NCIRS
National Centre for Immunisation Research and Surveillance

Surveillance of adverse events following immunisation in Australia, 2023

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Contents

Abbreviations

13vPCV	13-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine
7vPCV	7-valent pneumococcal conjugate vaccine
ABS	Australian Bureau of Statistics
AEFI	adverse event following immunisation
AEMS	Adverse Event Management System
AESI	adverse event of special interest
AIR	Australian Immunisation Register
ATAGI	Australian Technical Advisory Group on Immunisation
CI	confidence interval
DAEN	Database of Adverse Event Notifications
DTP	diphtheria-tetanus-pertussis vaccine – formulation unspecified
DTPa	diphtheria-tetanus-pertussis (acellular) vaccine – paediatric formulation
dTpa	diphtheria-tetanus-pertussis (acellular) vaccine – adult formulation
DTPa-HepB	combined diphtheria-tetanus-pertussis (acellular) and hepatitis B vaccine
DTPa-Hib	combined diphtheria-tetanus-pertussis (acellular) and *Haemophilus influenzae* type b vaccine
DTPa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus vaccine – paediatric formulation
DTPa-IPV-HepB-Hib	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus, hepatitis B and *Haemophilus influenzae* type b vaccine
dTpa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus vaccine – adult formulation
ERP	estimated resident population
GBS	Guillain Barré Syndrome
H1N1pdm09	pandemic H1N1 influenza 2009 vaccine
HepA	hepatitis A vaccine
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type b
Hib-MenC	combined *Haemophilus influenzae* type b and meningococcal C conjugate vaccine
Hib-MenCY	combined *Haemophilus influenzae* type b and meningococcal C and Y conjugate vaccine
Hib-HepB	combined *Haemophilus influenzae* type b and hepatitis B vaccine
HPV	human papillomavirus
ICU	intensive care unit
JE	Japanese encephalitis
LLT	lower level term(s)
MedDRA	Medical Dictionary for Regulatory Activities
MenACWY	quadrivalent meningococcal (serogroups A, C, W-135, Y) conjugate vaccine
MenB	meningococcal B vaccine
MenC	meningococcal C conjugate vaccine

MMR	measles-mumps-rubella vaccine
MMRV	measles-mumps-rubella-varicella vaccine
MVA-BN	modified vaccinia Ankara – Bavarian Nordic vaccine
NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
PCV	pneumococcal conjugate vaccine – formulation unspecified
PT	preferred term(s)
RZV	recombinant zoster vaccine
SMQ	standardised MedDRA query
TGA	Therapeutic Goods Administration
WHO	World Health Organization
ZVL	live-attenuated zoster vaccine

Summary

This report summarises Australia's spontaneous surveillance data for adverse events following immunisation (AEFI) for all vaccines administered in 2023, reported to the Therapeutic Goods Administration (TGA). This report combines COVID and non-COVID AEFI that were previously reported separately in 2022 and 2021.

Overall, there were 5,534 AEFI reports for vaccines administered in 2023. This represents an annual AEFI reporting rate of 20.8 per 100,000 population, compared with 79.2 per 100,000 population in 2022. The sharp decrease in the AEFI reporting rate in 2023 was likely driven by a change in COVID-19 vaccination policy. This included limiting COVID-19 vaccine booster dose recommendation to high-risk populations rather than the wider community, resulting in a steep decline in both the number of administered doses and the number of AEFIs reported. The most commonly reported adverse events were medication errors, injection site reaction, hypersensitivity, pyrexia, and gastrointestinal nonspecific symptoms. The most commonly reported adverse events for new vaccines introduced in 2023 were medication errors and headache for COVID-19 vaccines, hypersensitivity and pyrexia for DTPa-HepB-IPV-Hib vaccine (Vaxelis), and injection site reaction and hypersensitivity for recombinant zoster vaccine (Shingrix). There was reduction in deaths reported following vaccination in 2023 compared to 2022 and 2021. None of the 34 reported deaths in 2023 were determined to be causally related to the vaccine(s) received.

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Introduction

An adverse event(s) following immunisation (AEFI) is defined as any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine.[1] The AEFI may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. AEFI can be caused by the vaccine(s) or be a coincidental event and can be classified into the following categories:

1. Vaccine product-related reaction
2. Vaccine quality defect-related reaction
3. Immunisation error-related reaction
4. Immunisation anxiety-related reaction (also known as immunisation stress-related response)
5. Coincidental event.

Ongoing post-marketing AEFI surveillance through a national spontaneous (passive) surveillance system is important in detecting AEFI that may not have been identified in pre-registration vaccine trials.

Anyone can report AEFI to the TGA, with the main categories of reporters being state and territory health departments, health professionals, vaccine companies, and consumers (members of the public).[2] All reported AEFI are entered into the Australian Adverse Event Management System (AEMS) database. Where the initial report contains insufficient information, the TGA may contact the reporter or relevant state or territory health department to elicit further information. The TGA continually analyses AEFI data to detect new potential safety issues or changes to known safety issues that may require regulatory or other action. The TGA may also review select serious adverse events, using internationally consistent methods to identify whether there may be a link between a vaccine and the adverse event involved.[3]

Reports summarising Australian national spontaneous AEFI surveillance data have been published regularly since 2003.[4, 5] Trends in reported AEFI are influenced by many factors, including changes to the National Immunisation Program (NIP), vaccine introduction and availability, media coverage, awareness campaigns, and efforts to facilitate reporting, such as safety alerts on the TGA website and social media channels, as well as programs targeted at increasing health professional reporting. Changes to the NIP since 2005 are summarised in Table S1, and their impacts on reported AEFI trends are described in this and previous annual AEFI reports.

Immunisation recommendation changes in 2023[6] that impact on AEFI surveillance data presented in this report are:

February 2023:

- 9vHPV vaccine for immunocompetent adolescents and young adults aged 9–25 years was changed from a two-dose to a single dose schedule; eligibility for catch-up of 9vHPV vaccine was also expanded to include people aged up to 25 years.
- A COVID-19 vaccine booster dose was recommended for adults ≥65 years and adults 18–64 years with medical comorbidities or disability if ≥6 months passed since the last vaccine dose or infection. This replaced the previous 2022 recommendation of a winter booster dose for adults >50 years and people aged ≥16 with medical risk conditions or disability if ≥3 months had passed since their last vaccine or infection.

March 2023

- Vaxzevria (AstraZeneca COVID-19 vaccine) no longer available.

July 2023

- Vaxelis was funded under NIP as an alternative vaccine to Infanrix hexa.

September 2023:

- A 2023 COVID-19 vaccine booster dose was recommended for all adults aged ≥75 years and, for adults aged 65–74 and those 18–64 with severe immunocompromise after consulting their healthcare provider, if 6 months had passed since their last dose.

November 2023

- Shingrix replaced Zostavax under the NIP and was funded for adults aged ≥65 years, Aboriginal and Torres Strait Islander people ≥50 years and immunocompromised people ≥18 years at high risk of herpes zoster infection.

This report summarises national spontaneous (passive) surveillance data for all AEFI reported to the TGA, including COVID and non-COVID vaccines which were previously reported separately. The report focuses on AEFI reported for vaccines administered in 2023.

Methods

AEFI data

De-identified data on all AEFI reported to the TGA until 31 December 2023 and stored in the AEMS database were extracted in October 2024. Please refer to previous reports for a detailed description of the surveillance system.[4, 7]

Vaccine data

Vaccines were identified by trade name (standardised term in the TGA reference dataset), and where the trade name was not specified, the generic name (active ingredients associated with a trade name) and reported product name (product name used by the reporter). Individual vaccines were grouped by antigen (or combination of antigens) and, for seasonal influenza and other specific vaccines, by type (for influenza: standard-formulation vs high-dose or adjuvanted; for Japanese encephalitis and zoster, live vs recombinant or inactivated). Only vaccines with a role in relation to the reported adverse event of "suspect" were included in the analysis. To be accepted into the TGA AEMS database, the report must contain sufficient information to be valid, a condition requiring four key elements: a reporter; a patient; one or more suspected medicines or vaccines; and one or more reaction terms.[8] Valid reports are accepted by the TGA with a default decision type of "causality possible". More than one vaccine with a "suspect" role can be included in a report, without implying that all vaccines were necessarily co-administered on the same occasion.

Adverse event data

AEFI reports included reaction terms that are symptoms, signs, and/or diagnoses that were coded by TGA staff from the reporter's description into lower level terms (LLT), which were mapped to associated preferred terms (PT) using the Medical Dictionary for Regulatory Activities (MedDRA®).[8, 9]

Standardised MedDRA queries (SMQ) are sets of MedDRA terms that have been grouped after extensive testing, analysis, and expert discussion to facilitate pharmacovigilance investigation.[10] For this analysis, the MedDRA Browser SMQ Analysis tool, running MedDRA version 27.1, was used to group related PT to SMQ to reduce the number of unique PT under analysis while providing meaningful results.[11] A narrow search was performed to increase the specificity of the PT to SMQ mapping. As individual PT may map to zero, one, or more than one SMQ, the term selected (PT or SMQ) was determined as described in Table S2. Following the decision process, a one-to-one PT-SMQ mapping was performed to ensure that each PT was counted only once and there was no overlap in the included terms between different SMQ.

AEFI report data management

AEFI reports were defined by unique identifiers assigned by the TGA. In this analysis, each AEFI report was assigned a date based on:

1. the earliest vaccination date associated with the report; or where a vaccination date was missing:
2. the earliest symptom onset date was used; or where dates for both vaccination and symptom onset were missing:
3. the received date (the date when the reporter of the case first received the minimum valid information as described above from the primary source) was used.

Reports with a 2023 date of vaccination, symptom onset or received date, based on the hierarchy above, were included in the analysis.

Reports were grouped by age into <5 years, 5-11 years, 12-17 years, 18-64 years, and ≥65 years. Reports with a vaccination, symptom onset, or received date (as described above) prior to 2023 were excluded from the 2023 specific analysis.

Adverse events of special interest

Adverse events of special interest (AESI), defined as pre-specified, medically important events potentially associated with a vaccine requiring careful monitoring and confirmation by specialised studies, were reviewed for vaccines or vaccine formulations newly introduced in 2023. Brighton Collaboration and Safety Platform for Emergency Vaccines (SPEAC) Tier 1 AESIs,[12] which is used for all Coalition for Epidemic Preparedness Innovations (CEPI) vaccine development programs, were included for reporting. Specifically, these were:

- Anaphylaxis,[13]
- Thrombocytopenia,[14]
- Generalised convulsion,[15]
- Aseptic meningitis,[16]
- Encephalitis, myelitis, acute disseminated encephalomyelitis (ADEM),[17]
- Guillain Barré Syndrome (GBS) and Miller Fisher Syndrome,[18]
- Peripheral facial nerve palsy.[19]

In addition, given the ongoing use of mRNA COVID-19 vaccines, myocarditis and/or pericarditis[20] has also been included as an AESI for reporting.

The corresponding MedDRA LLT codes to these AESI were sourced from the guideline on Tier 1 AESI ICD9/10 and MedDRA Codes.[12] The narrow-search MedDRA LLT codes from the Brighton Collaboration and SPEAC guideline were mapped to the corresponding PT/SMQ, generating a PT/SMQ search list for each AESI (further details in Supplementary table S3). AEMS AEFI reports containing a PT/SMQ found in a particular search list were classified as having reported the corresponding AESI.

Serious and non-serious AEFI

AEFI reports were coded as “serious” or “non-serious” based on criteria used by the World Health Organization (WHO), where an adverse event report is defined as “serious” if it involves one or more of the following outcomes:

- fatal or life-threatening condition(s);
- new or prolonged hospitalisation;
- persistent or significant disability;
- congenital anomaly or birth defect; and
- any medical event that requires an intervention to prevent the above outcomes.[3]

For AEFI reports submitted by sponsors (pharmaceutical companies), the seriousness classification is applied by sponsors to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied by the TGA following review.

All AEFI reports where a fatal outcome is reported, or the individual was admitted to an intensive care unit (ICU) are reviewed by the TGA. This review is designed to assess whether the medical condition(s) that caused the ICU admission and/or death represents an emerging safety concern. The TGA reviews each of these reports and considers the strength of the evidence for a link between vaccination and the condition that caused the death using a standardised process based on the World Health Organization (WHO) causality assessment guidelines.[21] When the cause for the

event(s) that resulted in ICU admission and/or death is not medically obvious, not stated, or cannot be determined from the initial report, the TGA may request further information from the reporter, which may include the results of investigations relating to the ICU admission and/or death, past medical history, post-mortem examination findings, the death certificate, and/or results of a Coronial Office investigation.

In addition, the TGA can seek expert causality assessment advice from a Vaccine Safety Investigation Group (VSIG), which consists of clinical experts in domains including infectious diseases, vaccinology, haematology, respiratory medicine, immunology and public health, together with a consumer representative and often a communication expert.[22] The purpose of the VSIG is to provide independent specialist immunisation (and other relevant) expertise to assist the TGA to investigate and undertake regulatory action for vaccine safety signals of concern. Where a VSIG is required, an internationally accepted method is used to determine the level of certainty of a link between the event and vaccine.[21]

Data analysis

Average annual population-based AEFI reporting rates were calculated for each state and territory and by age group using June 2023 population estimates obtained from the Australian Bureau of Statistics (ABS).[23] Comparisons with previous years were made using ABS mid-year estimated resident population (ERP) data for each year from 2000 to 2022.

AEFI reporting rates per 100,000 administered doses were estimated for 2023. The number of doses administered for each vaccine in 2023 was obtained in February 2024 from the Australian Immunisation Register (AIR), a national population-based register.[24] Vaccination providers are required by law to enter into the AIR every NIP-funded vaccine as well as COVID-19 vaccines administered from 21 December 2022, and are strongly encouraged to provide information to the AIR on all other vaccines given.[25] Vaccine doses can also be entered into the AIR retrospectively, including those administered overseas.[26]

Confidence intervals presented are 95% exact binomial confidence intervals for proportions. All data cleaning and analyses were performed using R version 4.4.1.

Notes on interpretation

The data reported here are provisional, particularly for the fourth quarter of 2023 due to potential reporting delays. In addition, AEFI may have been reported in 2023 for vaccines administered in previous years. Therefore, statistics published in this report relating to AEFI reports from years prior to 2023, including accompanying figures, may not match those in previous reports.

It is possible for one case to be the subject of more than one AEFI report, where the reports have been submitted independently by multiple sources and there is insufficient information provided to confirm duplication.

As this report analysed data from the AEMS database, the numbers published in this report may be different to the numbers found the Database of Adverse Event Notifications (DAEN) – medicines, a public online database maintained by the TGA that contains reports of adverse events for all medicines and vaccines.[27] The AEMS database includes more detailed information on each AEFI report and incorporates amendments and updates to reports when additional information is made available to the TGA. As the data for this analysis were extracted from AEMS in October 2024, there may be discrepancies with the DAEN – medicines, which is a live database that reflects new information made available to the TGA after October 2024.

Results

In the AEMS database, there were 5,534 AEFI reports where the date of vaccination (or onset of adverse event or report received date if the date of vaccination was not reported) was between 1 January and 31 December 2023.

Of the 5,340 reports (96.5% of total) with information on sex provided, 3,076 (57.6%) were for females and 2,261 (42.3%) were for males. Of the 3,311 reports (59.8% of total) with Indigenous status provided, 190 AEFI reports (5.7%) were for people who identified as Aboriginal and/or Torres Strait Islander. Of the 5,157 reports (93.2% of total) with age or date of birth provided, 1,893 (36.7%) were for children aged <5 years, and 1178 (22.8%) were for people aged ≥65 years.

Most AEFI reports (3,906, 70.6%) were sent by a state or territory health department (termed "regional pharmacovigilance centre" in AEMS; Figure S1), and 15.3% (849) reports were direct submissions by health professionals or other organisation (including regulatory authorities) to the TGA. Consumers submitted 6.7% (372) of AEFI reports, and 7.3% (407) of reports were sent by pharmaceutical companies. The proportion of pharmaceutical company reports was similar to that of 2022 (7.1% overall, 13% for non-COVID-19 vaccines[28] and 3.8% for COVID-19 vaccines[29]) -.

Reporting rates

Dose-based reporting rates

The overall AEFI reporting rate for 2023 was 24.1 (95% CI 23.5, 24.8) per 100,000 doses of vaccines administered and recorded in the AIR, compared with 50.6 (49.9, 51.3) per 100,000 doses in 2022 (non-COVID-19 and COVID-19 vaccines combined, Table 1). When excluding COVID-19 vaccines, the AEFI rate for non-COVID-19 vaccines was 22.0 (95%CI 21.3, 22.7) per 100,000 doses. The rate for only COVID-19 vaccines was 32.0 (95%CI 30.5, 33.7) per 100,000 doses.

Population-based reporting rates

The overall AEFI reporting rate for 2023 was 20.8 (95% CI 20.2, 21.3) per 100,000 total population, compared with 79.2 per 100,000 in 2022 and 491.5 per 100,000 in 2021 during the peak of COVID-19 vaccine roll-out. In 2023, the AEFI reporting rate for non-COVID-19 vaccines was 14.8 (95%CI 14.4, 15.5) per 100,000 population and for COVID-19 vaccines it was 5.9 (5.6, 6.2) per 100,000 population.

The highest age-specific population-based AEFI reporting rate was in children aged <5 years (124.9 reports per 100,000 population; Table 2, Figure 2). Compared to 2022, the reporting rate in this group slightly increased but remained consistent with annual rates over the past decade. In contrast, AEFI reporting rates sharply declined in other age groups, returning to pre-pandemic levels.

By jurisdiction, the highest population-based AEFI reporting rates in 2023 were in Tasmania (38.4 reports per 100,000 population) and Western Australia (35.7 per 100,000 population). The lowest reporting rates were in Queensland (11.3 reports per 100,000 population) and New South Wales (12.0 per 100,000 population; Table 2).

Figure 1-7 show the annual trend in AEFI report counts and/or reporting rates per 100,000 population, including AEFI reports that had been entered into the AEMS database in the years subsequent to the year of events occurrence. Therefore, there may be discrepancies between the numbers in Figure 1-7 and the numbers in previous annual reports.

Vaccines

The vaccine most frequently listed in 2023 AEFI reports was the COVID-19 (Comirnaty) vaccine (1,037 reports; 18.7% of total reports), followed by standard-formulation seasonal influenza vaccine (905 reports; 16.4%), 13vPCV (556 reports; 10%), DTPa-IPV-HepB-Hib (484 reports; 8.7%), and COVID-19 (Spikevax) vaccine (441 reports; 8%, Table 3). Of the 1,037 AEFI reports following COVID-19 (Comirnaty) vaccine, 238 (23%) were classified as serious, 457 (44.1%) were reported in adults aged 18-64 years, 391 (37.7%) in adults aged ≥65 years, 37 (3.6%) in children aged 5-11 years, 35 (3,4%) in children aged 5-11 years, and only 11 (1.1%) in children under 5 years (Table 3).

For each respective age group, the vaccines with the highest number of AEFI reports in 2023 were 13vPCV (in children aged <5 years), standard-formulation seasonal influenza vaccine (in children aged 5-11 years), dTpa (in adolescents aged 12-17 years) and COVID-19 (Comirnaty) vaccine (in people aged 18-64 years, and ≥65 years) (Table 1).

In relation to new vaccines introduced in 2023, there was a slight increase in the number of AEFI reports for DTPa-IPV-HepB-Hib in 2023 (484 reports across all brands, including 97 for Vaxelis) compared to 409 reports in 2022, following the introduction of Vaxelis. There was an increase in AEFI reporting for recombinant zoster vaccine (RZV) vaccine, with 372 reports in 2023 compared to 99 reports in 2022, following the replacement of zoster live-attenuated vaccine (ZLV) with RZV under the NIP. The number of AEFI reports following the COVID-19 (Vaxzevria) vaccine declined significantly in 2023 (53 reports), compared to 2022 (454 reports) and 2021 (47,825 reports), as the vaccine was no longer available in Australia from March 2023.

