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Vaccinovigilance
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Summary of adverse events following immunization reported in Switzerland during 2024

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Summary of adverse events following immunization reported in Switzerland during 2024

During 2024, Swissmedic received a total of 504 case reports of suspected "adverse events following immunization (AEFIs)" from Switzerland. Although lower in number than in 2023, almost half of these reports were submitted in relation to COVID-19 vaccines. Overall, these figures are a consequence of a continuing, but decreasing, number of COVID-19 vaccinations, and most of these reports describe known reactions. In addition, 260 AEFI reports were submitted for **non**-COVID vaccines during 2024, which is a similar number compared with 2023 (264 reports) and higher than in 2022 (217 reports). The focus of this report is on **non**-COVID vaccines. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2024 is presented in the final section, see also (2).

AEFI reports were recorded, assessed and analysed in the Swiss pharmacovigilance database. Swissmedic is encouraging reporting of AEFIs in high quality, which enables early detection of new safety signals. Important safety issues are evaluated in international collaboration with other regulatory agencies and/or with the participation of the Human Medicines Expert Committee (HMEC) of Swissmedic, if necessary. An increased AEFI reporting rate, followed by an assessment of relevant cases, can lead to risk minimisation measures in order to ensure vaccine safety.

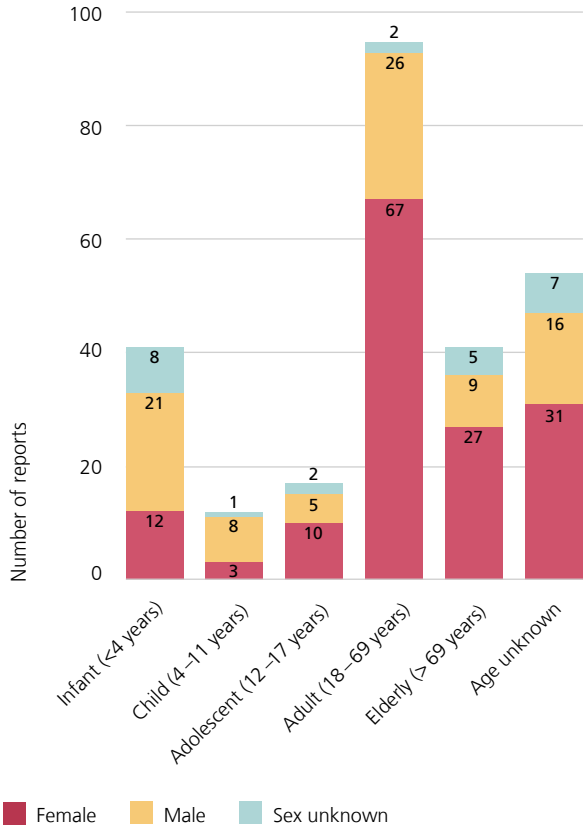


Figure 1: Number of AEFI reports by age group and sex, 2024

Figure 1 compares the number of reports by age group and sex. The largest number of AEFI reports involved adults (95 reports), followed by the elderly (41 reports), infants (41 reports), adolescents (17 reports) and children (12 reports). Overall in 2024, the number of reports concerning females (150 reports; 57.7%) exceeded those concerning males (85 reports; 32.7%). In 25 AEFI reports (9.6%), the sex of the persons remained unknown. In 54 case reports (20.8%), the age group of the patients was not recorded.

