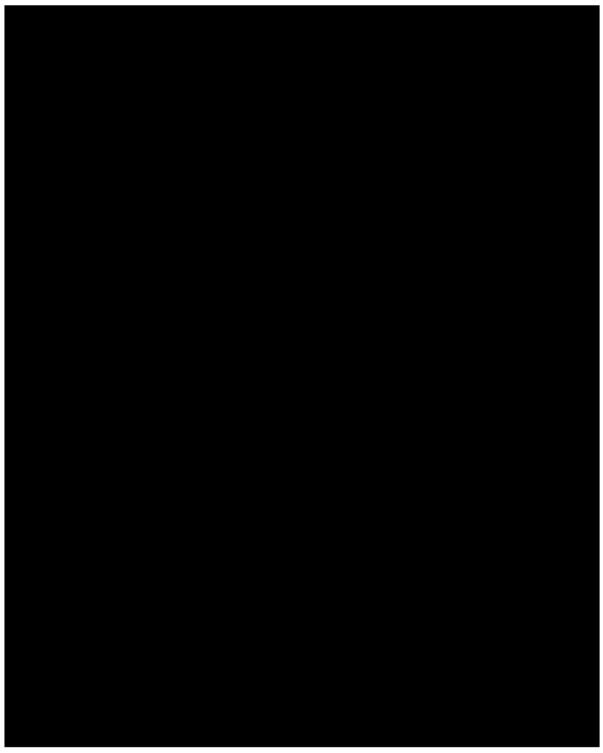
3.2 Company reports

[redacted]

[redacted]



[redacted]



3.5 Database of adverse event notifications (DAEN)

DAEN contains suspected adverse event reports for medicines in Australia. Up to 4 May 2023, there are 331 reports where [redacted] is the suspect vaccine. The top ten most commonly reported MedDRA PTs are injection site reaction (150), myalgia (88), headache (88), dyspnoea (73), fatigue (69), chest pain (65), palpitations (56), pyrexia (48), arthralgia (47), and rash (41).

There is one case each of myopericarditis and pericarditis, a summary of the reported cases and reaction terms are provided on Table 5.

Table 5. DAEN summary of myopericarditis and pericarditis reports following [redacted] vaccination. Source: https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen-medicines (accessed 5 May 2023)

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
767915	1/03/2023	36	Male	• [redacted]ive Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN)) - Suspected	• C-reactive protein increased • Chest pain • Dyspnoea • Hyperhidrosis • Myopericarditis • Nausea • Pericardial effusion • Sinus tachycardia • Troponin increased
765995	6/02/2023	29	Male	• [redacted](Live Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN)) - Suspected	• Chest pain • Dizziness • Dyspnoea • Palpitations • Pericardial effusion • Pericarditis • Tachypnoea

[redacted]

Comments:

ADRs reported for [redacted] vaccine in New Zealand are similar to those reported internationally, most reactions are non-serious and include injection site reactions, headaches, fatigue, and myalgia.

[redacted]

4 DISCUSSION AND CONCLUSIONS

Medsafe received two reports of pericarditis following mpox vaccination and both were assessed as 'possible'. In order to encourage further reporting of ADRs, a monitoring communication was published on the Medsafe website. Up to 10 May 2023, one further ADR report was received. The overall number of ADRs reported following mpox vaccination is low, which is expected given the low number of vaccines administered in New Zealand. [redacted]

Myo-/pericarditis following vaccination has been associated with older replication competent smallpox vaccines (ACAM2000) and cases have also been reported with mpox infection in the recent global outbreak. The mechanism behind vaccination- or infection induced pericarditis is unknown but is suspected to be immune-mediated.

Information relating to myo-/pericarditis following [redacted] vaccination remains limited, spontaneous case reports have been received in New Zealand, Australia, and the United States although the total number of reports is low. Medsafe will continue to monitor this safety concern via routine pharmacovigilance activities.

5 ANNEXES

1. Sharff et al (2023)- Cardiac events following [redacted] vaccination for prevention of Mpox

6 REFERENCES

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