Adverse events

The most frequently reported MedDRA PT or SMQ in 2023 was “medication errors” (1,278 reports; 23.1%; Table 4; further detail of terms included in Table S3), which, in the context of AEFI denotes vaccination errors. While the majority of these reports were in children aged <5 years (468 reports, 36.6% of all “medication errors” reports) and adults aged 18-64 years (390 reports, 30.5%), “medication error” was the most frequently reported PT/SMQ across all age groups in 2023. The most frequently reported errors included “inappropriate schedule of product administration” (358 reports, 28% of all “medication error” reports), “product administered to patient of inappropriate age” (311, 24.3%), “wrong product administered” (238, 18.6%), and “expired product administered” (177, 13.8%; see Table S4 for further details).

The number of reports involving “medication errors” decreased in 2023 compared to previous years, with 2,032 reports in 2022 (9.9% of all AEFI reports) and 2,065 reports in 2021 (1.6%), but was significantly higher than in 2020 (245 reports, 5.1%). Between 2021 and 2023, the number of reports on “medication errors” declined among individuals aged ≥5 years, but increased in children under 5 years over the same period (152 reports in 2021, 355 in 2022, and 468 in 2023).

The vaccines most frequently implicated in a report of “medication errors” for all age groups were the high dose or adjuvanted seasonal influenza vaccine (192 reports, 15.0% of reports with “medication errors” included), COVID-19 (Comirnaty) vaccine (177 reports, 13.8%), and standard-formulation seasonal influenza vaccine (166 reports, 13.0%). In 158 reports (12.4%), more than one vaccine was reported. Only 14 AEFI reports involving “medication errors” were classified as serious (1.1%). Notably, in the majority of reports (1144; 89.5%), no adverse event/s were reported in association with the error, noting that it is possible after the error has been reported for an associated adverse event to occur and not be captured in the error report.

Among children under 5 years in 2023, the most commonly reported medication errors were “inappropriate schedule of product administration” (178 reports, 38% of all “medication error” reports in this age group), “wrong product administered” (111, 23.7%), and “product administered to patient of inappropriate age” (98, 20.9%). The vaccines most commonly listed in a report of “medication errors” for children under 5 years were the standard-formulation seasonal influenza vaccine (70 reports, 15.0% of reports with “medication errors” included), DTPa-hepB-IPV-Hib (46 reports, 9.8%), and MMR vaccine (31 reports, 6.6%, see Table S4 for further details).

Following medication error, the next most frequently reported adverse events were injection site reaction (925 reports; 16.7%), hypersensitivity (904 reports; 16.3%), pyrexia (748 reports; 13.5%), and the SMQ grouping of “gastrointestinal non-specific symptoms and therapeutic procedures” (701 reports; 12.7%; further detail of terms included in Table S5).

Serious adverse events

In 2023, the majority of AEFI reports (4,836 reports; 87.4%) were classified as non-serious (Figure 1). The proportion of AEFI reports classified as serious was 12.6%, with 698 reports, representing a rate of 3.05 (95%CI 2.82, 3.28) serious AEFI reports per 100,000 doses administered, and 2.62 (95%CI 2.43, 2.82) serious AEFI reports per 100,000 population. This represents a decrease in both the proportion of AEFI reports classified as serious and the dose-based and population-based rates of serious AEFI compared to previous years. In 2022, 16.4% of AEFI reports were classified as serious, corresponding to 7.9 (95%CI 7.6, 8.2) per 100,000 doses administered, and 12.4 (95%CI 12.0, 12.8) per 100,000 population. Similarly, in 2021, 16.4% of AEFI reports in 2021 were also classified as serious, with higher rates of 29.2 (95%CI 28.8, 29.7) per 100,000 doses administered and 65.1 (95%CI 64.1, 66.1) per 100,000 population.

Vaccines with the highest counts of serious reports were COVID-19 (Comirnaty) vaccines (238 serious reports; 23% for vaccine), standard-formulation seasonal influenza (82, 9.1%), COVID-19 (Spikevax) vaccines (57, 12.9%), zoster (RZV) (55, 14.8%) and 13vPCV (46, 8.3%; Table 3).

The majority or serious reports were submitted to the TGA by pharmaceutical companies (398 reports, 57% of total serious reports), followed by state and territory health departments (128; 18.3%), health professional (89; 12.8%), and by patients directly to the TGA (83; 11.9%).

The PT/SMQ category with the highest number and proportion of serious adverse event reports was “lack of efficacy/effect”, with 158 serious reports (94.6% of all reports with “lack of efficacy/effect”). Of the 158 serious reports under “lack of efficacy/effect”, 62 reports included the term “herpes zoster” and 62 reported included the term “COVID-19”. All but two serious reports on “lack of efficacy/effect” were from pharmaceutical companies, of which 55 reports identified a social media page or journal article as the source of information and generally contained little data. The other PT/SMQ categories with the highest number of serious reports were “COVID-19” (73 serious reports, 85.9%), “hypersensitivity” (69 reports, 7.6%), and “herpes zoster” (65 reports, 59.1%).

Thirty-four adverse events with a fatal outcome were reported to the TGA following a vaccine in 2023. Among these, 20 (58.8%) were reported by pharmaceutical companies, 12 (35.3%) by state or territory health department or health professionals, and only 2 (5.9%) were reported by consumers. Following detailed review by the TGA, based on the information provided, none of the 34 reported deaths were determined, to be causally related to the vaccine(s) received. Nine cases were assessed against the criteria for convening a VSIG, and none were determined to require VSIG for additional causality assessment or investigation.

Twenty-five deaths (71.4%) were following COVID-19 vaccines (Comirnaty: 19 reports, Vaxzevria: 2 reports, Spikevax: 1 report, and unspecified COVID-19 vaccine: 3 reports). Twenty cases had

minimal information; 18 cases lacked both vaccination date and date of death, two cases lacked vaccination date and all had minimal clinical details. The majority of cases (18 out of 20) with minimal information were reported by pharmaceutical companies. The two reports following Vaxzevria were reported by pharmaceutical companies, one included a death date in 2021, while the other lacked a date of death. Neither report included a date of vaccination. Both cases are likely death cases following Vaxzevria vaccination in 2021 that have already been included in previous reports but due to the minimal data, they could not be matched to existing reports.[28, 30] Among the five fatal reports with a recorded date of death and date of COVID-19 vaccination, four were female, one was male, and ages ranged from 63 to 84 years (median age 78 years). Four reports followed Comirnaty, and one report followed Spikevax.

Of the nine deaths following vaccines other than COVID-19 vaccines, two were from pharmaceutical companies (one followed ZVL, and one followed standard-formulation seasonal influenza vaccine and unspecified zoster vaccine) with no date of death, date of vaccination, or age reported. Seven of the nine reports had a recorded date of death; two were reported in children under 18 years, including one infant (following 2-month NIP schedule vaccines) and one young adult with complex medical background (following RZV). Among adults, five deaths were recorded (four male, one female) aged 66 to 97 years (median age 83 years). Three followed high-dose or adjuvanted influenza vaccine (one also received live Japanese encephalitis vaccine [JE]), two followed standard-formulation seasonal influenza vaccine (one also received an unspecified zoster vaccine), and one followed RZV.

New vaccines

In 2023, several new vaccines were introduced to the NIP. In July, Vaxelis, a DTPa-HepB-IPV-Hib vaccine, was available as an alternative to Infanrix hexa. In November, RZV (Shingrix) replaced ZLV (Zostavax) on the NIP. Additionally, the bivalent COVID-19 vaccines (Comirnaty and Spikevax) replaced most of the original (ancestral virus-based) formulations used in 2022.[31] This section presents the reported AEFI and AESI following the introduction of theses vaccines in 2023. The results for Comirnaty and Spikevax vaccines may include ancestral strains as we were unable to accurately differentiate these in all reports. However, Comirnaty bivalent vaccines were used from 08/02/2023 and bivalent Spikevax vaccines were used from 24/02/2023 in Australia.

The dose-based AEFI rate for Vaxelis (101 [95%CI 81.9, 123.2] per 100,000 doses, Table 5) was significantly higher than that of Infanrix hexa (54.9 [49.5, 60.8]). However, the proportion of serious AEFI reports was lower for Vaxelis (4.1%) compared to Infanrix hexa (9.2%). The AEFI rate for RZV (84.3 [76.0, 93.3] per 100,000 doses for all age groups, Table 5) exceeded that of ZLV (42.9 [32.8, 55.1]), with a higher proportion of serious reports (14.8% for RZV vs. 1.6% for ZLV). For COVID-19 vaccines, the reported AEFI rate per 100,000 doses in 2023 was lower than in 2022 for both Comirnaty and Spikevax. Specifically, Comirnaty had an AEFI rate of 29.6 (27.8, 31.4) per 100,000 doses in 2023, compared to 73.6 (72.2, 74.9) in 2022. Similarly, Spikevax had a rate of 31.7 (28.8, 34.8) per 100,000 doses in 2023, down from 75.4 (72.7, 78.2) in 2022.

The most reported PT/SMQ for each new vaccine were similar to those observed across all vaccines (Table 6). These included including injection site reaction, gastrointestinal nonspecific symptoms, headache, fatigue, pyrexia, and hypersensitivity. Overall, serious AEFI accounted for 12% or less of the top ten reported PT/SMQ for each new vaccine, except for “lack of efficacy/effect” reports for Comirnaty (97.4% serious) and “herpes zoster” for RZV (46.9%). However, these reports originated from pharmaceutical companies and contained minimal clinical details, as discussed in the ‘Serious adverse event’ section.

The most common AESI across all new vaccines was hypersensitivity and angioedema. While these fall under the "anaphylaxis" AESI group, none resulted in anaphylaxis, and most were not serious (Table 6). "Hypersensitivity" was the only AESI in the top 10 PT/SMQ for each new vaccine (Table 7). The next most common Tier 1 AESI was seizures with 12 reports following COVID-19 vaccines, three following Vaxelis and two following RZV. Six cases of GBS and six cases of facial nerve palsy were report, all in adults following a bivalent COVID-19 vaccine and/or RZV. This corresponds to an estimated risk of 1.02 (95% CI, 0.33, 2.38) GBS cases per million doses of mRNA COVID-19 vaccines and 2.75 (95% CI, 0.07, 15.30) GBS cases per million RZV doses.

Discussion

In 2023, the annual AEFI reporting rate was 24.1 per 100,000 doses, and 20.8 per 100,000 population. Both rates significantly decreased from the 2021-2022 period, returning to pre-pandemic level across all age groups and vaccines.[32-35]

The highest AEFI reporting rate per 100,000 population in 2023 was observed in children <5 years of age, consistent with their receipt of multiple routine vaccine doses in early childhood.[36] By comparison, in 2022, adults aged 18-65 and ≥65 years had the highest reporting rates. The surge in overall and adult AEFI rates during 2021–2022 was driven by the widespread rollout of emergency COVID-19 vaccination, which included primary doses for those aged 5 and above, along with multiple booster doses.[31] The decline in AEFI reporting rate following COVID-19 vaccination in 2023 aligns with the typical pattern observed after the introduction of a new vaccine, where an initial increase in AEFI reporting is followed by a return to baseline levels. Similar trends were seen during the early rollout of the HPV vaccine.[37, 38] Additionally, in 2023, fewer people were recommended a COVID-19 vaccine[31] resulting in both a decrease in the number of doses administered and AEFI reported.[28, 30]

The AEFI rate per 100,000 doses for non-COVID-19 vaccines in 2023 (22.0 [95%CI 21.3, 22.7] per 100,000 doses administered) was significantly higher than that of 2022 (18.8 [95% CI 18.2, 19.5] per 100,000 doses).[29] Increases were observed across most vaccines and age groups in 2023 compared to 2022. However, in non-COVID-19 vaccines the highest AEFI reports in each age group remained largely consistent with 2022, except for the ≥65 age group, where Zoster (RZV) replaced adjuvanted or high-dose influenza vaccines as the most frequently reported AEFI (Figures 3a–d, 4–7). This change was not unexpected due to the introduction RZV on the NIP in late 2022, replacing ZVL for adults aged ≥65 years and RZV is known to be more reactogenic than ZVL.[39] Reassuringly, the proportion of serious AEFI reported for RZV in 2023 (14.8%) was lower than that of 2022 (27.8%),[29] and aligned with clinical trial findings, where the pooled incidence of serious adverse event was 10.1% (95%CI 9.6, 10.6).[40]

The higher rates observed in 2023 for non-COVID vaccines may be attributed to the increased AEFI reporting practices following the COVID-19 era (increasing the numerator).[41, 42] Additionally, fewer reports of unspecified vaccines were observed in 2023 compared to 2022, reducing the number of AEFI reports without corresponding dose count denominators from the AIR.[29] This allowed for more reliable reporting rate calculations per 100,000 doses, resulting in a higher dose-based rate in 2023.

“Medication error” was the most frequently reported AEFI in 2023, accounting for 23.1% of all AEFI reports, which was higher than that of 2022 (18.6% [2nd] among all non-COVID-19 AEFI reports, and 7.6% [10th] among COVID-19 AEFI reports). Most “medication error” reports did not include accompanying adverse event reports (89.5%) and were not classified as serious, suggesting that these errors did not result in adverse outcomes at the time of reporting or later. Previously submitted reports can be updated as new information emerges, and health professionals are encouraged to do so. State and territory health departments investigate and address vaccination errors as needed. The increase in both the number and proportion of vaccination error reports may reflect greater awareness among health professionals of importance of acknowledging and reporting errors, leading to more frequent reporting to the TGA.[41, 42]

Alternatively, as the two groups of vaccines that were the most frequently administered vaccines also had the higher error rates, it is possible that challenges with the influenza and COVID vaccines brand selection and age-specific recommendations resulted in added complexity and errors in

administration.[43, 44] Importantly, immunisation provider education and training continues to be undertaken across a range of fora and modalities to reduce likelihood of immunisation errors.

The most commonly reported serious AEFI was “lack of efficacy/effect,” which was also the most frequently reported serious AEFI in 2022. These reports primarily originated from pharmaceutical sponsors, often based on consumer self-reports from social media channels monitored by the sponsor/s. In 2023, pharmaceutical companies also retrospectively submitted a large volume of serious AEFI reports of “lack of efficacy/effect” for multiple vaccines between 2000 and 2022, most commonly pneumococcal vaccines (13vPCV, 23vPPV, 7vPCV) and COVID-19 vaccines (Comirnaty, Spikevax, Vaxzevria). The influx of retrospective reports has skewed overall analyses of serious AEFI trends. It is important to recognise that no vaccine is 100% effective, therefore reports of “lack of efficacy/effect” are expected and do not inherently indicate a safety concern. Furthermore, most of these reports lacked sufficient clinical detail to confirm whether a clinically serious adverse event had occurred.

The most commonly reported AEFI included injection site reaction, pyrexia, gastrointestinal nonspecific symptoms, headache, myalgia/arthralgia, fatigue/lethargy. These findings were generally consistent with those from Australia’s national active participant-based surveillance system (AusVaxSafety).[45] Although differences in methodology between the TGA and AusVaxSafety preclude direct comparisons of rates, AusVaxSafety data has largely supported TGA’s spontaneous surveillance findings, indicating a high level of safety for NIP, influenza and COVID-19 vaccines, consistent with known profiles.

Of the AESIs examined for new vaccines and vaccine formulations introduced in 2023, it is reassuring that the most common AESI across all new vaccines were hypersensitivity reactions, none of which resulted in anaphylaxis. Finally, while there were reports of serious neurological conditions, the reporting rates of GBS for both COVID-19 vaccines and RZV remained within the expected background rate of the condition, estimated at 0.69 (95% CI, 0.38, 1.06) cases per million doses for mRNA vaccines[46] and 3.0 cases per million RZV doses (95% CI, 0.62, 5.64).[47]

The number of reports with fatal outcome declined in 2023 compared to 2022 following both COVID-19 (25 in 2023 and 160 in 2022)[28] and non-COVID-19 vaccines (9 in 2023 and 13 in 2022).[29] The majority of death reports came from pharmaceutical sponsors and contained minimal clinical information for verification.

Reporting of a death to the TGA does not mean that the vaccine caused the death, or that the individual completing the report considers that the death was caused by a vaccine. None of the deaths reported to the TGA in 2023 were determined to be causally related to the vaccines administered.

The TGA strongly encourages consumers and health professionals to report suspected adverse events, particularly serious or fatal events, regardless of the likelihood that the vaccine was the cause of an individuals’ death. All reports, including fatal reports, are de-identified and published in the Database of Adverse Event Notification (DAEN).[27] Publication of a report in the DAEN does not mean that the vaccine caused the adverse event. All reports of death are also included in the TGA safety monitoring data, even if a coroner or expert panel has concluded that the death is unrelated to vaccination.

Limitations

As with any spontaneous surveillance system, the TGA’s vaccine safety monitoring relies on adverse events being reported. Therefore, a limitation to this analysis is underreporting, which

means that AEFI reporting rates cannot be used as proxy for AEFI incidence rates.[8, 48] Reporting rates may also be affected by external factors, such as media or social media attention. AEFI reports may vary significantly in completeness and quality of information and are not always verified against verifiable clinical data. Each AEFI report may include multiple vaccines, vaccination dates, AEFI, and/or AEFI onset dates, making it difficult to directly associate specific vaccines with particular AEFI and/or AEFI onset dates. Additionally, seriousness criteria may be applied inconsistently by different reporters and therefore may not necessarily be a reliable guide to the safety profile of a vaccine.

In addition, vaccination data from the AIR, used to calculate AEFI rates per 100,000 vaccine doses, may not be comprehensive. The legal requirement for vaccination providers to report vaccines administered was only applicable to NIP, influenza, COVID-19 and JE vaccines throughout 2023.[25] The AIR is also limited in its capture of demographic and clinical detail, meaning that it may not be possible to calculate dose-based AEFI reporting rates for specific subgroups.

Finally, it is important to note that the AEFI reported here are not necessarily causally related to vaccination. The TGA strongly encourages consumers and health professionals to report suspected adverse events, even if there is only a very small chance the event was caused by a vaccine.

Conclusion

Trends observed in spontaneous AEFI reporting in Australia in 2023 returned to pre-pandemic levels. Overall, the 2023 spontaneous AEFI reports demonstrate a high level of safety for vaccines, including for vaccines in the NIP schedule.