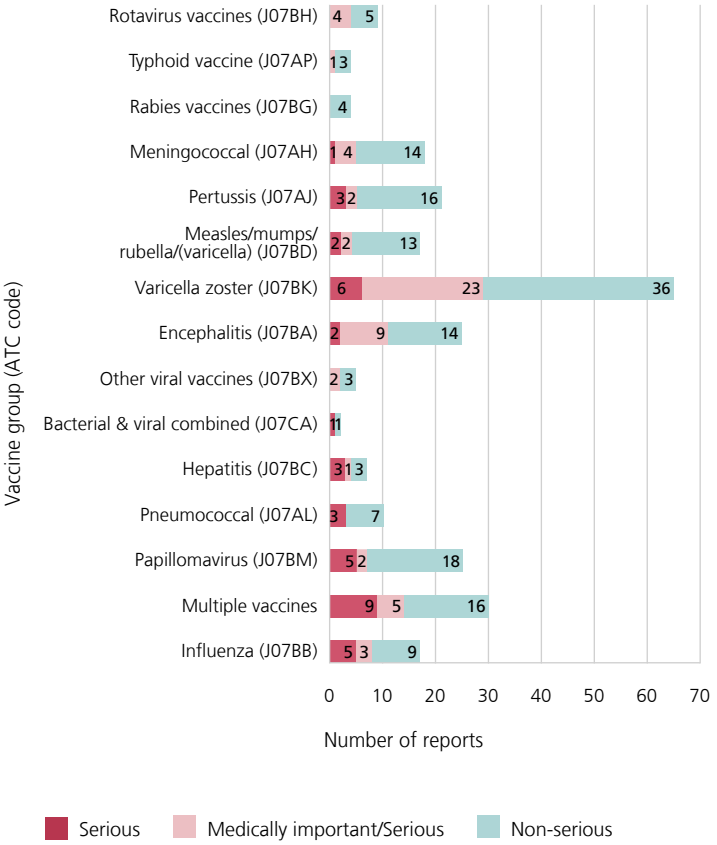


Figure 2: Number of reports by vaccine group (ATC code) and seriousness, 2024

Figure 2 shows the number of spontaneous AEFI reports by vaccine group (ATC code) and seriousness. Generally, a safety report is assessed as "serious" if it involves an adverse event leading to death, to hospitalisation or to prolongation of an existing hospitalisation, if it is life-threatening or results in a significant or persistent disability or a congenital anomaly. Furthermore, a report is assessed as "medically important" (and therefore, also as "serious") even if it does not fulfil the aforementioned criteria for "seriousness", but involves an event considered to be significant by medical judgement. All other reports are assessed as "non-serious" (e.g. self-limiting adverse events with good recovery). Of the 260 spontaneous reports received in 2024, 162 (62.3%) were "non-serious", 58 (22.3%) included only medically important events and 40 (15.4%) of the reports involved AEFIs with serious consequences.

Generally, considering all vaccines in 2024, the relative frequency (percentage) of "serious", including "medically important", cases taken together (98 reports; 37.7%) was quite similar to 2023 (36%) and 2022 (37.3%).

Case reports where several (n >1) different vaccines were administered and were reported relating to suspected AEFIs are shown in Figure 2 as "Multiple vaccines". Many of these cases concerned multiple immunisations in children.

As in 2023, during 2024 a higher number of cases was submitted relating to the herpes zoster vaccination, and these are shown in Figure 2 as ATC code "Varicella zoster (J07BK)". The majority of these case reports were assessed as "non-serious" (36 of 65 cases; 55.4%), which was a similar percentage to 2023 (54.8%).

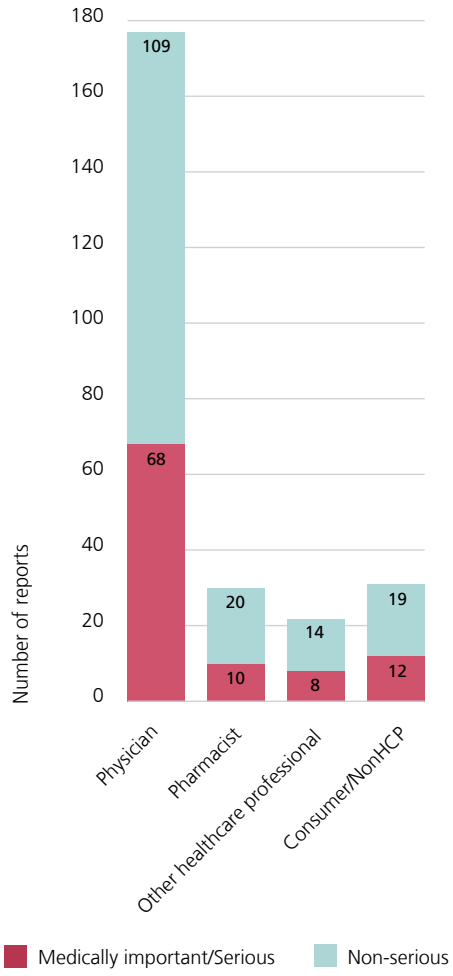


Figure 3: Number of AEFI reports by reporter qualification and seriousness, 2024

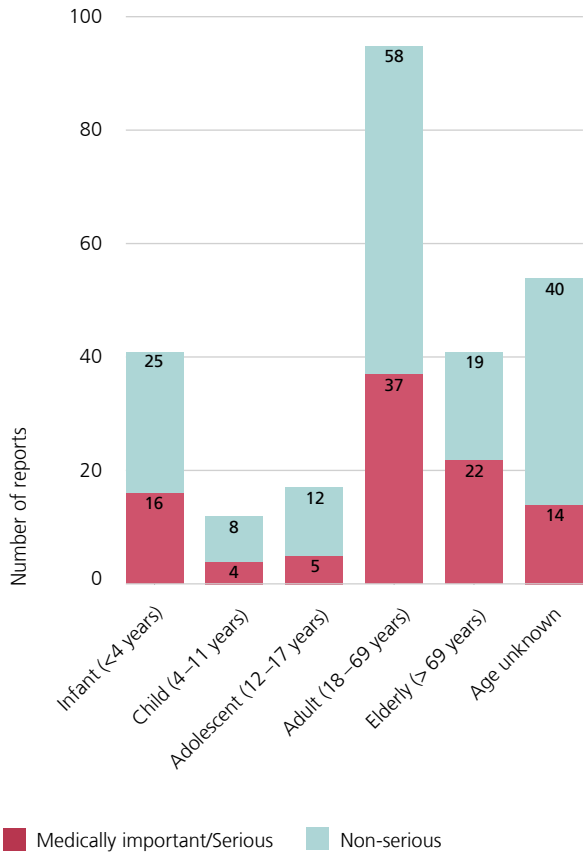


Figure 4: Number of AEFI reports by age group and seriousness, 2024

Figure 3 shows the number of Swiss AEFI reports in 2024 grouped by primary reporter and seriousness. Healthcare professionals – providing medically confirmed data and good quality individual AEFI reports – were primary reporters in the vast majority of cases. Physicians submitted the largest number of AEFI reports (177 of 260), including a higher number of reports assessed as "serious" or "medically important" (68 of 177 reports). Consumers/patients submitted the second-highest number (31 AEFI reports), followed by pharmacists (30 reports).

Figure 4 shows the number of spontaneous AEFI reports by age group and seriousness. It is evident that the highest number of "serious" or "medically important" cases (37 of 95 AEFI reports in total) were recorded in the adult age group, followed by the elderly (22 of 41 reports), infants (16 of 41 reports), adolescents (5 of 17 reports) and children (4 of 12 reports).