References

1. Council for International Organizations of Medical Sciences (CIOMS) c/o World Health Organization. *Definition and Application of Terms for Vaccine Pharmacovigilance: Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance*. 2012.
2. Therapeutic Goods Administration. Reporting adverse events, https://www.tga.gov.au/resources/resource/reference-material/reporting-adverse-events (2021, Accessed 2024).
3. World Health Organization. Global manual on surveillance of adverse events following immunization (revised). 2016.
4. Lawrence G, Menzies R, Burgess M, et al. Surveillance of adverse events following immunisation: Australia, 2000–2002. *Communicable Diseases Intelligence* 2003; 27: 307-323.
5. Glover C, Deng L, Larter C, et al. Surveillance of adverse events following immunisation in Australia annual report, 2021. *Communicable Diseases Intelligence* 2024; 48 24/06/2024. DOI: 10.33321/cdi.2024.48.1.
6. National Centre for Immunisation Research and Surveillance. History of immunisation in Australia, https://ncirs.org.au/health-professionals/history-immunisation-australia (2025, Accessed 2025).
7. Lawrence G, Boyd I, McIntyre P and Isaacs D. Surveillance of adverse events following immunisation: Australia 2002 to 2003. *Communicable Diseases Intelligence* 2004; 28: 324-338.
8. O'Moore M, Jones B, Hickie M, et al. National pharmacovigilance of seasonal influenza vaccines in Australia. *Medical Journal of Australia* 2024; 221: 178-181. DOI: doi.org/10.5694/mja2.52381.
9. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *Introductory Guide MedDRA Version 27.1*. 2024.
10. Medical Dictionary fo Regulatory Agencies. Standardised MedDRA Queries, https://www.meddra.org/standardised-meddra-queries (2024, Accessed 2025).
11. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *Introductory Guide for Standardised MedDRA Queries (SMQs) Version 27.1*. 2024.
12. Law B and Sturkenboom M. *D2.3.1 Tier 1 AESI: ICD-9/10-CM and MedDRA Codes*. 2020. Safety Platform for Emergency vACcines (SPEAC).
13. Law B, Huang W-T and Sturkenboom M. *AESI Case Definition Companion Guide: Anaphylaxis Version 2*. 2022. Safety Platform for Emergency vACcines (SPEAC).
14. Wise RP, Bonhoeffer J, Beeler J, et al. Thrombocytopenia: Case definition and guidelines for collection, analysis, and presentation of immunization safety data. *Vaccine* 2007; 25: 5717-5724. DOI: https://doi.org/10.1016/j.vaccine.2007.02.067.
15. Bonhoeffer J, Menkes J, Gold MS, et al. Generalized convulsive seizure as an adverse event following immunization: case definition and guidelines for data collection, analysis, and presentation. *Vaccine* 2004; 22: 557-562. DOI: https://doi.org/10.1016/j.vaccine.2003.09.008.
16. Tapiainen T, Prevots R, Izurieta HS, et al. Aseptic meningitis: Case definition and guidelines for collection, analysis and presentation of immunization safety data. *Vaccine* 2007; 25: 5793-5802. DOI: https://doi.org/10.1016/j.vaccine.2007.04.058.
17. Sejvar JJ, Kohl KS, Bilynsky R, et al. Encephalitis, myelitis, and acute disseminated encephalomyelitis (ADEM): Case definitions and guidelines for collection, analysis, and presentation of immunization safety data. *Vaccine* 2007; 25: 5771-5792. DOI: https://doi.org/10.1016/j.vaccine.2007.04.060.
18. Sejvar JJ, Kohl KS, Gidudu J, et al. Guillain–Barré syndrome and Fisher syndrome: Case definitions and guidelines for collection, analysis, and presentation of immunization safety data. *Vaccine* 2011; 29: 599-612. DOI: https://doi.org/10.1016/j.vaccine.2010.06.003.
19. Rath B, Gidudu JF, Anyoti H, et al. Facial nerve palsy including Bell's palsy: Case definitions and guidelines for collection, analysis, and presentation of immunisation safety data. *Vaccine* 2017; 35: 1972-1983. DOI: https://doi.org/10.1016/j.vaccine.2016.05.023.
20. Law B. *AESI Case Definition Companion Guide: Myocarditis and Pericarditis*. 2022. Safety Platform for Emergency vACcines (SPEAC).
21. World Health Organization. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update. 2021.

22. Therapeutic Goods Administration. Third Australian case of thrombosis likely linked to AstraZeneca ChAdOx1-S COVID-19 vaccine, https://www.tga.gov.au/news/safety-alerts/third-australian-case-thrombosis-likely-linked-astrazeneca-chadox1-s-covid-19-vaccine (2021, Accessed 2025).
23. Australian Bureau of Statistics. National, state and territory population, https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/jun-2023 (2023, Accessed 2024).
24. Services Australia. Australian Immunisation Register, https://www.servicesaustralia.gov.au/australian-immunisation-register (2024, accessed 2024).
25. Australian Government Department of Health and Aged Care. Mandatory reporting of Japanese encephalitis virus vaccines to the Australian Immunisation Register began on 21 December 2022, https://www.health.gov.au/news/mandatory-reporting-of-japanese-encephalitis-virus-vaccines-to-the-australian-immunisation-register-began-on-21-december-2022 (2023, Accessed 2024).
26. Hull B, Hendry A, Dey A, et al. *Annual Immunisation Coverage Report 2022*. 2023. National Centre for Immunisation Research and Surveillance.
27. Therapeutic Goods Administration. Database of Adverse Event Notifications., https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen (2023, Accessed 2024).
28. Huang Y, O'Moore M, Larter C, et al. [PLACEHOLDER] Surveillance of adverse events following immunisation in Australia, COVID-19 vaccines, 2022. *Communicable Diseases Intelligence* TBD.
29. Huang Y, O'Moore M, Larter C, et al. [PLACEHOLDER] Surveillance of adverse events following immunisation in Australia, 2022. *Communicable Diseases Intelligence* TBD.
30. Glover C, Deng L, Larter C, et al. Surveillance of adverse events following immunisation in Australia, COVID-19 vaccines, 2021. *Commun Dis Intell (2018)* 2024; 48 20240624. DOI: 10.33321/cdi.2024.48.2.
31. National Centre for Immunisation Research and Surveillance. Significant events in COVID-19 vaccination practice in Australia, https://ncirs.org.au/sites/default/files/2024-05/COVID-19_May%202024.pdf (2025, Accessed 2025).
32. Dey A, Wang H, Quinn H, et al. Surveillance of adverse events following immunisation in Australia annual report, 2020. *Commun Dis Intell (2018)* 2022; 46 20220721. DOI: 10.33321/cdi.2022.46.47.
33. Dey A, Wang H, Quinn H, et al. Surveillance of adverse events following immunisation in Australia annual report, 2019. *Commun Dis Intell (2018)* 2021; 45 20210430. DOI: 10.33321/cdi.2021.45.23.
34. Dey A, Wang H, Quinn H, et al. Surveillance of adverse events following immunisation in Australia: annual report, 2018. *Commun Dis Intell (2018)* 2020; 44 20200316. DOI: 10.33321/cdi.2020.44.12.
35. Dey A, Wang H, Quinn H, et al. Surveillance of adverse events following immunisation in Australia annual report, 2017. *Commun Dis Intell (2018)* 2019; 43 20190716. DOI: 10.33321/cdi.2019.43.29.
36. Hull B, Hendry A, Macartney K and Beard F. *Annual Immunisation Coverage Report 2023*. 2024.
37. Phillips A, Hickie M, Totterdell J, et al. Adverse events following HPV vaccination: 11 years of surveillance in Australia. *Vaccine* 2020; 38: 6038-6046. DOI: https://doi.org/10.1016/j.vaccine.2020.06.039.
38. Egoavil CM, Tuells J, Carreras JJ, et al. Trends of Adverse Events Following Immunization (AEFI) Reports of Human Papillomavirus Vaccine in the Valencian Community-Spain (2008-2018). *Vaccines (Basel)* 2020; 8 20200302. DOI: 10.3390/vaccines8010117.
39. Tricco AC, Zarin W, Cardoso R, et al. Efficacy, effectiveness, and safety of herpes zoster vaccines in adults aged 50 and older: systematic review and network meta-analysis. *Bmj* 2018; 363: k4029. 20181025. DOI: 10.1136/bmj.k4029.
40. López-Fauqued M, Campora L, Delannois F, et al. Safety profile of the adjuvanted recombinant zoster vaccine: Pooled analysis of two large randomised phase 3 trials. *Vaccine* 2019; 37: 2482-2493. 20190329. DOI: 10.1016/j.vaccine.2019.03.043.
41. Therapeutic Goods Administration - TGA. Therapeutic Goods Administration - TGA's Post October 5 2021. Facebook, 2021.

42. Therapeutic Goods Administration - TGA. Therapeutic Goods Administration - TGA's Post March 1 2022. Facebook, 2022.
43. ATAGI. ATAGI advice on seasonal influenza vaccines in 2023, https://www.health.gov.au/resources/publications/atagi-advice-on-seasonal-influenza-vaccines-in-2023?language=en (2023, 2025).
44. ATAGI. ATAGI Update on the COVID-19 Vaccination Program, https://www.health.gov.au/news/atagi-update-on-the-covid-19-vaccination-program (2023, 2025).
45. Australian Government Department of Health and Aged Care. *Vaccine safety in Australia AusVaxSafety – Summary report 2023*. 2024.
46. Censi S, Bisaccia G, Gallina S, et al. Guillain-Barré syndrome and COVID-19 vaccination: a systematic review and meta-analysis. *J Neurol* 2024; 271: 1063-1071. 20240117. DOI: 10.1007/s00415-024-12186-7.
47. Goud R, Lufkin B, Duffy J, et al. Risk of Guillain-Barré Syndrome Following Recombinant Zoster Vaccine in Medicare Beneficiaries. *JAMA Internal Medicine* 2021; 181: 1623-1630. DOI: 10.1001/jamainternmed.2021.6227.
48. Shimabukuro T, Nguyen M, Martin D and DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine* 2015; 33: 4398-4405. DOI: doi.org/10.1016/j.vaccine.2015.07.035.

Tables

Table 1. Vaccines listed as 'suspect' in reports of adverse events following immunisation (AEFI) in the Adverse Event Management System database in 2023 by age group

Age group	Vaccine	AEFI reports (n)[a]	Vaccine Doses[b,c]	Reporting rate per 100,000 doses (95% CI) - 2023	Reporting rate per 100,000 doses (95% CI) - 2022[d]
All age groups	All vaccines	5534	28,631,137	24.1 (23.5–24.8)	50.6 (49.9–51.3)
<5 years	13vPCV	494	792,615	62.3 (57–68.1)	56.2 (51.3–61.5)
	DTPa-HepB-IPV-Hib	466	770,323	60.8 (55.4–66.5)	47 (42.4–51.8)
	DTPa-HepB-IPV-Hib (Infanrix hexa)	*369*	*673,457*	*54.8 (49.3–60.7)*	*47 (42.4–51.8)*
	DTPa-HepB-IPV-Hib (Vaxelis)	*97*	*96,038*	*101 (81.9–123.2)*	*Vaccine not available*
	DTPa-IPV	365	255,999	142.6 (128.3–158)	111.3 (98.8–125)
	Rotavirus	323	480,980	67.2 (60–74.9)	50.7 (44.8–57.1)
	Influenza (seasonal - standard formulation)	302	472,330	63.9 (56.9–71.6)	41.7 (36.4–47.5)
	DTPa	287	293,382	97.8 (86.8–109.8)	77.1 (67.3–87.9)
	MMR	256	288,176	88.8 (78.3–100.4)	78.3 (68.7–89)
	Hib	247	289,846	85.2 (74.9–96.5)	72.4 (62.9–82.9)
	MMRV	240	290,664	82.6 (72.5–93.7)	75.5 (65.8–86.3)
	MenB	230	321,116	71.6 (62.7–81.5)	62.9 (54.2–72.5)
	MenACWY	227	302,249	75.1 (65.7–85.5)	59.9 (51.6–69)
	Tuberculosis	34	12,410	274 (189.8–382.6)	137.4 (73.2–234.8)
	Hepatitis A	30	38,093	78.8 (53.1–112.4)	67.6 (39.4–108.2)
	23vPPV	23	8,421	273.1 (173.2–409.5)	167.1 (89–285.5)
	Varicella	20	11,901	168.1 (102.7–259.4)	95.5 (45.8–175.6)
	Hepatitis B	17	24,235	70.1 (40.9–112.3)	81.3 (48.2–128.4)
	Typhoid	5	12,651	39.5 (12.8–92.2)	22 (2.7–79.5)
	Polio	4	4,464	89.6 (24.4–229.3)	43.9 (5.3–158.4)
	Japanese encephalitis (live)	3	2,153	139.3 (28.7–406.7)	42.3 (1.1–235.5)
5-11 years	Influenza (seasonal - standard formulation)	66	418,404	15.8 (12.2–20.1)	15.2 (12.2–18.7)
	COVID-19 (all brands)	41	28,814	142.3 (102.1–193)	81.8 (77.9–85.9)
	COVID-19 (Comirnaty)	*37*	*28,587*	*129.4 (91.1–178.4)*	*80.8 (76.9–84.8)*
	dTpa	8	4,830	165.6 (71.5–326.1)	103.8 (28.3–265.7)
	MenACWY	7	11,844	59.1 (23.8–121.7)	45.5 (12.4–116.4)
	DTPa-HepB-IPV-Hib	7	3,298	212.2 (85.4–436.8)	129.4 (42–301.8)
	23vPPV	6	2,880	208.3 (76.5–452.9)	340 (146.9–668.8)
	Hepatitis A	6	33,236	18.1 (6.6–39.3)	19.4 (4–56.8)
	Japanese encephalitis (live)	6	2,745	218.6 (80.3–475.1)	No AEFI reported
	DTPa-IPV	4	39,843	10 (2.7–25.7)	27.9 (13.4–51.2)
	Hepatitis B	4	7,043	56.8 (15.5–145.4)	31.7 (3.8–114.6)
	MenB	4	9,866	40.5 (11–103.8)	83 (26.9–193.5)
	13vPCV	3	1,618	185.4 (38.3–540.9)	67.1 (1.7–373.4)
	DTPa	3	4,427	67.8 (14–197.9)	80.3 (16.6–234.6)
	Typhoid	3	29,452	10.2 (2.1–29.8)	11.7 (1.4–42.2)
	MMR	2	5,408	37 (4.5–133.5)	36.4 (4.4–131.6)
	MMRV	2	4,870	41.1 (5–148.3)	46.3 (5.6–167)
	Typhoid-hepatitis A	2	2,655	75.3 (9.1–271.8)	346.6 (94.5–885.1)
	Varicella	2	4,856	41.2 (5–148.7)	No AEFI reported
	DT	1	2,371	42.2 (1.1–234.8)	No AEFI reported
	Hib	1	1,218	82.1 (2.1–456.6)	No AEFI reported
	Influenza (seasonal - high-dose or adjuvanted)	1	1,038	96.3 (2.4–535.6)	216.6 (44.7–631.7)
	Polio	1	3,950	25.3 (0.6–141)	No AEFI reported
	Yellow fever	1	1,785	56 (1.4–311.7)	No AEFI reported
12-17 years	dTpa	113	293,201	38.5 (31.8–46.3)	28 (22.2–35)
	HPV	108	289,340	37.3 (30.6–45.1)	29.6 (25.2–34.4)
	MenACWY	82	240,116	34.2 (27.2–42.4)	23.4 (17.7–30.4)
	COVID-19 (all brands)	46	28,570	161 (117.9–214.7)	107.1 (100.2–114.4)
	COVID-19 (Comirnaty)	*35*	*23,226*	*150.7 (105–209.5)*	*94.1 (87.4–101.1)*
	COVID-19 (Spikevax)	*11*	*4,136*	*266 (132.8–475.4)*	*296.8 (248.7–351.4)*
	Influenza (seasonal - standard formulation)	24	293,572	8.2 (5.2–12.2)	10.8 (7.9–14.3)
	MenB	22	36,368	60.5 (37.9–91.6)	93.4 (63.9–131.9)
	Hepatitis B	7	11,972	58.5 (23.5–120.4)	77 (33.2–151.6)
	MMR	5	5,866	85.2 (27.7–198.8)	17.8 (0.5–99.3)
	Hepatitis A	4	18,502	21.6 (5.9–55.3)	55.1 (15–140.9)
	Typhoid-hepatitis A	4	9,515	42 (11.5–107.6)	31.4 (0.8–174.6)
	23vPPV	3	1,570	191.1 (39.4–557.4)	528.6 (194.2–1147)
	Influenza (seasonal - high-dose or adjuvanted)	3	1,123	267.1 (55.1–778.7)	58.8 (1.5–326.9)
	Varicella	3	7,299	41.1 (8.5–120.1)	46.6 (9.6–136)
	Hepatitis A-hepatitis B	1	1,307	76.5 (1.9–425.5)	124.1 (3.1–689.3)
	MMRV	1	1,947	51.4 (1.3–285.8)	108.9 (13.2–392.9)
	Polio	1	6,341	15.8 (0.4–87.8)	No AEFI reported
	Rabies	1	4,044	24.7 (0.6–137.7)	No AEFI reported
	Typhoid	1	19,685	5.1 (0.1–28.3)	10.3 (0.3–57.5)
	Yellow fever	1	1,676	59.7 (1.5–332)	No AEFI reported
18-64 years	COVID-19 (all brands)	733	1,931,733	37.9 (35.2–40.8)	92.8 (91.1–94.6)
	COVID-19 (Comirnaty)	*457*	*1,324,806*	*34.5 (31.4–37.8)*	*85.1 (83.1–87)*
	COVID-19 (Spikevax)	*192*	*586,853*	*32.7 (28.3–37.7)*	*83.1 (79.6–86.7)*
	COVID-19 (Nuvaxovid)	*30*	*19,291*	*155.5 (104.9–221.9)*	*442.1 (412.4–473.3)*
	Influenza (seasonal - standard formulation)	414	4,643,642	8.9 (8.1–9.8)	7.2 (6.5–7.9)

	Influenza (seasonal - high-dose or adjuvanted)	145	46,352	312.8 (264–368)	75.6 (55.4–100.9)
	dTpa	111	723,194	15.3 (12.6–18.5)	9.7 (7.6–12.4)
	MVA-BN	64	25,839	247.7 (190.8–316.2)	609.8 (539.6–686.5)
	Zoster (RZV)	63	78,138	80.6 (62–103.1)	81 (55.1–115)
	Hepatitis B	48	256,540	18.7 (13.8–24.8)	9.9 (6.1–15.1)
	MMR	25	104,485	23.9 (15.5–35.3)	18.4 (10.7–29.4)
	Hepatitis A	23	89,068	25.8 (16.4–38.7)	9.4 (3–21.8)
	23vPPV	22	13,456	163.5 (102.5–247.4)	144 (85.4–227.5)
	Typhoid-hepatitis A	17	154,961	11 (6.4–17.6)	13.5 (6.2–25.6)
	Varicella	17	36,655	46.4 (27–74.2)	30.7 (14.7–56.5)
	DT	15	267,810	5.6 (3.1–9.2)	3.8 (1.7–7.6)
	MenB	13	14,718	88.3 (47–151)	60.6 (27.7–115)
	Hepatitis A-hepatitis B	12	52,033	23.1 (11.9–40.3)	10.1 (2.7–25.8)
	MenACWY	11	29,723	37 (18.5–66.2)	16.1 (4.4–41.2)
	Rabies	10	40,650	24.6 (11.8–45.2)	20.1 (5.5–51.4)
	DTPa-IPV	9	1,460	616.4 (282.3–1167)	387.9 (126.1–902.9)
	HPV	8	37,711	21.2 (9.2–41.8)	22.2 (10.1–42)
	Typhoid	8	135,296	5.9 (2.6–11.7)	7.4 (2.7–16)
	Polio	6	31,363	19.1 (7–41.6)	13.2 (2.7–38.4)
	13vPCV	5	30,167	16.6 (5.4–38.7)	55.7 (31.9–90.5)
	Japanese encephalitis (live)	5	27,838	18 (5.8–41.9)	39 (23.1–61.7)
	MMRV	5	2,521	198.3 (64.4–462.2)	142.8 (29.5–416.7)
	Zoster (ZVL)	5	4,075	122.7 (39.9–286.1)	174.3 (92.8–297.8)
	Yellow fever	4	25,823	15.5 (4.2–39.7)	No AEFI reported
	DTPa	3	2,880	104.2 (21.5–304.1)	137.4 (44.6–320.4)
	Hib	2	3,223	62.1 (7.5–224)	No AEFI reported
	dTpa-IPV	2	12,746	15.7 (1.9–56.7)	17.5 (2.1–63.1)
	Japanese encephalitis (inactivated)	1	4,144	24.1 (0.6–134.4)	54.7 (1.4–304.2)
	Rotavirus	1	1,192	83.9 (2.1–466.5)	No AEFI reported
≥65 years	COVID-19 (all brands)	629	2,944,087	21.4 (19.7–23.1)	37.7 (36.2–39.3)
	COVID-19 (Comirnaty)	*391*	*2,131,417*	*18.3 (16.6–20.3)*	*34.7 (33.1–36.4)*
	COVID-19 (Spikevax)	*191*	*798,094*	*23.9 (20.7–27.6)*	*36.8 (33.5–40.4)*
	COVID-19 (Nuvaxovid)	*5*	*13,980*	*35.8 (11.6–83.4)*	*153 (121.1–190.6)*
	Influenza (seasonal - high-dose or adjuvanted)	175	3,079,542	5.7 (4.9–6.6)	5.9 (5.1–6.8)
	Zoster (RZV)	271	362,990	74.7 (66–84.1)	73.5 (54.7–96.6)
	Zoster (ZVL)	51	138,205	36.9 (27.5–48.5)	40.2 (31.7–50.1)
	13vPCV	45	312,321	14.4 (10.5–19.3)	20.5 (16.1–25.7)
	Influenza (seasonal - standard formulation)	45	210,450	21.4 (15.6–28.6)	18.2 (13.5–24)
	23vPPV	27	27,219	99.2 (65.4–144.3)	36.3 (18.1–64.9)
	dTpa	18	141,978	12.7 (7.5–20)	6.7 (2.9–13.2)
	DT	7	114,025	6.1 (2.5–12.6)	2.5 (0.3–8.9)
	Japanese encephalitis (live)	4	9,422	42.5 (11.6–108.7)	9.9 (2–28.9)
	Hepatitis B	3	24,312	12.3 (2.5–36.1)	No AEFI reported
	Polio	3	3,174	94.5 (19.5–276)	No AEFI reported
	MVA-BN	2	3,311	60.4 (7.3–218)	448.4 (231.9–782)
	MenACWY	2	4,947	40.4 (4.9–146)	29.6 (0.7–164.9)
	Typhoid	2	38,082	5.3 (0.6–19)	No AEFI reported
	Hepatitis A	1	11,969	8.4 (0.2–46.5)	No AEFI reported
	Hib	1	1,948	51.3 (1.3–285.7)	No AEFI reported
	MenB	1	3,261	30.7 (0.8–170.7)	No AEFI reported
	Rabies	1	4,842	20.7 (0.5–115)	No AEFI reported
	Typhoid-hepatitis A	1	28,304	3.5 (0.1–19.7)	12.8 (0.3–71.4)
	Yellow fever	1	3,453	29 (0.7–161.2)	No AEFI reported

[a] Number of AEFI reports in which the vaccine was coded as “suspected” of causal involvement in the reported adverse event and the vaccine was administered between 1 January and 31 December 2022. More than one vaccine may be coded as “suspected” if several were administered or reported at the same time.
[b] Number of vaccine doses administered between 1 January and 31 December 2022 and recorded on the Australian Immunisation Register as at 4 February 2024.
[c] Only vaccines with more than 1,000 doses administered in the respective age group in 2023 are included in the table.
[d] The number of AEFI reports for 2022 was obtained from the latest 2023 data, which included additional reports submitted in 2023 for vaccinations administered in 2022. As a result, the dose-based rate for 2022 in this table may differ from the figures published in the 2022 report.

Table 2. Adverse event following immunisation reports in the Adverse Event Management System database in 2023, by jurisdiction

Jurisdiction[a]	AEFI reports n (%)	Annual reporting rate per 100,000 population[b]						
		Overall (95% CI)[c]	Aged <5 years[d]	Aged 5-11 years[d]	Aged 12-17 years[d]	Aged 18-64 years[d]	Aged ≥65 years[d]	Serious AEFI[e]
ACT	89 (1.6)	19.1 (15.3–23.5)	68.1	10.0	37.1	12.8	21.9	1.5
NSW	1,004 (18.1)	12 (11.3–12.8)	45.4	1.8	8.7	7.0	17.0	3.5
NT	42 (0.8)	16.6 (12–22.5)	41.2	4.1	15.2	12.5	42.8	1.2
Qld	619 (11.2)	11.3 (10.5–12.3)	74.7	3.4	7.4	5.8	15.4	1.0
SA	284 (5.1)	15.3 (13.6–17.2)	65.5	2.7	22.9	8.0	25.4	0.9
Tas	220 (4)	38.4 (33.5–43.8)	159.3	20.2	19.5	23.5	59.7	2.3
Vic	2,042 (36.9)	30 (28.7–31.3)	255.6	10.6	20.5	11.4	28.1	1.6
WA	1,029 (18.6)	35.7 (33.6–38)	185.1	18.2	32.2	18.8	53.5	1.4
Unknown	205 (3.7)	-	-	-	-	-	-	-
Australia	5,534 (100)	20.8 (20.2–21.3)	124.9	6.8	15.7	9.9	25.9	2.6

[a] ACT: Australian Capital Territory; NSW: New South Wales; NT: Northern Territory; Qld: Queensland; SA: South Australia; Tas.: Tasmania; Vic: Victoria; WA: Western Australia.

[b] Average annual rates per 100,000 population calculated using June 2023 jurisdiction and total ERP estimates from the Australian Bureau of Statistics.

[c] 95% CI: 95% confidence interval.

[d] Includes only AEFI reports where an age or date of birth was reported.

[e] An adverse event report is defined as “serious” if it involves one or more of the following outcomes: (1) fatal or life-threatening condition(s); (2) new or prolonged hospitalisation; (3) persistent or significant disability; (4) congenital anomaly or birth defect; and (5) any medical event that requires an intervention to prevent the above outcomes. For AEFI reports submitted by sponsors (vaccine companies), the seriousness classification is applied by sponsors to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied by the TGA following review.

Table 3. Vaccines listed as "suspect" in reports of adverse events following immunisation in the Adverse Event Management System (AEMS) database in 2023

Vaccine[a]	AEFI reports n (%)[b]	Serious AEFI n (%)[c,e]	Age group n (%)[d,e]				
			<5 years	5-11 years	12-17 years	18-64 years	≥65 years
COVID-19 (Comirnaty)	1037 (18.7)	238 (23)	11 (1.1)	37 (3.6)	35 (3.4)	457 (44.1)	391 (37.7)
Influenza (seasonal - standard formulation)	905 (16.4)	82 (9.1)	302 (33.4)	66 (7.3)	24 (2.7)	414 (45.7)	45 (5)
13vPCV	556 (10)	46 (8.3)	494 (88.8)	3 (0.5)	1 (0.2)	5 (0.9)	45 (8.1)
DTPa-HepB-IPV-Hib	484 (8.7)	37 (7.6)	466 (96.1)	7 (1.4)	0 (0)	0 (0)	0 (0)
COVID-19 (Spikevax)	441 (8)	57 (12.9)	3 (0.7)	4 (0.9)	11 (2.5)	192 (43.5)	191 (43.3)
DTPa-IPV	386 (7)	8 (2.1)	365 (94.6)	4 (1)	2 (0.5)	9 (2.3)	1 (0.3)
Zoster (RZV)	372 (6.7)	55 (14.8)	0 (0)	0 (0)	1 (0.3)	63 (16.9)	271 (72.8)
Influenza (seasonal - high-dose or adjuvanted)	336 (6.1)	13 (3.9)	5 (1.5)	1 (0.3)	3 (0.9)	145 (43.2)	175 (52.1)
MenACWY	331 (6)	16 (4.8)	227 (68.6)	7 (2.1)	82 (24.8)	11 (3.3)	2 (0.6)
Rotavirus	327 (5.9)	37 (11.3)	323 (98.8)	0 (0)	0 (0)	1 (0.3)	0 (0)
DTPa	304 (5.5)	9 (3)	287 (94.4)	3 (1)	5 (1.6)	3 (1)	2 (0.7)
MMR	292 (5.3)	14 (4.8)	256 (87.7)	2 (0.7)	5 (1.7)	25 (8.6)	0 (0)
MenB	284 (5.1)	20 (7)	230 (81)	4 (1.4)	22 (7.7)	13 (4.6)	1 (0.4)
dTpa	274 (5)	4 (1.5)	19 (6.9)	8 (2.9)	113 (41.2)	111 (40.5)	18 (6.6)
Hib	251 (4.5)	8 (3.2)	247 (98.4)	1 (0.4)	0 (0)	2 (0.8)	1 (0.4)
MMRV	248 (4.5)	8 (3.2)	240 (96.8)	2 (0.8)	1 (0.4)	5 (2)	0 (0)
HPV	129 (2.3)	4 (3.1)	3 (2.3)	9 (7)	108 (83.7)	8 (6.2)	0 (0)
Hepatitis B	84 (1.5)	10 (11.9)	17 (20.2)	4 (4.8)	7 (8.3)	48 (57.1)	3 (3.6)
23vPPV	81 (1.5)	5 (6.2)	23 (28.4)	6 (7.4)	3 (3.7)	22 (27.2)	27 (33.3)
COVID-19 Vaccine (unspecified)	72 (1.3)	59 (81.9)	0 (0)	0 (0)	0 (0)	30 (41.7)	23 (31.9)
MVA-BN	66 (1.2)	2 (3)	0 (0)	0 (0)	0 (0)	64 (97)	2 (3)
Hepatitis A	65 (1.2)	2 (3.1)	30 (46.2)	6 (9.2)	4 (6.2)	23 (35.4)	1 (1.5)
Zoster (ZVL)	61 (1.1)	1 (1.6)	0 (0)	1 (1.6)	2 (3.3)	5 (8.2)	51 (83.6)
COVID-19 (Vaxzevria)	53 (1)	44 (83)	0 (0)	0 (0)	0 (0)	24 (45.3)	19 (35.8)
Zoster (unspecified)	47 (0.8)	47 (100)	0 (0)	0 (0)	0 (0)	3 (6.4)	1 (2.1)
Varicella	45 (0.8)	2 (4.4)	20 (44.4)	2 (4.4)	3 (6.7)	17 (37.8)	0 (0)
Tuberculosis	39 (0.7)	4 (10.3)	34 (87.2)	2 (5.1)	0 (0)	1 (2.6)	2 (5.1)
COVID-19 (Nuvaxovid)	36 (0.7)	12 (33.3)	0 (0)	0 (0)	0 (0)	30 (83.3)	5 (13.9)
Q Fever	30 (0.5)	27 (90)	0 (0)	0 (0)	0 (0)	3 (10)	0 (0)
DT	26 (0.5)	2 (7.7)	1 (3.8)	1 (3.8)	0 (0)	15 (57.7)	7 (26.9)
Typhoid-hepatitis A	25 (0.5)	2 (8)	1 (4)	2 (8)	4 (16)	17 (68)	1 (4)
Japanese encephalitis (live)	19 (0.3)	3 (15.8)	3 (15.8)	6 (31.6)	0 (0)	5 (26.3)	4 (21.1)
Typhoid	19 (0.3)	1 (5.3)	5 (26.3)	3 (15.8)	1 (5.3)	8 (42.1)	2 (10.5)
Polio	15 (0.3)	1 (6.7)	4 (26.7)	1 (6.7)	1 (6.7)	6 (40)	3 (20)
Hepatitis A-hepatitis B	14 (0.3)	0 (0)	0 (0)	0 (0)	1 (7.1)	12 (85.7)	0 (0)
Rabies	12 (0.2)	0 (0)	0 (0)	0 (0)	1 (8.3)	10 (83.3)	1 (8.3)
Pneumococcal (unspecified)	9 (0.2)	1 (11.1)	8 (88.9)	0 (0)	0 (0)	0 (0)	0 (0)
Yellow fever	7 (0.1)	3 (42.9)	0 (0)	1 (14.3)	1 (14.3)	4 (57.1)	1 (14.3)
DTP	6 (0.1)	0 (0)	2 (33.3)	0 (0)	1 (16.7)	2 (33.3)	1 (16.7)
Pertussis	6 (0.1)	3 (50)	1 (16.7)	0 (0)	0 (0)	3 (50)	0 (0)
Hib-HepB	4 (0.1)	1 (25)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Tetanus	3 (0.1)	2 (66.7)	0 (0)	0 (0)	0 (0)	1 (33.3)	0 (0)
Japanese encephalitis (inactivated)	2 (0.04)	0 (0)	1 (50)	0 (0)	0 (0)	1 (50)	0 (0)
dTpa-IPV	2 (0.04)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)
Cholera	1 (0.02)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)
DTPa-HepB	1 (0.02)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)
DTPa-HepB-Hib	1 (0.02)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)

[a] See abbreviations for vaccine names.
[b] Number of AEFI reports in which the vaccine was coded as 'suspected' of causal involvement in the reported adverse event and the vaccination was administered between 1 January and 31 December 2023. More than one vaccine may be coded as 'suspected' if several were administered or reported at the same time.
[c] An adverse event report is defined as "serious" if it involves one or more of the following outcomes: (1) fatal or life-threatening condition(s); (2) new or prolonged hospitalisation; (3) persistent or significant disability; (4) congenital anomaly or birth defect; and (5) any medical event that requires an intervention to prevent the above outcomes. For AEFI reports submitted by sponsors (vaccine companies), the seriousness classification is applied by sponsors to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied by the TGA following review.
[d] Includes only AEFI reports where an age or date of birth has been reported.
[e] Percentages are calculated for the number of AEFI reports where the vaccine was suspected of causal involvement in the event.

Table 4. The 50 most frequently reported adverse events classified by MedDRA Preferred Terms or Standardised MedDRA queries in reports of adverse events following immunisation in the Adverse Event Management System database in 2023

PT or SMQ	AEFI reports n (%)[a]	Serious AEFI n (%)[b,d]	Age group n (%)[cd]				
			<5 years	5-11 years	12-17 years	18-64 years	≥65 years
Medication errors	1278 (23.1)	14 (1.1)	468 (36.6)	59 (4.6)	83 (6.5)	390 (30.5)	230 (18)
Injection site reaction	925 (16.7)	9 (1)	449 (48.5)	27 (2.9)	34 (3.7)	193 (20.9)	200 (21.6)
Hypersensitivity	904 (16.3)	69 (7.6)	458 (50.7)	24 (2.7)	43 (4.8)	194 (21.5)	144 (15.9)
Pyrexia	748 (13.5)	59 (7.9)	375 (50.1)	20 (2.7)	52 (7)	171 (22.9)	114 (15.2)
Gastrointestinal nonspecific symptoms and therapeutic procedures	701 (12.7)	59 (8.4)	246 (35.1)	24 (3.4)	59 (8.4)	201 (28.7)	152 (21.7)
Headache	511 (9.2)	24 (4.7)	23 (4.5)	14 (2.7)	66 (12.9)	241 (47.2)	148 (29)
Myalgia	381 (6.9)	16 (4.2)	30 (7.9)	11 (2.9)	31 (8.1)	173 (45.4)	119 (31.2)
Fatigue	367 (6.6)	13 (3.5)	73 (19.9)	11 (3)	31 (8.4)	139 (37.9)	104 (28.3)
Haemodynamic oedema, effusions and fluid overload	273 (4.9)	18 (6.6)	128 (46.9)	9 (3.3)	10 (3.7)	67 (24.5)	52 (19)
Lethargy	266 (4.8)	26 (9.8)	85 (32)	6 (2.3)	30 (11.3)	81 (30.5)	61 (22.9)
Arthralgia	260 (4.7)	8 (3.1)	15 (5.8)	5 (1.9)	17 (6.5)	128 (49.2)	91 (35)
Pain in extremity	230 (4.2)	11 (4.8)	19 (8.3)	6 (2.6)	12 (5.2)	114 (49.6)	68 (29.6)
Lack of efficacy/effect	167 (3)	158 (94.6)	2 (1.2)	0 (0)	0 (0)	50 (29.9)	43 (25.7)
Dizziness	164 (3)	12 (7.3)	3 (1.8)	3 (1.8)	39 (23.8)	69 (42.1)	44 (26.8)
Injection site pain	164 (3)	6 (3.7)	14 (8.5)	8 (4.9)	17 (10.4)	72 (43.9)	48 (29.3)
Malaise	163 (2.9)	15 (9.2)	11 (6.7)	3 (1.8)	12 (7.4)	72 (44.2)	55 (33.7)
Dyspnoea	157 (2.8)	25 (15.9)	26 (16.6)	5 (3.2)	13 (8.3)	77 (49)	30 (19.1)
Cough	145 (2.6)	12 (8.3)	63 (43.4)	4 (2.8)	16 (11)	35 (24.1)	26 (17.9)
Chills	142 (2.6)	9 (6.3)	17 (12)	6 (4.2)	9 (6.3)	57 (40.1)	51 (35.9)
Oropharyngeal conditions (excl neoplasms, infections and allergies)	141 (2.5)	18 (12.8)	14 (9.9)	4 (2.8)	12 (8.5)	68 (48.2)	38 (27)
Syncope	134 (2.4)	14 (10.4)	15 (11.2)	6 (4.5)	44 (32.8)	35 (26.1)	30 (22.4)
Angioedema	128 (2.3)	8 (6.2)	41 (32)	6 (4.7)	6 (4.7)	48 (37.5)	22 (17.2)
Convulsions	122 (2.2)	28 (23)	80 (65.6)	8 (6.6)	13 (10.7)	14 (11.5)	5 (4.1)
Chest pain	113 (2)	30 (26.5)	1 (0.9)	1 (0.9)	5 (4.4)	69 (61.1)	28 (24.8)
Herpes zoster	110 (2)	65 (59.1)	0 (0)	0 (0)	0 (0)	20 (18.2)	37 (33.6)
Irritability	107 (1.9)	8 (7.5)	101 (94.4)	0 (0)	2 (1.9)	2 (1.9)	1 (0.9)
Injection site erythema	104 (1.9)	1 (1)	63 (60.6)	4 (3.8)	2 (1.9)	20 (19.2)	12 (11.5)
Paraesthesia	101 (1.8)	12 (11.9)	1 (1)	0 (0)	5 (5)	68 (67.3)	22 (21.8)
Lymphadenopathy	97 (1.8)	5 (5.2)	14 (14.4)	2 (2.1)	3 (3.1)	62 (63.9)	12 (12.4)
COVID-19	85 (1.5)	73 (85.9)	1 (1.2)	0 (0)	0 (0)	34 (40)	36 (42.4)
Erythema	84 (1.5)	2 (2.4)	48 (57.1)	0 (0)	3 (3.6)	18 (21.4)	13 (15.5)
Influenza like illness	84 (1.5)	7 (8.3)	11 (13.1)	2 (2.4)	4 (4.8)	39 (46.4)	25 (29.8)
Haemorrhage terms (excl laboratory terms)	81 (1.5)	8 (9.9)	30 (37)	0 (0)	3 (3.7)	24 (29.6)	19 (23.5)
Decreased appetite	79 (1.4)	5 (6.3)	42 (53.2)	3 (3.8)	3 (3.8)	15 (19)	13 (16.5)
Pruritus	79 (1.4)	1 (1.3)	11 (13.9)	0 (0)	5 (6.3)	41 (51.9)	21 (26.6)
Shoulder injury related to vaccine administration	75 (1.4)	8 (10.7)	0 (0)	0 (0)	0 (0)	58 (77.3)	11 (14.7)
Pain	72 (1.3)	18 (25)	14 (19.4)	1 (1.4)	2 (2.8)	27 (37.5)	20 (27.8)
Pallor	66 (1.2)	8 (12.1)	38 (57.6)	4 (6.1)	15 (22.7)	7 (10.6)	1 (1.5)
Palpitations	65 (1.2)	12 (18.5)	0 (0)	0 (0)	3 (4.6)	42 (64.6)	17 (26.2)
Non-infectious myocarditis/pericarditis	61 (1.1)	46 (75.4)	0 (0)	0 (0)	5 (8.2)	35 (57.4)	8 (13.1)
Hyperhidrosis	57 (1)	8 (14)	3 (5.3)	1 (1.8)	2 (3.5)	31 (54.4)	19 (33.3)
Injection site mass	50 (0.9)	2 (4)	20 (40)	2 (4)	1 (2)	15 (30)	9 (18)
Chest discomfort	49 (0.9)	8 (16.3)	0 (0)	1 (2)	3 (6.1)	37 (75.5)	8 (16.3)
Hypotonic-hyporesponsive episode	48 (0.9)	7 (14.3)	49 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Tremor	46 (0.8)	3 (6.5)	8 (17.4)	0 (0)	3 (6.5)	20 (43.5)	14 (30.4)
Hypertension	45 (0.8)	12 (26.7)	0 (0)	1 (2.2)	0 (0)	23 (51.1)	17 (37.8)
Somnolence	45 (0.8)	4 (8.9)	28 (62.2)	1 (2.2)	0 (0)	8 (17.8)	8 (17.8)
Tachycardia	39 (0.7)	13 (33.3)	10 (25.6)	0 (0)	5 (12.8)	19 (48.7)	3 (7.7)
Crying	38 (0.7)	2 (5.3)	38 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Asthenia	37 (0.7)	7 (18.9)	0 (0)	0 (0)	2 (5.4)	14 (37.8)	18 (48.6)

[a] Number of AEFI reports in which the PT or SMQ was reported. More than one PT/SMQ may be recorded on the same report.
[b] An adverse event report is defined as "serious" if it involves one or more of the following outcomes: (1) fatal or life-threatening condition(s); (2) new or prolonged hospitalisation; (3) persistent or significant disability; (4) congenital anomaly or birth defect; and (5) any medical event that requires an intervention to prevent the above outcomes. For AEFI reports submitted by sponsors (vaccine companies), the seriousness classification is applied by sponsors to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied by the TGA following review.
[c] Includes only AEFI reports where an age or date of birth has been reported.
[d] Percentages are calculated for the number of AEFI reports where the PT or SMQ was reported.