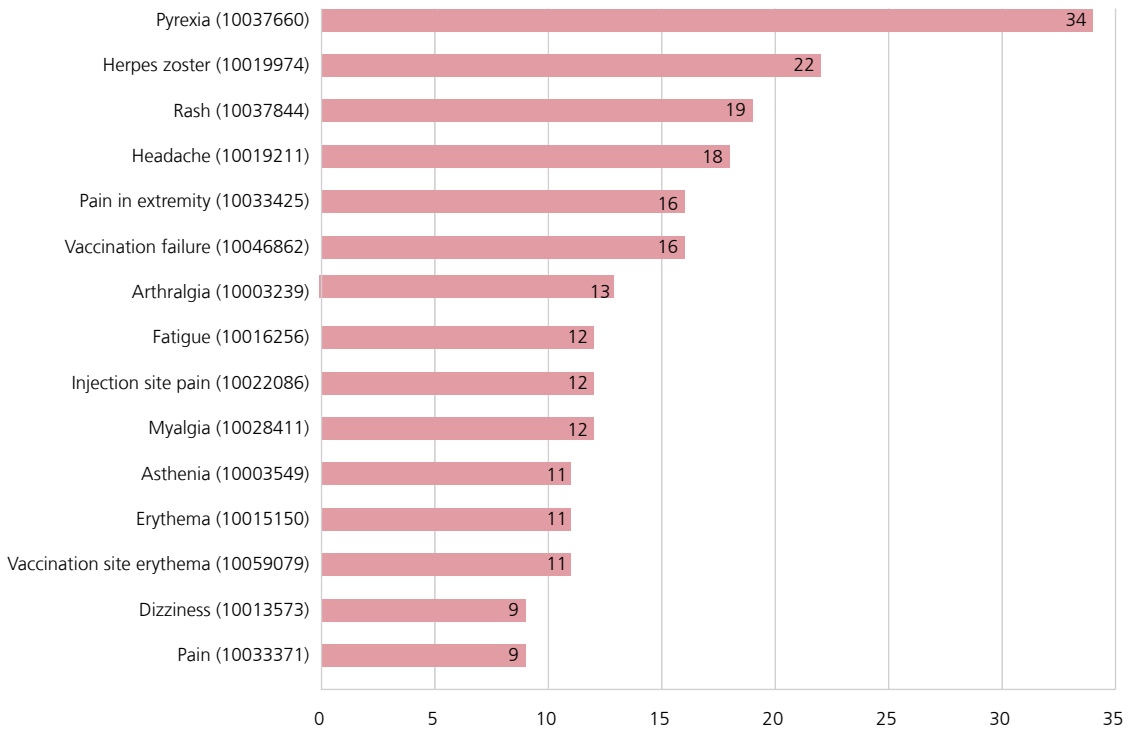


Figure 5: Overview of the most frequent AEFIs of all reports, 2024

Figure 5 shows the most frequent AEFIs reported during 2024 as MedDRA Preferred Terms, including: pyrexia; herpes zoster; rash; headache; pain in extremity; vaccination failure; arthralgia; injection site pain; myalgia; asthenia; erythema; vaccination site erythema; dizziness; and pain. Notably, some reports of herpes zoster were received as suspected cases of vaccination failure following varicella zoster immunisation (see also "serious reports" below).