Table 5. Adverse event of special interest reports in the Adverse Event Management System database for newly introduced vaccines in 2023

Vaccine	AEFI reports (n)	Vaccine Doses	Reporting rate per 100,000 doses (95% CI) - 2023	AESI n (serious reports)					
				Anaphylaxis		Generalised convulsion	Guillain Barré Syndrome and Miller Fisher Syndrome	Peripheral facial nerve palsy	Noninfectious myocarditis/pericarditis
				Angio-edema	*Hyper-sensitivity*	*Seizures*	*Guillain-Barre syndrome*	*Facial paralysis*	*Myocarditis/pericarditis*
COVID-19 (Comirnaty)[a]	1037	3,508,549	29.6 (27.8-31.4)	24 (4)	83 (9)	11 (3)	3 (2)	4 (1)	27 (21)
COVID-19 (Spikevax)[a]	441	1,389,644	31.7 (28.8-34.8)	10 (1)	39 (3)	1 (1)	2 (2)	0 (0)	13 (11)
DTPa-HepB-IPV-Hib (Vaxelis)	97	96,038	101 (81.9–123.2)	4 (0)	33 (0)	3 (2)	0 (0)	0 (0)	0 (0)
RZV (Shingrix)	372	441,138	84.3 (76.0-93.3)	9 (0)	77 (8)	2 (0)	1 (1)	2 (1)	2 (0)

[a] Comirnaty and Spikevax vaccines may include ancestral strains as we were unable to accurately differentiate these in all reports. However, Comirnaty bivalent vaccines were used from 08/02/2023 and bivalent Spikevax vaccines were used from 24/02/2023 in Australia.

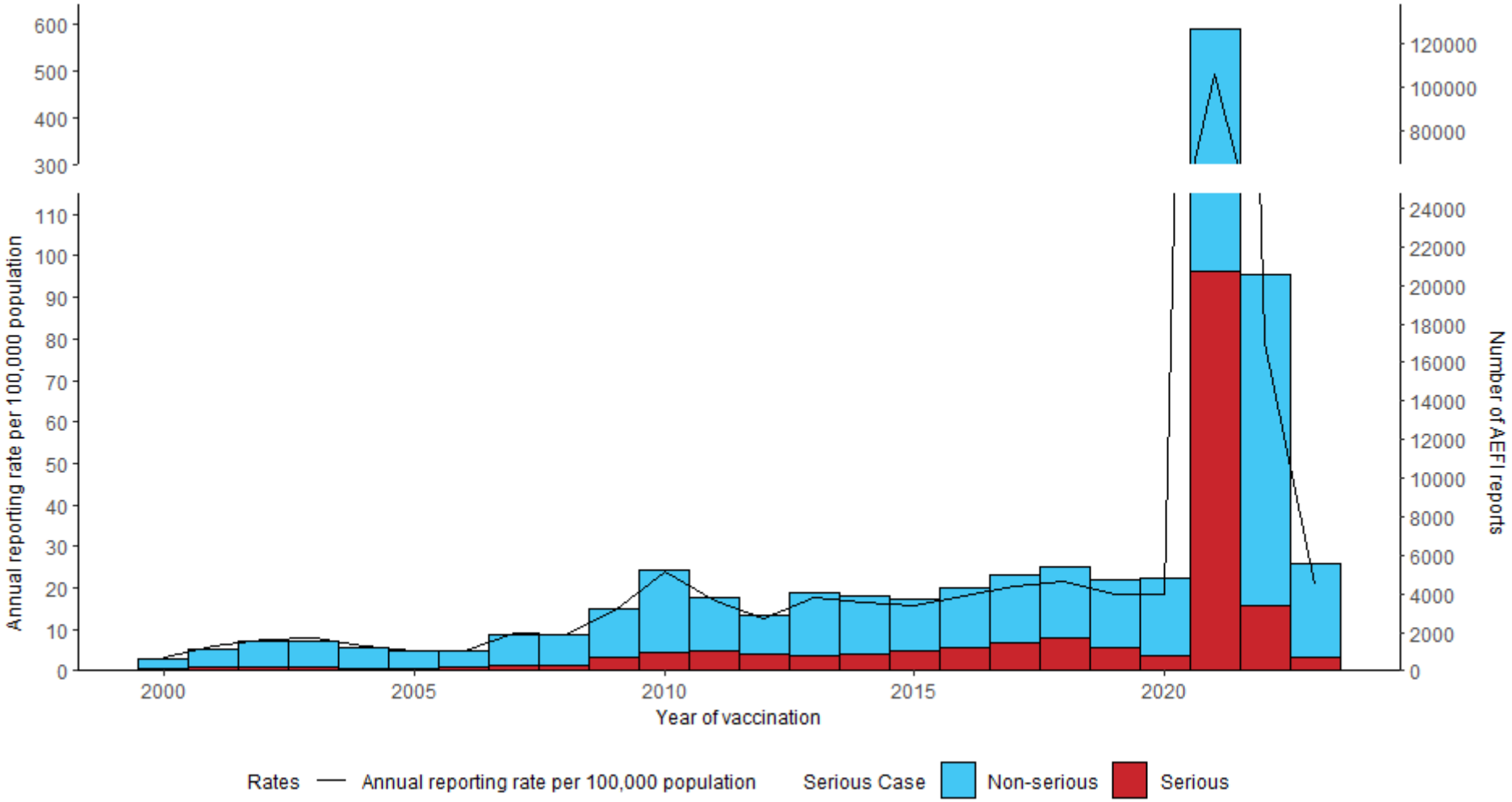
Table 6. The 10 most frequently reported adverse events following immunisation classified by MedDRA Preferred Terms or Standardised MedDRA queries in the Adverse Event Management System database for newly introduced vaccines in 2023

Vaccine	PT or SMQ	AEFI reports[a] n (%)	Serious AEFI[b,d] n (%)	Age group[c,d] n (%)				
				<5 years	5-11 years	12-17 years	18-64 years	≥65 years
COVID-19 (Comirnaty)[e]	Medication errors	177 (3.2)	5 (2.8)	7 (4)	30 (16.9)	22 (12.4)	52 (29.4)	56 (31.6)
	Headache	151 (2.7)	9 (6)	0 (0)	0 (0)	2 (1.3)	89 (58.9)	51 (33.8)
	Gastrointestinal nonspecific symptoms and therapeutic procedures	145 (2.6)	13 (9)	4 (2.8)	1 (0.7)	3 (2.1)	74 (51)	53 (36.6)
	Myalgia	124 (2.2)	5 (4)	0 (0)	0 (0)	2 (1.6)	69 (55.6)	46 (37.1)
	Fatigue	101 (1.8)	6 (5.9)	0 (0)	1 (1)	1 (1)	58 (57.4)	39 (38.6)
	Pyrexia	93 (1.7)	10 (10.8)	3 (3.2)	2 (2.2)	3 (3.2)	56 (60.2)	27 (29)
	Arthralgia	85 (1.5)	3 (3.5)	0 (0)	0 (0)	1 (1.2)	50 (58.8)	33 (38.8)
	Hypersensitivity	83 (1.5)	9 (10.8)	1 (1.2)	1 (1.2)	2 (2.4)	46 (55.4)	28 (33.7)
	Injection site reaction	78 (1.4)	1 (1.3)	1 (1.3)	0 (0)	0 (0)	45 (57.7)	27 (34.6)
	Lack of efficacy/effect	78 (1.4)	76 (97.4)	0 (0)	0 (0)	0 (0)	33 (42.3)	32 (41)
COVID-19 (Spikvax)[e]	Medication errors	107 (1.9)	0 (0)	0 (0)	4 (3.7)	10 (9.3)	37 (34.6)	44 (41.1)
	Headache	80 (1.4)	4 (5)	0 (0)	0 (0)	0 (0)	49 (61.3)	28 (35)
	Pyrexia	74 (1.3)	4 (5.4)	2 (2.7)	1 (1.4)	0 (0)	37 (50)	30 (40.5)
	Gastrointestinal nonspecific symptoms and therapeutic procedures	67 (1.2)	5 (7.5)	1 (1.5)	1 (1.5)	0 (0)	36 (53.7)	26 (38.8)
	Myalgia	50 (0.9)	3 (6)	0 (0)	0 (0)	0 (0)	28 (56)	20 (40)
	Fatigue	46 (0.8)	3 (6.5)	0 (0)	0 (0)	0 (0)	22 (47.8)	21 (45.7)
	Arthralgia	41 (0.7)	2 (4.9)	0 (0)	0 (0)	0 (0)	18 (43.9)	23 (56.1)
	Hypersensitivity	39 (0.7)	3 (7.7)	1 (2.6)	0 (0)	0 (0)	21 (53.8)	15 (38.5)
	Injection site reaction	39 (0.7)	2 (5.1)	0 (0)	0 (0)	0 (0)	20 (51.3)	18 (46.2)
	Pain in extremity	28 (0.5)	1 (3.6)	0 (0)	0 (0)	0 (0)	19 (67.9)	8 (28.6)
DTPa-HepB-IPV-Hib (Vaxelis)	Hypersensitivity	33 (0.6)	0 (0)	32 (97)	0 (0)	0 (0)	0 (0)	0 (0)
	Pyrexia	27 (0.5)	2 (7.4)	25 (92.6)	1 (3.7)	0 (0)	0 (0)	0 (0)
	Gastrointestinal nonspecific symptoms and therapeutic procedures	25 (0.5)	0 (0)	25 (100)	0 (0)	0 (0)	0 (0)	0 (0)
	Medication errors	15 (0.3)	0 (0)	13 (86.7)	1 (6.7)	0 (0)	0 (0)	0 (0)
	Hypotonic-hyporesponsive episode	13 (0.2)	0 (0)	13 (100)	0 (0)	0 (0)	0 (0)	0 (0)
	Injection site reaction	12 (0.2)	0 (0)	11 (91.7)	1 (8.3)	0 (0)	0 (0)	0 (0)
	Lethargy	10 (0.2)	1 (10)	10 (100)	0 (0)	0 (0)	0 (0)	0 (0)
	Fatigue	9 (0.2)	0 (0)	8 (88.9)	1 (11.1)	0 (0)	0 (0)	0 (0)
	Irritability	9 (0.2)	1 (11.1)	9 (100)	0 (0)	0 (0)	0 (0)	0 (0)
	Crying	5 (0.1)	0 (0)	5 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Zoster (RZV) [Shingrix]	Injection site reaction	121 (2.2)	4 (3.3)	0 (0)	0 (0)	0 (0)	19 (15.7)	96 (79.3)
	Hypersensitivity	77 (1.4)	8 (10.4)	0 (0)	0 (0)	0 (0)	16 (20.8)	58 (75.3)
	Gastrointestinal nonspecific symptoms and therapeutic procedures	59 (1.1)	7 (11.9)	0 (0)	0 (0)	0 (0)	9 (15.3)	50 (84.7)
	Headache	55 (1)	1 (1.8)	0 (0)	0 (0)	0 (0)	8 (14.5)	44 (80)
	Pyrexia	52 (0.9)	6 (11.5)	0 (0)	0 (0)	0 (0)	10 (19.2)	39 (75)
	Herpes zoster	49 (0.9)	23 (46.9)	0 (0)	0 (0)	0 (0)	7 (14.3)	26 (53.1)
	Myalgia	45 (0.8)	1 (2.2)	0 (0)	0 (0)	0 (0)	7 (15.6)	33 (73.3)
	Fatigue	32 (0.6)	1 (3.1)	0 (0)	0 (0)	0 (0)	2 (6.2)	28 (87.5)
	Pain in extremity	31 (0.6)	2 (6.5)	0 (0)	0 (0)	0 (0)	4 (12.9)	25 (80.6)
	Injection site reaction	121 (2.2)	4 (3.3)	0 (0)	0 (0)	0 (0)	19 (15.7)	96 (79.3)
	Malaise	29 (0.5)	3 (10.3)	0 (0)	0 (0)	0 (0)	4 (13.8)	21 (72.4)

[a] Number of AEFI reports in which the PT or SMQ was reported. More than one PT/SMQ may be recorded on the same report.
[b] An adverse event report is defined as "serious" if it involves one or more of the following outcomes: (1) fatal or life-threatening condition(s); (2) new or prolonged hospitalisation; (3) persistent or significant disability; (4) congenital anomaly or birth defect; and (5) any medical event that requires an intervention to prevent the above outcomes. For AEFI reports submitted by sponsors (vaccine companies), the seriousness classification is applied by sponsors to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied by the TGA following review.
[c] Includes only AEFI reports where an age or date of birth has been reported.
[d] Percentages are calculated for the number of AEFI reports where the PT or SMQ was reported.
[e] Comirnaty and Spikevax vaccines may include ancestral strains as we were unable to accurately differentiate these in all reports. However, Comirnaty bivalent vaccines were used from 08/02/2023 and bivalent Spikevax vaccines were used from 24/02/2023 in Australia.

Figures

Figure 1. Adverse event following immunisation reports in the Adverse Event Management System database from 2000 to 2023, by year



For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1. Population data was sourced from ABS and represents the mid-year total Australian ERP for each calendar year.

Figure 2. Reporting rates of adverse events following immunisation per 100,000 population in the Adverse Event Management System database from 2000 to 2023, by year and age group

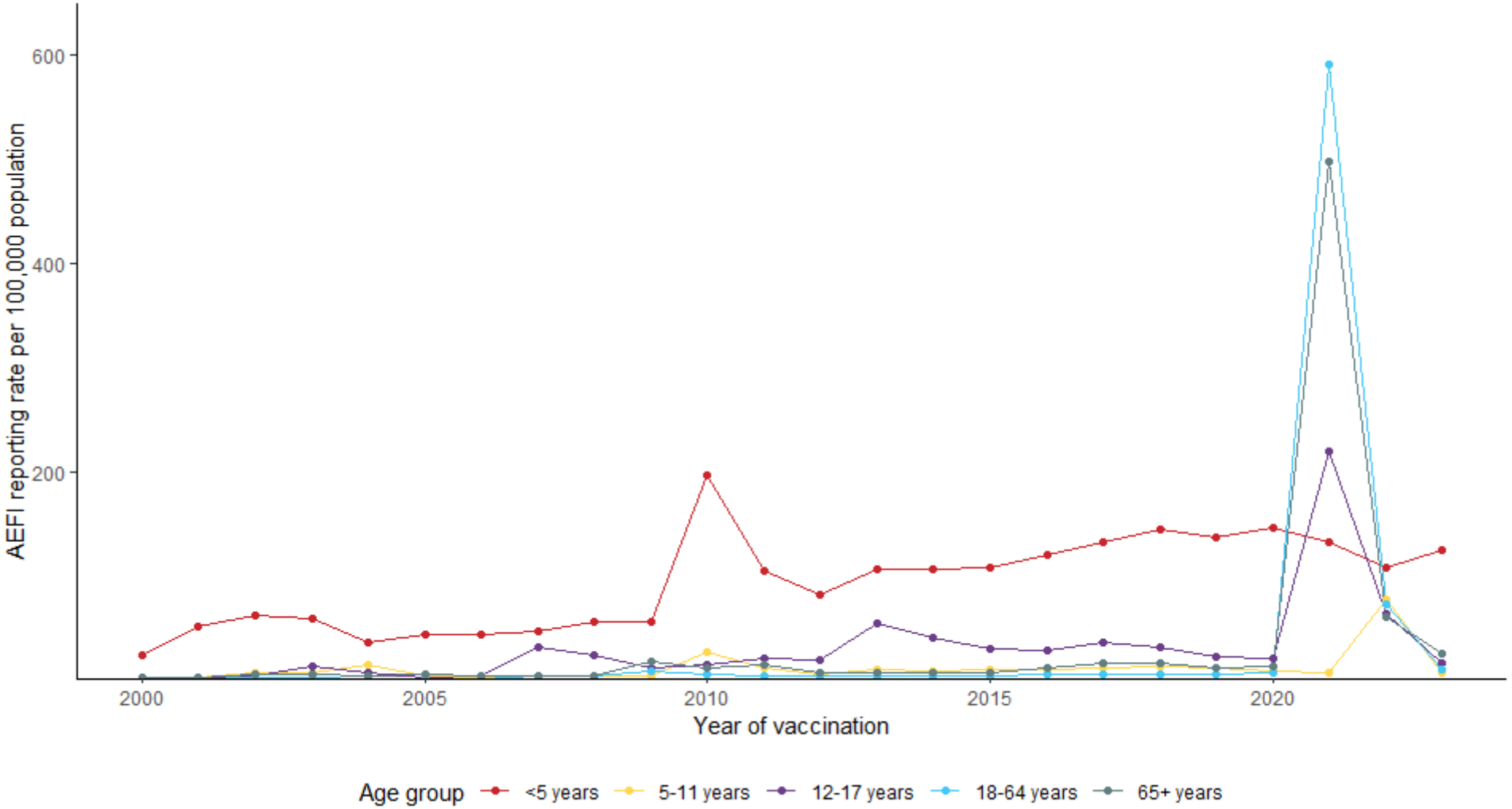


Figure 3a. Adverse event following immunisation reports for children aged <5 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines**), by year and vaccine - vaccines with first NIP-funded primary dose administered at under 6 months of age

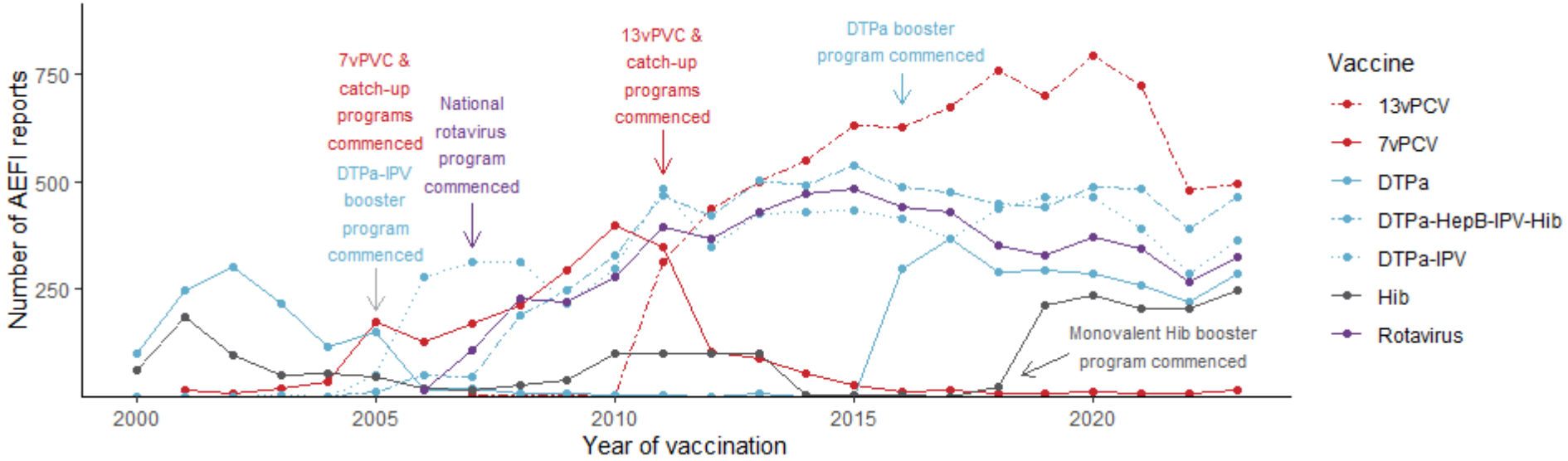


Figure 4b. Adverse event following immunisation reports for children aged <5 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines**), by year and vaccine - vaccines with first NIP-funded primary dose administered at or above 6 months of age

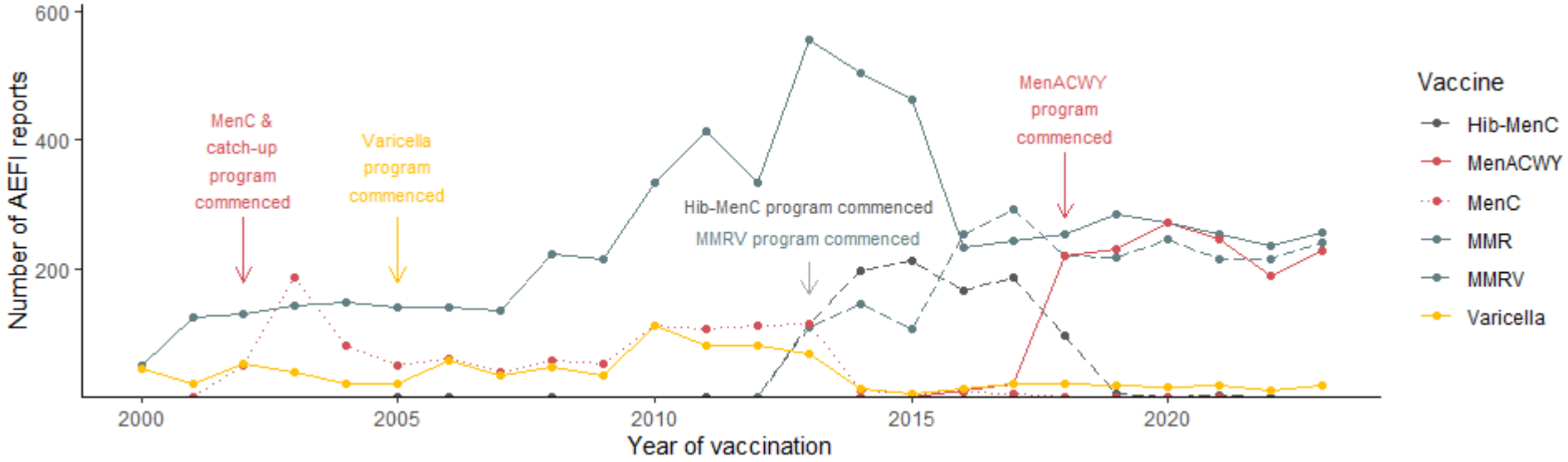


Figure 5c. Adverse event following immunisation reports for children aged <5 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines**), by year and vaccine - vaccines funded under NIP for specific population subgroups only

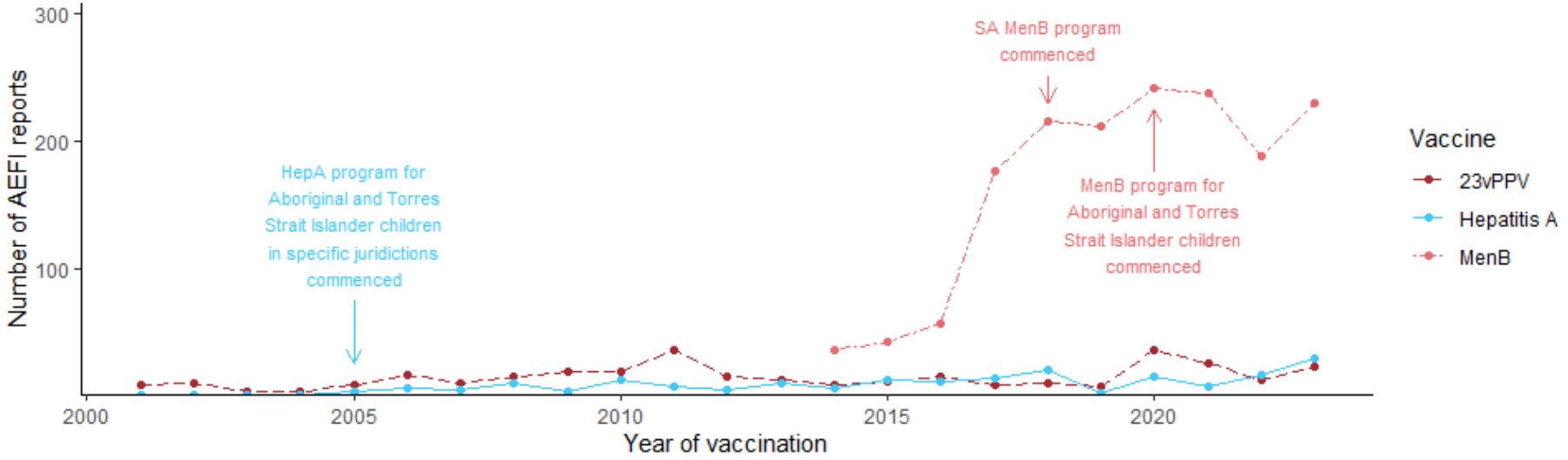


Figure 3d. Adverse event following immunisation reports for children aged <5 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines**), by year and vaccine - influenza vaccines

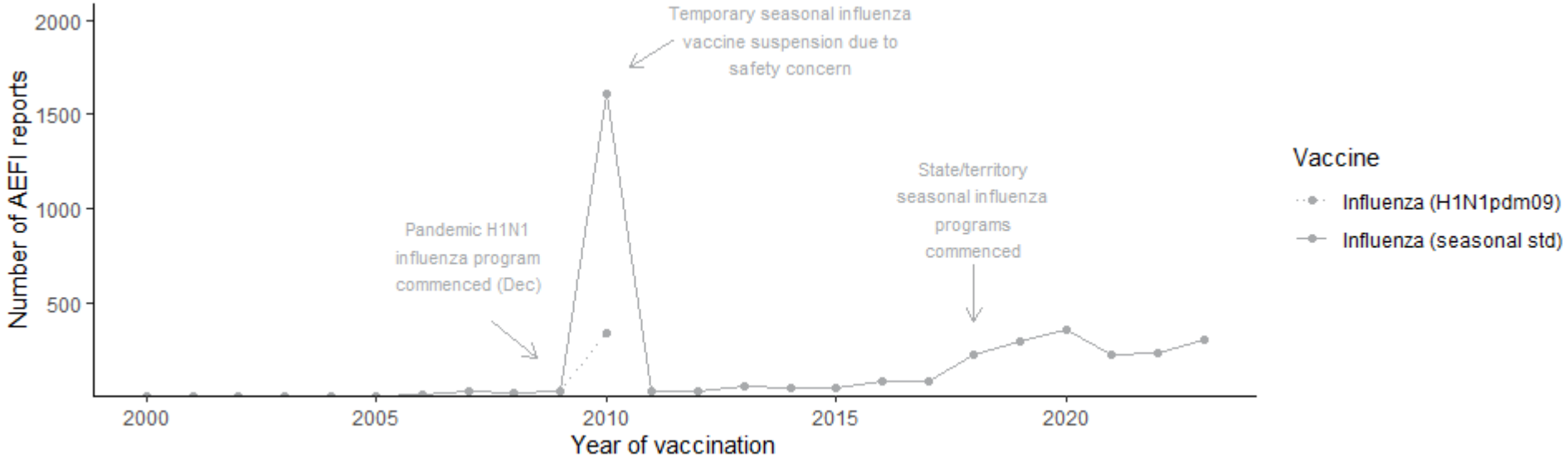


Figure 4. Adverse event following immunisation reports for people aged 5 to 11 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines only**), by year and vaccine

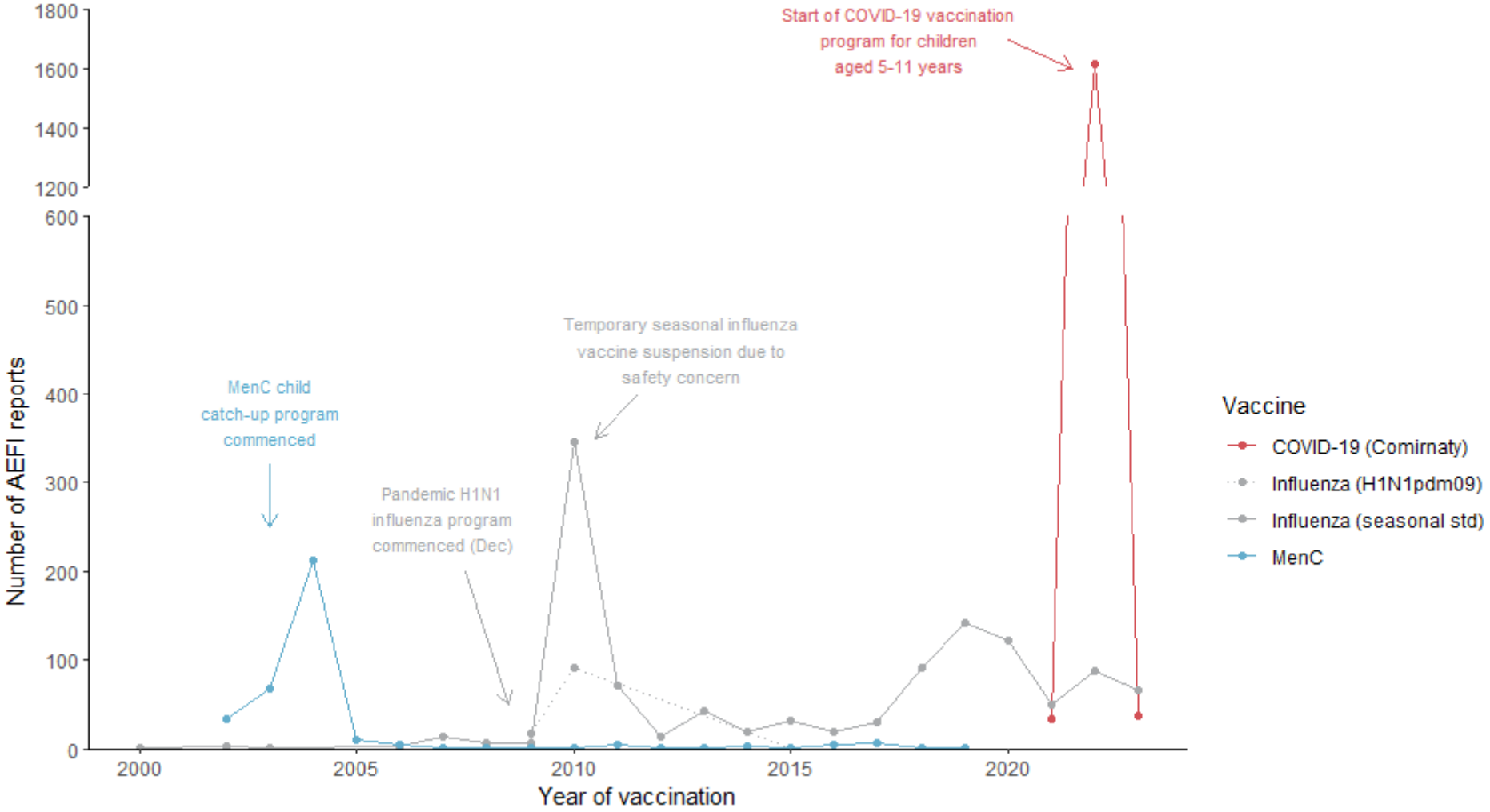


Figure 5. Adverse event following immunisation reports for people aged 12 to 17 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines only**), by year and vaccine

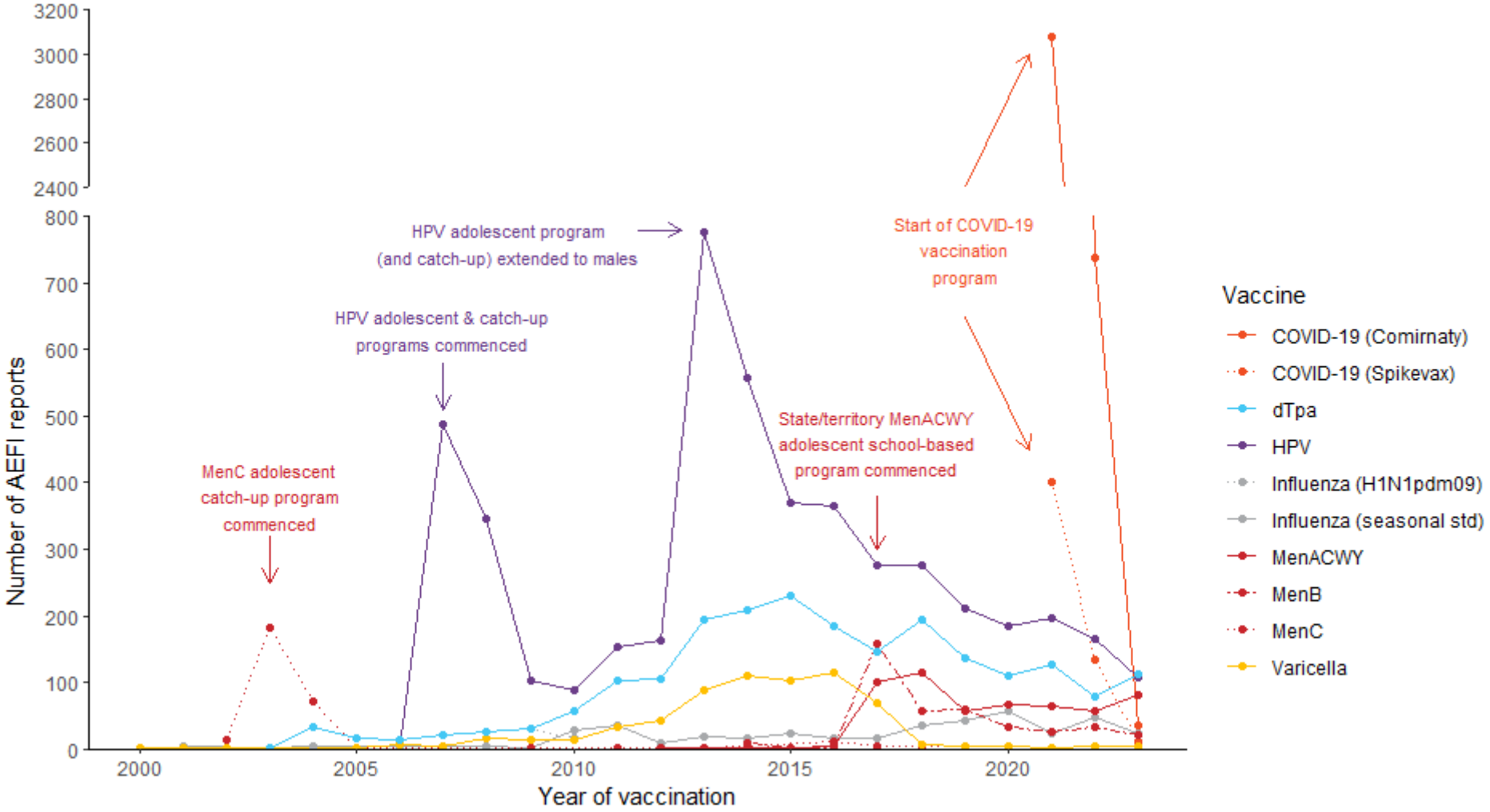


Figure 6. Adverse event following immunisation reports for people aged 18 to 64 years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines only**), by year and vaccine

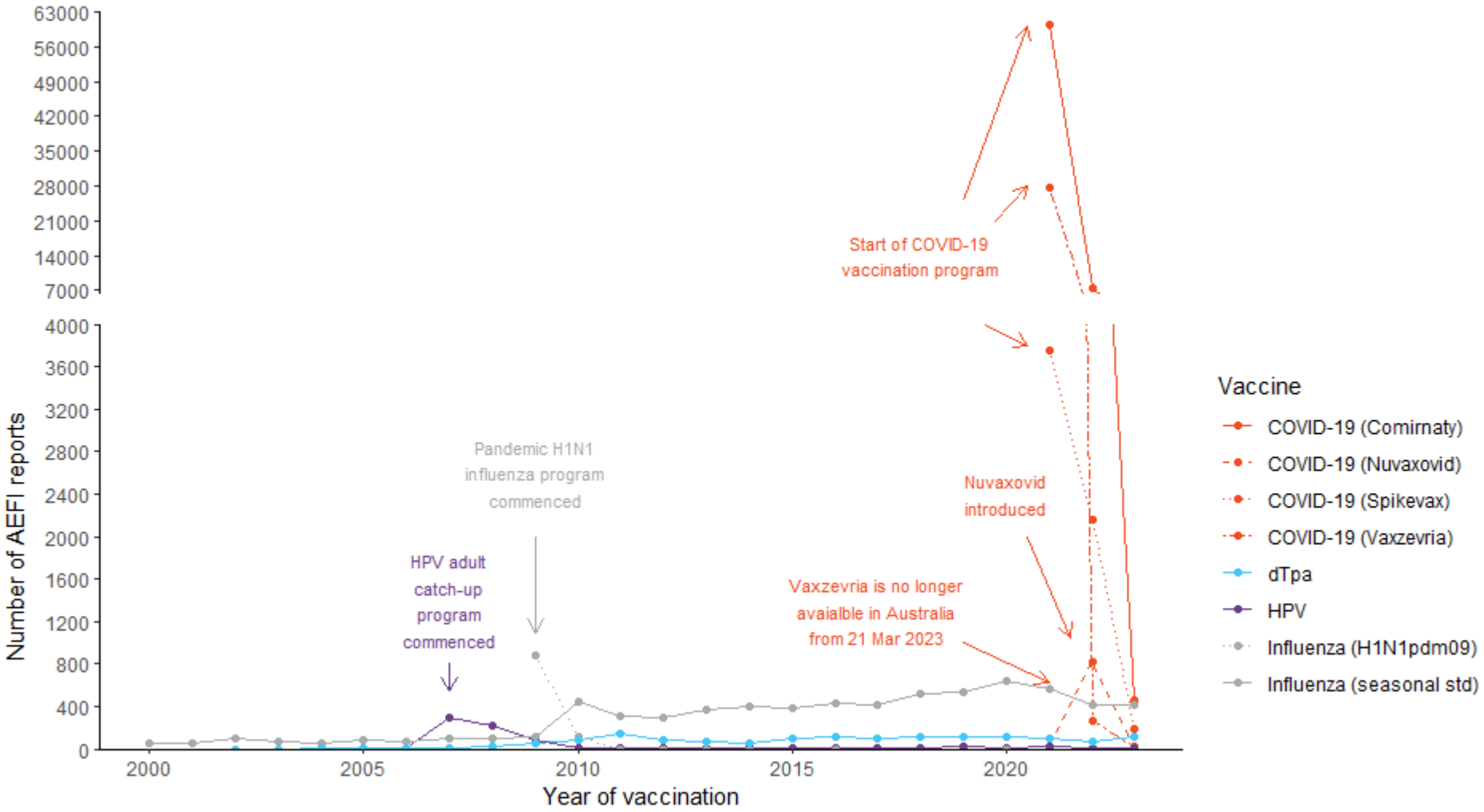
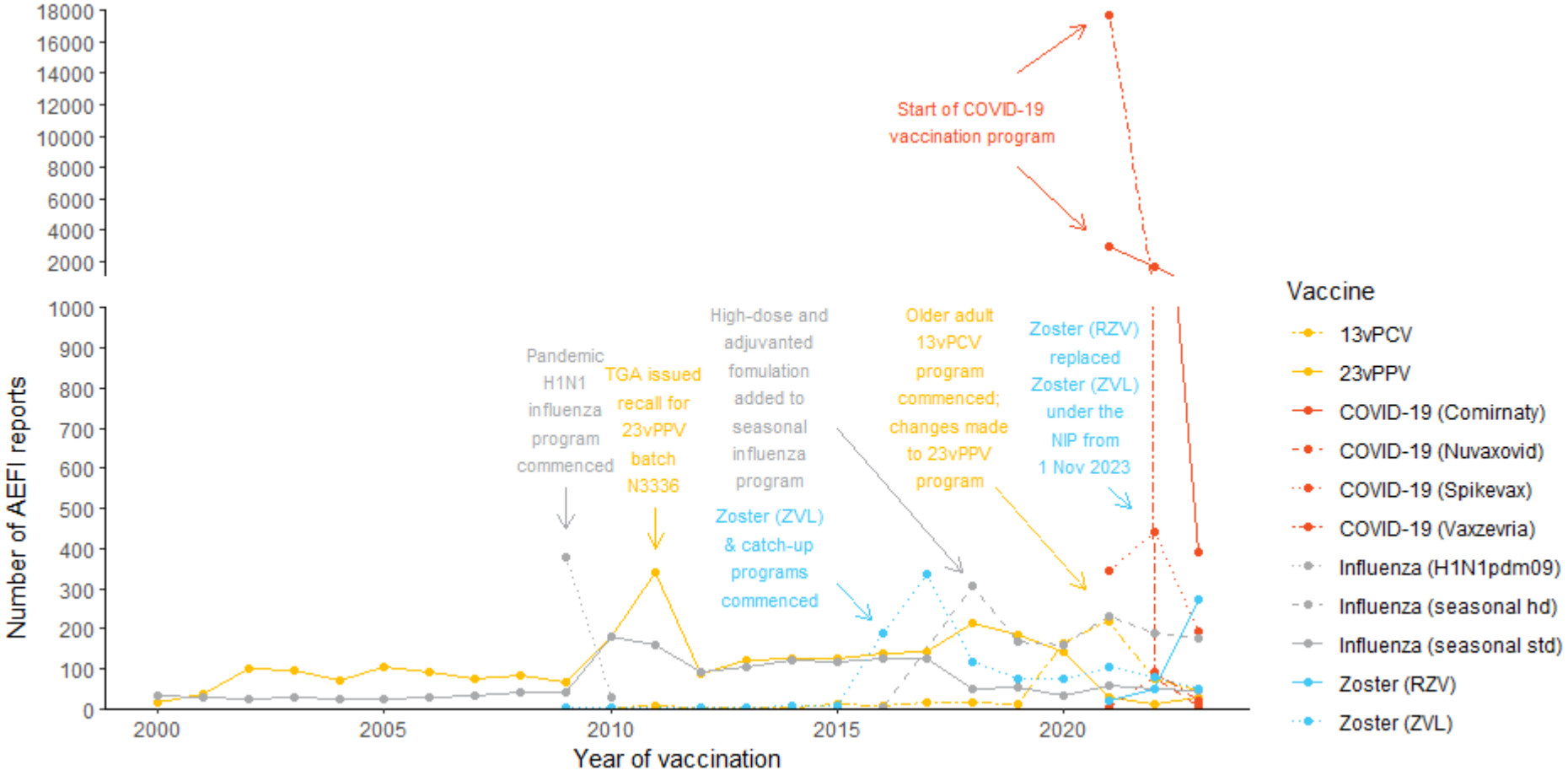