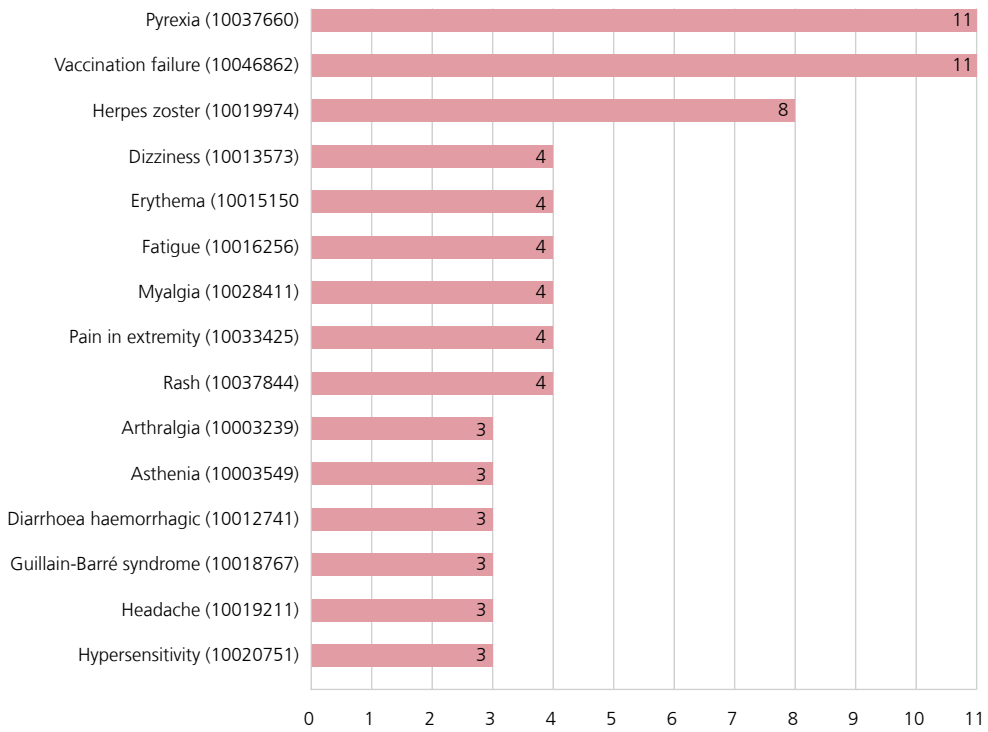


Figure 6: The most frequent AEFIs in "serious" reports, 2024

Figure 6 summarises the most frequent AEFIs submitted as MedDRA Preferred Terms in reports assessed as "serious", including: pyrexia; vaccination failure; herpes zoster; dizziness; erythema; fatigue; myalgia; pain in extremity; and rash.

In 2024, 11 "serious" reports of "vaccination failure" were received, including seven cases following herpes zoster vaccination and four single cases following different other vaccines.

Neurological complications are significant among the various AEFIs due to their possible persistence and debilitating sequelae. Reports of "serious" neurological AEFIs occurring in Switzerland during 2024 included:

- Two cases of "hypotonic-hyporesponsive episode", both cases occurring in 2-month-old infants (one male and one female) following administration of multiple different vaccines in both cases (diphtheria / hepatitis B / HIB / pertussis / pneumococcal / polio / tetanus); the outcome of both episodes was reported as "recovered".
- Three cases of Guillain-Barré syndrome, one in a 37-year-old female following the hepatitis B vaccine, with outcome "recovering". Two additional cases occurred in two females (61- and 84-year-olds) after the varicella zoster vaccine, with the outcomes reported as "unknown" in both cases.
- Two cases of "Bell's palsy", one case in a 19-year-old female following administration of combined vaccines (diphtheria / pertussis / polio / tetanus), with outcome "not recovered". The second case occurred in a 41-year-old male after the monkeypox vaccine, with the outcome "not recovered".
- One case of "facial paralysis" in a 61-year-old male following the tick-borne encephalitis vaccine, with outcome "recovered".
- One case of "facial paresis" in a 72-year-old male after the varicella zoster vaccine, with the outcome reported as "recovered".
- Three cases of "aseptic meningitis", one case in a 4-year-old male and the second case in a 30-year-old female. Both cases occurred following the

tick-borne encephalitis vaccine and were reported as "recovered". The third case occurred in a 28-year-old female after the administration of combined vaccines (diphtheria vaccine / pertussis vaccine / tetanus vaccine), with outcome "recovering" at the time of reporting.

- One case of "brachial radiculitis" in a 46-year-old female following the administration of combined vaccines (diphtheria / pertussis / tetanus), with outcome "recovered".
- One case of "neuralgic amyotrophy" in a 60-year-old female after the varicella zoster vaccine, with outcome "not recovered".
- Two cases of "seizure", one case in a 6-month-old male infant after meningitis vaccination, with outcome "recovered". The second case occurred in a 7-month-old female infant after the administration of the measles / mumps / rubella / varicella zoster vaccine, with outcome "recovered".
- One case of reported "epilepsy" in a 2-month-old male infant following meningococcal vaccination, with outcome "recovered".
- Three cases of "syncope" were received as serious (including medically important) AEFI reports, one case in a one-year-old female after the administration of combined vaccines, with outcome "unknown". The second case occurred in an 8-year-old male after the meningococcal vaccine, with outcome "recovered". The third case occurred in an 86-year-old elderly person after the varicella zoster vaccine, with outcome "recovered".
- One case of "sensory loss" in a 28-year-old male following the tick-borne encephalitis vaccine, with outcome "recovering".
- One case of "dysarthria" in a 31-year-old female after the human papilloma virus vaccine, with outcome "unknown".
- One case of "dizziness" and "confusional state" in a 20-year-old female after the human papilloma virus vaccine, with outcome of both AEFIs reported as "recovered".
- One case report of "febrile convulsions" in a 1-year-old female infant following pneumococcal vaccination, with outcome "recovered".

Four AEFI reports with fatal outcome were received by Swissmedic in 2024 in association with **non**-COVID-19 vaccines.

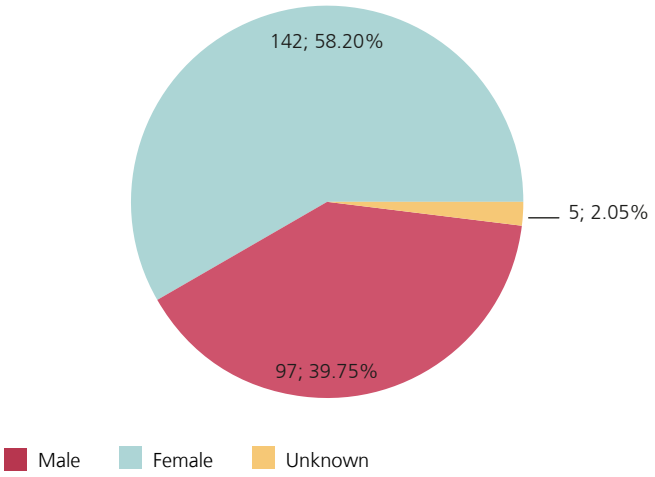
- One case report in a 75-year-old female after varicella zoster vaccination; however, this was a case of acute myocardial infarction with cardiac arrest and needing cardiac resuscitation measures, followed by an embolic cerebral infarction, in an elderly patient with severe underlying coronary three-vessel disease.
- One case report in an 80-year-old female following varicella zoster vaccination; a Guillain-Barré syndrome was clinically suspected as the triggering cause of death but could not be confirmed diagnostically, and an autopsy was not performed. The patient had severe comorbidities: an epidermoid lung carcinoma with left pneumonectomy, chronic obstructive pulmonary disease, and a myocardial infarction.
- One case report in an 86-year-old female following pneumococcal vaccination; this patient, living in a retirement home, showed a worsening of her general condition and died a few days later. The cause of death remained unclear since an autopsy was not performed.
- One case report in a female of unknown age following pneumococcal vaccination. This patient developed an invasive pneumococcal infection, however a pneumococcal serotype that was not covered by the vaccination was identified as the cause of the fatal infection.

AEFI reports received by Swissmedic in 2024 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccinations continued during 2024; Swissmedic received far fewer reports of suspected adverse reactions in this year (244 cases) compared to the previous years of the immunisation campaign (2023: 727 reports; 2022: > 5,000 reports).