Figure 7. Adverse event following immunisation reports for people aged 65+ years in the Adverse Event Management System database from 2000 to 2023 (selected vaccines only**), by year and vaccine



Notes for Figure 3-7: *"Seasonal std" = standard formulation of the seasonal influenza vaccine; "seasonal hd" = high-dose or adjuvanted formulation of the seasonal influenza vaccine; **Vaccines are selected for inclusion in figure if they have been in use in the selected age group for ≥2 consecutive years, **and** if they are a) funded under the NIP for any population subgroup within the selected age group in 2023; b) one of the five most common vaccines associated with spontaneous AEFI reports in 2023; or c) have been implicated in a vaccine safety event of note from year 2000 onwards and/or have been implicated in a large proportion of historical spontaneous AEFI reports; or d) provides useful information as a comparator to another vaccine included in the figure (example: RZV as a comparator to ZVL).

For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to immunisation programs (including the National Immunisation Program), please see Table S1.

Supplementary Material

Table S6. Notable changes in national or jurisdictional immunisation policy, and in the National Immunisation Program (2005–2023)[6]

Year	Change[a]
2023	**November 2023**
	Qld government committed to providing ongoing free influenza vaccinations in 2024 flu season for all Qld residents aged ≥6 months.
	First recombinant neutralising human immunoglobulin G1 kappa (IgG1κ) long-acting monoclonal antibody, nirsevimab (Beyfortus), registered for use in neonates and children up to 24 months of age for RSV protection through passive immunisation.
	Shingrix replaced Zostavax under the NIP and was funded for adults aged ≥65 years, Aboriginal and Torres Strait Islander people ≥50 years and immunocompromised people ≥18 years at high risk of herpes zoster infection.
	The monovalent Omicron XBB.1.5 vaccines are preferred over other vaccines for use in individuals aged ≥5 years who are currently recommended primary or additional doses of COVID-19 vaccine according to the Australian Immunisation Handbook.
	October 2023
	In the absence of confirmed detection of B Yamagata lineage virus circulating since 2020, the World Health Organization (WHO) recommended continued inclusion of this antigen in quadrivalent influenza vaccines no longer warranted. The Australian Influenza Vaccine Committee supported WHO's position to exclude this component from influenza vaccines as soon as possible.
	15vPCV recommended as a non-preferential alternative to 13vPCV in children aged ≥6 weeks.
	Spikevax (omicron XBB 1.5) granted full registration for individuals aged ≥12 years.
	Comirnaty (omicron XBB 1.5) granted full registration for individuals aged ≥5 years.
	Nuvaxovid vaccine (containing ancestral strain only) granted full registration for individuals aged ≥12 years.
	September 2023
	ATAGI recommended that all adults aged ≥ 75 years receive an additional 2023 COVID-19 vaccine dose if 6 months had passed since their last dose.
	ATAGI recommended an additional 2023 COVID-19 vaccine dose for adults aged 65–74 and those 18–64 with severe immunocompromise, if 6 months had passed since their last dose, after consulting their healthcare provider. The greatest benefit was expected for those without a history of SARS-CoV-2 infection, with high-risk comorbidities, significant disabilities, or living in residential aged care.
	August 2023
	Spikevax bivalent (original/omicron BA.4/5) granted full registration for individuals aged ≥12 years.
	July 2023
	Vaxelis eligible for funding under NIP as an alternative vaccine to Infanrix hexa.
	Flucelvax Quad vaccine indication age extended to include use in children aged ≥6 months.
	Qld government provided free influenza vaccinations from 17 July to 31 August 2023 for all Qld residents aged ≥6 months.
	Catch-up program of meningococcal B vaccine (Bexsero) available for all Aboriginal and Torres Strait Islander infants under 2 years of age (originally due to end on 30 June 2023).
	Comirnaty vaccine (containing ancestral strain only) granted full registration for individuals aged ≥6 months.
	June 2023
	15vPCV and 20vPCV available on private prescription.

	The original Comirnaty (12 years and over formulations) and Spikevax vaccines (containing ancestral strain only) no longer available.
	May 2023
	20vPCV recommended as a non-preferential alternative to 13vPCV in adults aged ≥18 years.
	A BA.4/5-containing bivalent COVID-19 vaccine preferred over original (ancestral) vaccines for use as the primary course and for booster doses in people aged 12–17 years.
	Either BA.1- or BA.4/5-containing COVID-19 vaccine recommended for use as the primary course and for booster doses in people aged ≥18 years.
	April 2023
	Spikevax vaccine (containing ancestral strain only) granted full registration for individuals aged ≥6 years.
	March 2023
	15vPCV registered for use in children aged ≥6 weeks. Vaxzevria (AstraZeneca COVID-19 vaccine) no longer available.
	February 2023
	Recommended schedule of 9vHPV for immunocompetent adolescents and young adults aged 9–25 years becomes a single dose.
	Eligibility for a catch-up program of 9vHPV expanded to include people aged up to 25 years.
	A COVID-19 vaccine booster dose is recommended if ≥6 months have passed since the last vaccine or infection for adults ≥65 years and adults 18–64 years with medical comorbidities or disability. After a risk–benefit assessment, it may also be considered for adults 18–64 years without risk factors and children 5–17 years with high-risk conditions or disability.
	Comirnaty bivalent (original/omicron BA.4/5) vaccine provisionally registered for use as a booster dose in adolescents and individuals aged ≥12 years
	Moderna bivalent (original/omicron BA.4/5) vaccine provisionally registered for use as a booster dose in adolescents and individuals aged ≥12 years
	January 2023
	15vPCV recommended as a non-preferential alternative to 13vPCV in adults aged ≥18 years.
2022	**December 2022**
	Mandatory reporting to AIR for all JE vaccines administered.
	October 2022
	Spikevax approved as booster dose for individuals ≥12 years by TGA.
	ATAGI recommends booster dose for individuals aged 5-11 years in high-risk groups.
	Comirnaty bivalent (original/omicron BA.1) approved as booster dose for individuals ≥18 years by TGA.
	September 2022
	Comirnaty approved as booster dose for individuals 5-11 years by TGA.
	Comirnaty approved as primary dose for individuals ≥6 months by TGA.
	August 2022
	Intradermal administration of MVA-BN added to recommendations as an alternative route for pre-exposure prophylaxis.
	Nuvaxovid approved as primary dose for individuals 12-17 years by TGA.
	Spikevax bivalent (original/omicron BA.1) approved as booster dose for individuals ≥18 years by TGA.
	July 2022

	First replication-deficient modified vaccinia Ankara–Bavarian Nordic, MVA-BN vaccine made available via a special emergency pathway under section 18A of the *Therapeutic Goods Act 1989*.
	MVA-BN recommended for both pre-exposure and post-exposure prophylaxis against mpox.
	Nuvaxovid approved as booster dose for individuals ≥12 years by TGA.
	Spikevax approved as primary dose for individuals ≥6 months by TGA.
	ATAGI recommends a second booster dose for individuals ≥50 years; individuals 30-49 years can also receive a second booster dose.
	June 2022
	NSW, Qld, Vic, SA and WA governments provided state-funded influenza vaccination program for all residents from 1 June–30 June 2022.
	Nuvaxovid approved as booster dose for individuals ≥18 years by TGA.
	ATAGI recommends booster dose for individuals aged 12-15 years in high-risk groups.
	May 2022
	ATAGI expands population groups recommended to receive a second booster dose.
	April 2022
	The recombinant zoster vaccine is recommended for use in immunocompromised adults aged ≥18 years.
	Comirnaty approved as booster dose for individuals 12-15 years by TGA.
	March 2022
	Due to changes in the epidemiology of JE in Australia, JE vaccination recommended in individuals aged ≥2 months in high-risk settings (as advised by jurisdictional public health authorities).
	ATAGI recommends a second booster dose for specific population groups ≥18 years.
	February 2022
	ATAGI recommends booster dose for individuals aged 16-17 years.
	Spikevax approved as primary dose for individuals ≥6 years by TGA.
	Vaxzevria approved as booster dose for individuals ≥18 years by TGA.
	January 2022
	Nuvaxovid approved as primary dose for individuals ≥18 years by TGA.
	Comirnaty approved as booster dose for individuals 16-17 years by TGA.
	COVID-19 vaccination commences for children 5-11 years.
2021	**December 2021**
	Spikevax booster dose approved for for ≥18 years by TGA.
	Comirnaty approved for 5-11 years by TGA[b]
	November 2021
	COVID-19 booster program commences.
	October 2021
	Comirnaty booster dose approved for ≥18 years by TGA.
	September 2021
	Spikevax approved for ≥12 years by TGA.
	COVID-19 vaccination with Spikevax commences.
	COVID-19 vaccination commences for Phase 3 population.
	August 2021
	Spikevax approved for ≥18 years by TGA.
	COVID-19 vaccination commences for Phase 2b population.

	July 2021
	Mandatory reporting to AIR for all NIP vaccines administered.
	June 2021
	ATAGI recommends preferential use of Comirnaty to Vaxzevria in <60-year-olds due to risk of TTS.
	ATAGI/RANZCOG recommends COVID-19 vaccination for pregnant women Janssen approved for ≥18 years by TGA[b]
	May 2021
	COVID-19 vaccination commences for Phase 2a population group.
	First reports of myocarditis following Comirnaty in Australia.
	April 2021
	First thrombosis with thrombocytopenia syndrome case reported in Australia.
	ATAGI recommends preferential use of Comirnaty to Vaxzevria in <50-year-olds due to risk of TTS.
	March 2021
	Mandatory reporting to AIR for all influenza vaccines administered.
	COVID-19 vaccination with Vaxzevria commences.
	COVID-19 vaccination commences for Phase 1b population group.
	February 2021
	Vaxzevria approved for ≥18 years by TGA.
	COVID-19 vaccination commences for Phase 1a population group, with Comirnaty.
	January 2021
	Comirnaty approved for ≥16 years by TGA.
2020	**July 2020**
	Funded schedule expanded for Aboriginal and Torres Strait Islander children living in the NT, SA, QLD and WA from 13vPCV at 2, 4, 6 and 12 months (3+1) to include an additional dose of 23vPPV at 4 years of age and a 2nd dose 5–10 years later.
	A single dose of 13vPCV is recommended and funded for Aboriginal and Torres Strait Islander adults at 50 years of age, followed by a dose of 23vPPV 12 months later and a 2nd dose of 23vPPV 5–10 years after that.
	A single dose of 13vPCV is recommended and funded for non- Aboriginal and Torres Strait Islander adults at 70 years of age, replacing the previously funded dose of 23vPPV at 65 years of age.
	Meningococcal B vaccine funded for all Aboriginal and Torres Strait Islander children (age <12 months) and individuals of any age with specified high risk medical conditions. Catch-up available for all Aboriginal and Torres Strait Islander children <2 years of age (up to 23 months) for 3 years - until 30 June 2023.
	March 2020
	All children aged 6 months to <5 years funded for influenza vaccine under NIP.
	First enhanced quadrivalent influenza vaccine (adjuvanted) funded nationally for adults aged 65 years and over.
2019	**December 2019**
	In SA, multicomponent recombinant meningococcal B vaccine catch-up for children from 12 months to <4 years of age ceased on 31 December 2019
	April 2019
	Meningococcal ACWY conjugate vaccine funded under the NIP for adolescents aged 14–16 years delivered through a school-based program and adolescents aged 15 to 19 years delivered through primary care providers as part of an ongoing catch-up program.
	March 2019

	NT: annual seasonal influenza vaccination program funded for all children aged 6 months to < 5 years.
	February 2019
	Annual seasonal influenza vaccination funded on the national childhood vaccination schedule for all Australian children aged 6 months – <5 years.
	Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years of age funded for influenza vaccine under NIP.
2018	**October 2018**
	Multicomponent recombinant meningococcal B vaccine funded by SA for children 6 weeks to 12 months of age, with catch-up for children from 12 months to <4 years of age
	July 2018
	Meningococcal ACWY conjugate vaccine funded for all children at 12 months of age, replacing combined Hib and meningococcal C-containing vaccine
	Hib dose moved to 18 months and given as monovalent Hib vaccine.
	Schedule for routine childhood vaccination with 13vPCV changed from 2, 4 and 6 months of age to 2, 4 and 12 months of age.
	April 2018
	Enhanced trivalent influenza vaccines (high-dose and adjuvanted) funded nationally for all adults aged ≥65 years.
	Annual seasonal influenza vaccination funded by ACT, NSW, QLD, SA, TAS and VIC for all children aged 6 months – <5 years
	Meningococcal A, C, Y, W-135 conjugate vaccine funded by SA for Aboriginal and Torres Strait Islander children and adolescents aged 12 months to 19 years living in the Eyre and Far North, and Flinders and Upper North regions
	February 2018
	Meningococcal A, C, W, Y-135 conjugate vaccine funded by ACT for grade 10 students and persons aged 16–19 years who no longer attend school
	A 2-dose schedule of 9vHPV funded for adolescents aged 12–14 years, delivered through a school-based program; 4vHPV ceased to be used in the program.
	January 2018
	Meningococcal A, C, Y, W-135 conjugate vaccine funded by WA for children aged 12 months to <5 years
	Meningococcal ACWY school-based vaccination program funded for all NSW secondary school students in Years 10 and 11, as well as adolescents aged 15 to 19 years who have not received the vaccine at school.
2017	**April 2017**
	Meningococcal B vaccine study commenced in South Australia for grade 10–12 students at participating schools.
	January 2017
	Meningococcal ACWY conjugate vaccine funded until December 2017in Western Australia, Victoria and Tasmania for grade 10-12 students; New South Wales for grade 11-12; Queensland grade 10 students and persons aged 15-19 years who no longer attend school. The Northern Territory introduced the vaccine for at-risk people aged 1–19 years living in specified remote regions and all children aged 12 months.
2016	**November 2016**
	Zoster vaccine (Zostavax®) provided free for people aged 70 years under the National Immunisation Program (NIP) with a five-year catch-up program for people aged 71 – 79 years.
	September 2016

	The Australian Childhood Immunisation Register expands to become the Australian Immunisation Register (AIR). **March 2016** Free booster dose of the diphtheria, tetanus, and acellular pertussis-containing vaccine (DTPa) at 18 months of age.
2015	**April 2015** New immunisation requirements for family assistance payments were announced by the federal government (the 'No Jab, No Pay' policy), to come into effect on 1 January 2016. Only parents of children (aged less than 20 years) who are 'fully immunised' or on a recognised catch-up schedule remain eligible to receive the Child Care Benefit, Child Care Rebate, and/or the Family Tax Benefit Part A end-of-year supplement. **March 2015** Seasonal influenza vaccine funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years. From March to June 2015, the dTpa vaccine for women during the third trimester of pregnancy was funded by New South Wales, South Australia, Western Australia, the Australian Capital Territory, Victoria and Tasmania. The Northern Territory had funded it since September 2013 and Queensland since July 2014. A booster dose of DTPa vaccine recommended at 18 months of age (funded in March 2016).
2014	**December 2014** 4vHPV vaccine catch-up program for males aged 14–15 years ceased **July 2014** dTpa vaccine was funded by Queensland for women during the third trimester of pregnancy.
2013	**December 2013** Secondary school Year 7 hepatitis B vaccine catch-up program ceased, as all younger age cohorts were eligible for infant immunisation under the NIP (commenced 2000). **September 2013** dTpa vaccine funded by NT for women during the third trimester of pregnancy and for parents of infants aged <7 months under cocoon strategy **July 2013** Second dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as MMRV vaccine. Combined *Haemophilus influenzae* type b (Hib) and meningococcal serogroup C (MenC) vaccine, Menitorix®, was funded for infants aged 12 months. This combination vaccine replaced the single dose of monovalent meningococcal C conjugate vaccine (MenCCV) and booster dose of monovalent Hib vaccine previously scheduled at 12 months of age. **February 2013** 4vHPV vaccine was extended to males aged 12–13 years, delivered through a school-based program, with a catch-up program for males aged 14–15 years in 2013 and 2014.
2012	**October 2012** A fourth dose of Prevenar 13®, (13vPCV, a 13-valent pneumococcal conjugate vaccine) was listed on the National Immunisation Program (NIP) for Indigenous children, aged 12-18 months, residing in Queensland, South Australia, Western Australia and the Northern Territory. This replaced the booster dose of Pneumovax23®, (23vPPV, a 23-valent pneumococcal polysaccharide vaccine) administered between 18 and 24 months of age for Indigenous children from these jurisdictions.
2011	**1 October 2011 to 30 September 2012**