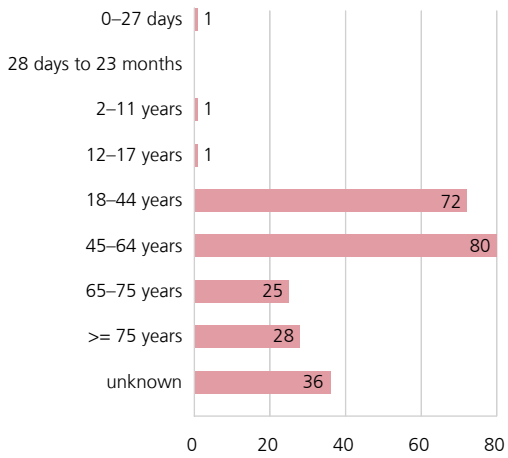
Sex of persons affected

Among the 244 COVID-19 AEFI reports received in 2024, 142 (58.2%) referred to women and 97 (39.7%) to men. The sex was not specified in some cases.



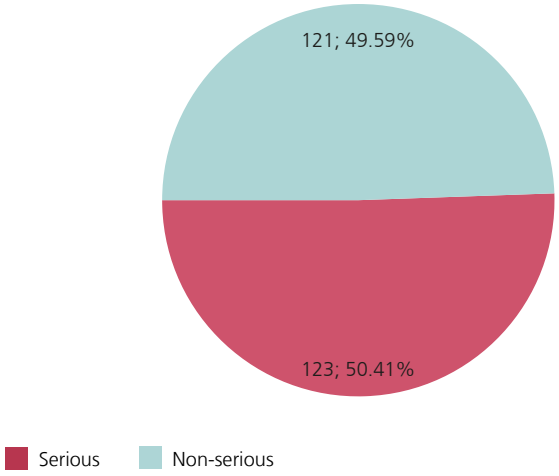
Age of persons affected

AEFI reports from COVID-19 vaccines were most frequent in the 45–64 age group, followed by the 18–44 age group. No age was specified in more than 30 cases. The reported age ranged between 6 and 92 years, with an average of 52.6 years.



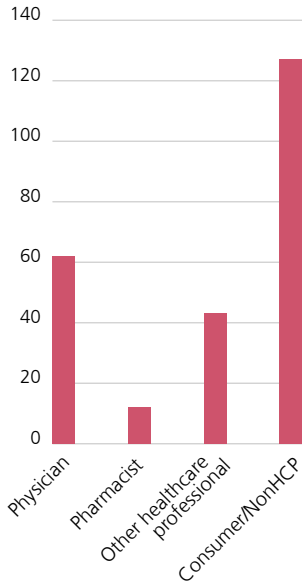
Seriousness of COVID-19 AEFI reports in 2024

Of the 244 spontaneous reports received in 2024, 121 (49.6%) were "non-serious", whereas 123 (50.4%) involved "serious", including "medically important", AEFIs.



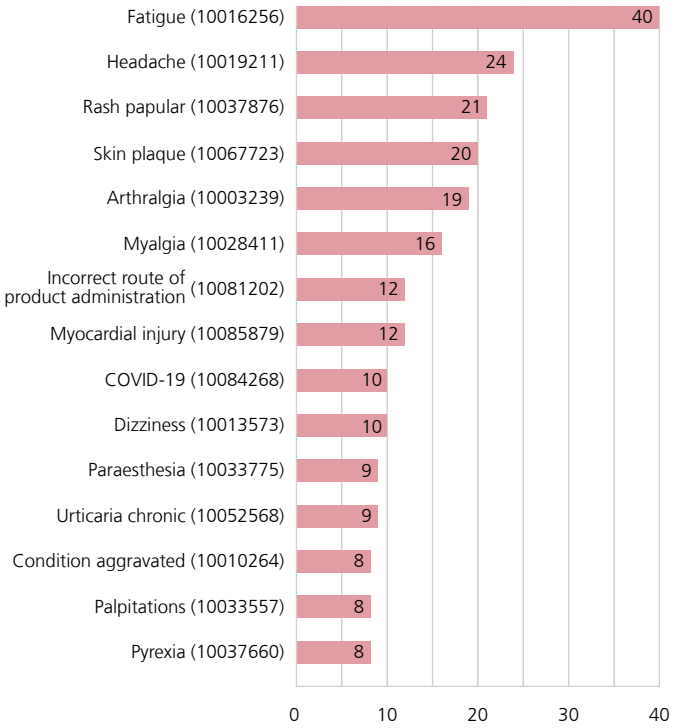
Primary reporters of COVID-19 AEFI in 2024

The primary reporters of the highest number of cases in 2024 were consumers/patients (127 of 244 cases; 52%), followed by physicians (62 reports; 25.4%).



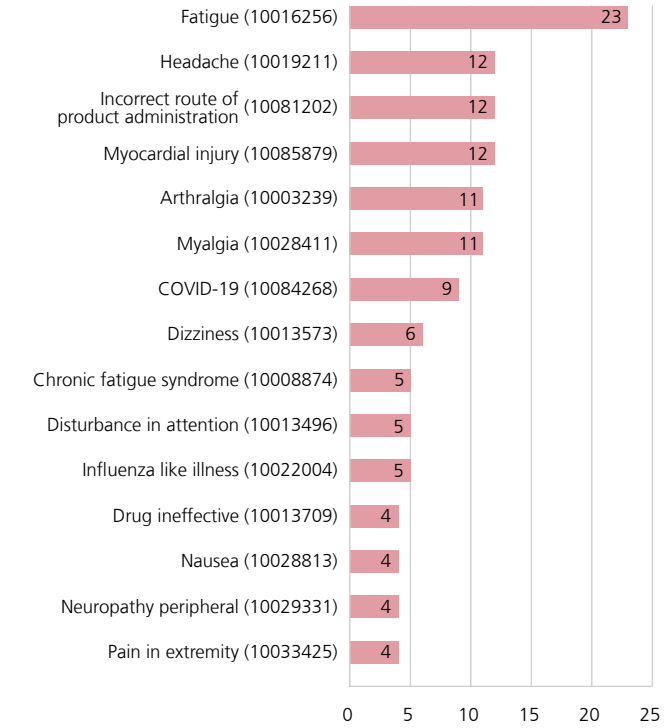
The following suspected reactions were reported most frequently for all COVID-19 vaccines in 2024:

Ranking of Top 15 Preferred Terms



The most frequent suspected reactions reported as **serious** for all COVID-19 vaccines were:

Ranking of Top "serious" 15 Preferred Terms



The 12 cases of "myocardial injury" listed in both figures above were received as literature reports from a Swiss publication investigating the possible incidence of myocardial damage after COVID-19 mRNA-1273 booster vaccination, by cardiac troponin T testing (1). Notably, "myocarditis/pericarditis" is a well-known safety topic, which is listed in the Swiss product information texts of several COVID-19 vaccines (3).

On 5 July 2024, Swissmedic published a "**Report of suspected adverse reactions to COVID-19 vaccines in Switzerland**" (2). This report presents, in a **cumulative** manner, a summary of the suspected adverse drug reactions following COVID-19 immunisation in the period from 1 January 2021 to the publication of the respective report by Swissmedic.

This report includes statistical data (cumulative figures), the ranking of the most frequently suspected reactions for all vaccines, the organ systems affected, as well as the ranking of reactions in non-serious and serious reports.

Among other topics, cases of longer-lasting symptoms with a temporal relationship to a vaccination against COVID-19 are addressed in this report. Swissmedic evaluates such reports thoroughly, continually reviews the latest drug safety findings, follows the scientific literature and works in close contact with international regulatory authorities.

Overall, the reports of suspected adverse reactions received and analysed did not alter the positive benefit-risk profile of the COVID-19 vaccines used in Switzerland, largely confirming their known safety profile. Known side effects of COVID-19 vaccines are listed in the continually updated, published Swiss product information texts (3).

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1
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2
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3
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