	All children aged between 12 - 35 months who had completed a primary pneumococcal vaccination course with 7vPCV were eligible to receive a free supplementary dose of Prevenar 13® **July 2011** Prevenar 13® replaced Prevenar® on the NIP for children at 2, 4 and 6 months of age in all states and territories except the Northern Territory which adopted 13vPCV from 1 October 2011. **25 March 2011** TGA issued a recall of Batch N3336 of the 23 valent pneumococcal polysaccharide vaccine 23vPPV, Pneumovax® 23. April 2011 - health professionals were advised not to administer a second or subsequent dose of Pneumovax 23 vaccine. December 2011 - Revised recommendations regarding which patients should be re-vaccinated under the NIP were provided.
2010	Annual vaccination with seasonal trivalent influenza vaccine (TIV, containing 3 influenza strains: A/H1N1, A/H3N2 and B) was funded under the NIP for people aged ≥6 months with medical risk factors (previously subsidised through the Pharmaceutical Benefits Scheme) and all Indigenous people aged ≥15 years (previously all Indigenous adults ≥50 years and 15–49 years with medical risk factors). On 23 April 2010, the use of the 2010 seasonal TIV in children <5 years of age was suspended by Australia's Chief Medical Officer due to an increased number of reports of fever and febrile convulsions post vaccination. A subsequent investigation identified that Fluvax® and Fluvax junior® (CSL Biotherapies), but neither of the other two available brands registered for use in young children, were associated with an unacceptably high risk of febrile convulsions. The recommendation to resume the use of seasonal influenza vaccine in children aged 6 months to 5 years, using brands other than Fluvax® and Fluvax junior®, was made in August 2010.
2009	**Late 2009** All states and territories were using the single hexavalent DTPa-IPV-Hib-HepB (Infanrix hexa®) vaccine for all children at 2, 4 and 6 months of age, due to an international shortage of *Haemophilus influenzae* type b (Hib) (PedvaxHib® [monovalent] and Comvax® [Hib-HepB]) vaccines. **September 2009** Pandemic H1N1 2009 influenza vaccine (Panvax®) was rolled out across Australia from 30 September 2009 for people aged ≥10 years. From December 2009, the pandemic vaccine was made available to children aged 6 months to 10 years.
2008	**April 2008** Western Australia commenced a seasonal influenza vaccination program for all children aged 6 months to <5 years (born after 1 April 2003). **March 2008** Queensland, South Australia and Victoria changed from using two combination vaccines (quadrivalent DTPa-IPV and Hib-HepB) to the single hexavalent DTPa-IPV-HepB-Hib vaccine.
2007	**July 2007** Universal funded immunisation against rotavirus at 2 and 4 months of age (Rotarix®) or at 2, 4 and 6 months of age (Rotateq®). **April 2007** Funded immunisation against human papillomavirus for all Australian girls aged 12–13 years delivered through a school-based program from April 2007, with a temporary catch-up program through schools or primary care providers for females aged 13–26 years until December 2009.
2005	**November 2005**

	Universal funded immunisation against varicella at 18 months of age with a school-based catch-up program for children at 10–13 years of age not previously vaccinated and without a history of varicella infection (no funded catch-up for children 2–10 years of age). IPV was funded to replace OPV, in combination vaccines. **January 2005** Universal funded infant 7-valent pneumococcal conjugate vaccine (7vPCV) program replaced the previous targeted childhood program, with a catch-up program for children aged <2 years. Universal 23-valent pneumococcal polysaccharide vaccine (23vPPV) for adults aged ≥65 years replaced previous subsidy through the Pharmaceutical Benefits Scheme.

[a] Includes immunisation-related policy and key recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI).
[b] Vaccine not used or not in circulation

Table S2. Description of PT to SMQ mapping

Number of SMQ mapped	Term reported
0	PT
1	SMQ
>1	SMQ chosen by clinician, or PT if preferred SMQ could not be chosen

Table S3. Narrow MedDRA SMQ for Tier 1 Adverse events of special interest[12]

Tier 1 AESI	Medical concept	Narrow-search MedDRA lower level term
Anaphylaxis	Anaphylaxis	Anaphylactic reaction; Anaphylactic shock; Anaphylaxis; Systemic anaphylactic reaction; Systemic anaphylaxis; Allergic shock
	Anaphylactic transfusion reaction	Anaphylactic transfusion reaction
	Angioedema	Angio-edema; Angio-oedema; Angioedema; Angioedemas; Angioedema and urticaria; Giant hives; Giant urticaria; Hives giant; Urticaria giant
	Allergic urticaria	Allergic urticaria
	Hypersensitivity	Allergic reaction; Allergic reaction NOS; Allergy; Allergy NOS; Hypersensitivity; Hypersensitivity NOS; Hypersensitivity reaction; Hypersensitivity reaction (NOS); Hypersensitivity symptom; HYSN; Reaction allergic (NOS); Reaction hypersensitivity (NOS); Allergic reaction (NOS)
	Food anaphylaxis	Anaphylactic shock due to adverse food reaction; Anaphylactic reaction to food
Thrombocytopenia	Thrombocytopenia	Thrombocytopaenia; Thrombocytopenia; Thrombocytopenias; Thrombocytopenia, unspecified; Thrombopenia
	Acquired thrombocytopenia	Secondary thrombocytopenia
	Decreased platelet count	Low platelets; Platelet count decreased; Platelet count low; Platelets decreased; Reduced platelet count; Thrombocyte count decreased
	Immune thrombocytopenic purpura	Immune thrombocytopenic purpura; Idiopathic purpura; Idiopathic thrombocytopenic purpura; ITP; Werlhof's syndrome
	Thrombocytopenic purpura	Thrombocytopaenic purpura; Thrombocytopenia purpura; Thrombocytopenic purpura; Purpura thrombocytopenic
	Primary thrombocytopenia	Primary thrombocytopenia
	Transient neonatal thrombocytopenia	Transient neonatal thrombocytopenia
Generalised convulsion	Generalized seizures	Convulsions generalised; Generalized convulsion
	Seizures	Convulsions; Unspecified convulsions; Convulsion; Convulsion (NOS); Convulsions (NOS); Seizure; Seizures; Fit; Fits NOS; Fitting
	Classic fit	Classic fit
	Convulsions aggravated	Convulsions aggravated; Convulsions NOS aggravated
	Convulsive seizures	Convulsive seizure
	Non-epileptic convulsion	Fit (non-epileptic)
	Epileptic drop attack	Atonic seizures; Drop seizures
	Epilepsy	Epileptic fit; Epileptic seizure
	Tonic-clonic seizures	Grand mal seizure; Grand mal fit; Grand mal epileptic fit; Seizure grand mal; Generalised tonic-clonic seizure; Generalised tonic-clonic seizures
	Seizures, Clonic	Clonic seizures; Clonic convulsion
	Seizures, Tonic	Tonic convulsion; Tonic seizure; Tonic seizures
	Febrile convulsions	Febrile convulsions; Convulsion febrile; Febrile convulsion seizure; Febrile seizure; Febrile fits; Fever convulsions; Pyrexial fit; Grand mal status (epileptic); Status epilepticus grand mal; Convulsive status epilepticus; Petit mal status (epileptic); Status epilepticus petit mal; Afebrile seizure; Afebrile convulsion; Convulsions in newborn; Convulsion neonatal; Convulsions in newborn; Neonatal convulsion; Neonatal seizures; Neonatal fit
	Epilepsy	Epilepsy, unspecified; Epilepsy NOS; Epilepsy; Epileptic fit; Epileptic seizure
	Generalised convulsive epilepsy	Generalised convulsive epilepsy
	Generalised convulsive epilepsy, without mention of intractable epilepsy	Generalized convulsive epilepsy, without mention of intractable epilepsy

	Generalised nonconvulsive seizure disorder	Generalised non- convulsive epilepsy
	Idiopathic generalised epilepsy	Idiopathic generalised epilepsy
	Familial benign neonatal epilepsy	Benign familial neonatal convulsions
Aseptic meningitis	Aseptic meningitis	Aseptic meningitis; Meningitis aseptic
	Non- pyogenic meningitis	Non-pyogenic meningitis
	Viral meningitis	Viral meningitis; Viral meningitis, unspecified; Meningitis viral; Meningitis viral NOS
	Mumps meningitis	Mumps meningitis; Mumps virus meningitis; Meningitis mumps; Meningitis due to mumps virus
	Enterovirus meningitis	Meningitis due to enterovirus; Meningitis due to enterovirus, other; Meningitis due to other enterovirus; Meningitis due to enterovirus, unspecified; Meningitis due to unspecified enterovirus
	Coxsackie meningitis	Meningitis due to coxsackie virus; Coxsackie aseptic meningitis; Meningitis coxsackie viral
	Echovirus meningitis	Meningitis due to echo virus; Meningitis echo viral
	Other specified viral meningitis	Other specified viral meningitis
Guillain Barré Syndrome and Miller Fisher Syndrome	Guillain-Barre Syndrome	Guillain-Barre syndrome; Guillain Barre syndrome; Syndrome Guillain-Barre; Acute infective polyneuritis; Acute inflammatory demyelinating polyradiculoneuropathy; Paralysis ascending
	Miller Fisher Syndrome	Miller Fisher Syndrome
Encephalitis, Myelitis and Acute disseminated encephalomyelitis	Encephalitis	Encephalitis; Encephalitis NOS
	Post-vaccinal encephalitis	Encephalitis following immunization procedures
	Post-immunization encephalitis	Encephalitis post immunization
	Myelitis	Myelitis; Myelitis NOS
	Myelitis, Transverse	Myelitis, transverse
	Encephalomyelitis, Acute Disseminated	Acute disseminated encephalomyelitis
Peripheral facial nerve palsy	Bell Palsy	Bell’s palsy; Palsy Bells
	Facial paralysis	Facial palsy; Facial paralysis; Paralysis facial

Table S4. Most commonly reported medication errors by top five vaccines and age groups

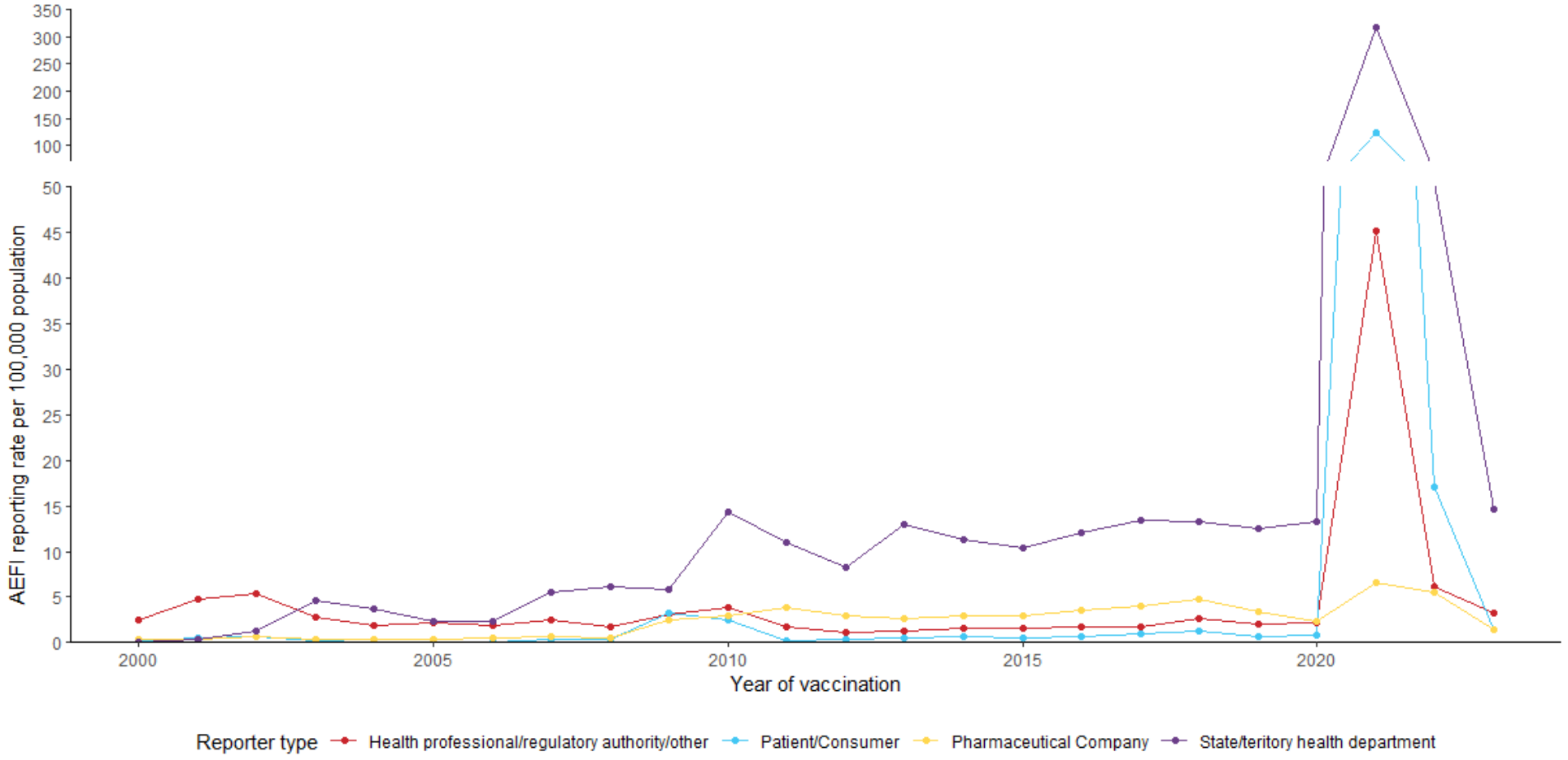
Vaccines	Detailed preferred terms for the SMQ "Medication errors"					
	Inappropriate schedule of product administration	Product administered to patient of inappropriate age	Wrong product administered	Expired product administered	Extra dose administered	Other preferred terms
<5 years (n=468)	**178 (38%)**	**98 (21%)**	**111 (24%)**	**23 (5%)**	**16 (3%)**	**50 (11%)**
Influenza (seasonal - standard formulation)	17 (4%)	46 (10%)	7 (1%)	0 (0%)	0 (0%)	0 (0%)
DTPa-hepB-IPV-Hib	13 (3%)	2 (0%)	12 (3%)	0 (0%)	2 (0%)	16 (0%)
MMR	5 (1%)	1 (0%)	17 (4%)	5 (1%)	2 (0%)	1 (0%)
MenB	15 (3%)	3 (1%)	2 (0%)	5 (1%)	3 (0%)	4 (1%)
DTPa-IPV	12 (3%)	2 (0%)	10 (2%)	0 (0%)	4 (0%)	3 (1%)
5-11 years (n=59)	**7 (12%)**	**27 (46%)**	**10 (17%)**	**8 (14%)**	**2 (3%)**	**6 (10%)**
Comirnaty	2 (3%)	16 (27%)	1 (2%)	8 (14%)	0 (0%)	2 (3%)
HepA	0 (0%)	2 (3%)	3 (5%)	0 (0%)	0 (0%)	1 (2%)
Influenza (seasonal - standard formulation)	0 (0%)	1 (2%)	2 (3%)	0 (0%)	0 (0%)	0 (0%)
Spikevax	0 (0%)	2 (3%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)
DTPa-hepB-IPV-Hib	1 (2%)	1 (2%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)
12-17 years (n=83)	**23 (28%)**	**25 (30%)**	**25 (30%)**	**3 (4%)**	**4 (5%)**	**1 (1%)**
Comirnaty	4 (5%)	10 (12%)	9 (11%)	0 (0%)	0 (0%)	0 (0%)
Spikevax	0 (0%)	7 (8%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)
dTpa	4 (5%)	0 (0%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)
DTPa	0 (0%)	0 (0%)	5 (6%)	0 (0%)	0 (0%)	0 (0%)
dTpa, HPV	3 (4%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
18-64 years (n=390)	**62 (16%)**	**146 (37%)**	**48 (12%)**	**70 (18%)**	**10 (3%)**	**35 (9%)**
Influenza (seasonal - high-dose or adjuvanted)	4 (1%)	129 (33%)	7 (2%)	0 (0%)	0 (0%)	1 (0%)
Comirnaty	12 (3%)	0 (0%)	8 (2%)	18 (5%)	1 (0%)	6 (2%)
Influenza (seasonal - standard formulation)	9 (2%)	2 (1%)	2 (1%)	9 (2%)	1 (0%)	12 (3%)
Spikevax	6 (2%)	0 (0%)	1 (0%)	19 (5%)	0 (0%)	0 (0%)
HepB	7 (2%)	5 (1%)	1 (0%)	3 (1%)	1 (0%)	2 (1%)
≥65 years (n=230)	**79 (34%)**	**11 (5%)**	**41 (18%)**	**54 (23%)**	**7 (3%)**	**22 (10%)**
Comirnaty	20 (9%)	1 (0%)	0 (0%)	18 (8%)	0 (0%)	2 (1%)
Spikevax	6 (3%)	1 (0%)	0 (0%)	31 (13%)	1 (0%)	0 (0%)
Influenza (seasonal - high-dose or adjuvanted)	25 (11%)	6 (3%)	3 (1%)	0 (0%)	1 (0%)	4 (2%)
Influenza (seasonal - standard formulation)	3 (1%)	1 (0%)	27 (12%)	0 (0%)	0 (0%)	0 (0%)
Zoster (ZVL)	8 (3%)	2 (1%)	2 (1%)	1 (0%)	2 (1%)	5 (2%)

Table S5. PT mapped to specific SMQ[a]

SMQ	PTs mapped
Gastrointestinal nonspecific symptoms and therapeutic procedures	Abdominal discomfort; Abdominal distension; Abdominal pain; Abdominal pain lower; Abdominal pain upper; Abdominal symptom; Abdominal tenderness; Abnormal faeces; Anorectal discomfort; Bowel movement irregularity; Change of bowel habit; Constipation; Defaecation disorder; Defaecation urgency; Diarrhoea; Discoloured vomit; Epigastric discomfort; Eructation; Faecal volume decreased; Faeces hard; Faeces soft; Flatulence; Frequent bowel movements; Gastrointestinal pain; Gastrointestinal sounds abnormal; Infrequent bowel movements; Nausea; Non-cardiac chest pain; Oesophageal discomfort; Oesophageal pain; Overflow diarrhoea; Vomiting
Medication errors	Accidental exposure to product; Accidental overdose; Accidental underdose; Circumstance or information capable of leading to medication error; Contraindicated product administered; Device use error; Drug monitoring procedure incorrectly performed; Expired product administered; Exposure via eye contact; Extra dose administered; Inadequate aseptic technique in use of product; Inappropriate schedule of product administration; Incomplete course of vaccination; Incorrect dosage administered; Incorrect dose administered; Incorrect dose administered by device; Incorrect product administration duration; Incorrect product dosage form administered; Incorrect product formulation administered; Incorrect route of product administration; Intercepted product storage error; Labelled drug-drug interaction medication error; Medication error; Multiple use of single-use product; Product administered at inappropriate site; Product administered to patient of inappropriate age; Product administration error; Product dispensing error; Product preparation error; Product prescribing error; Product storage error; Vaccination error; Wrong patient received product; Wrong product administered; Wrong schedule; Wrong technique in product usage process

[a]Table includes only those PTs found in the AEMS database, and not all possible MedDRA PTs that map to each MedDRA SMQ; mapping hierarchy in MedDRA version 27.1 used

Figure S1. Reporting rates of adverse events following immunisation per 100,000 population in the Adverse Event Management System database from 2000 to 2023, by year and reporter type



For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to immunisation programs (including the National Immunisation Program), please see Table S1. Population data was sourced from ABS, and represents the mid-year total Australian ERP for each calendar year.