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Vaccinovigilance
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Summary of adverse events following immunization reported in Switzerland during 2025

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Summary of adverse events following immunization reported in Switzerland during 2025

Summary

During 2025, Swissmedic received a total of 356 reports of "adverse events following immunization (AEFIs)" from Switzerland. The decrease in total AEFI reports compared to 2024 (n=504) was caused mainly by a lower number of reports in relation to COVID-19 vaccinations (n=100 case reports in 2025 compared to 244 cases in 2024). In addition, 256 AEFI reports were submitted for **non-**COVID vaccines during 2025, which is a slightly lower number compared with 2024 (260 reports) and with 2023 (264 reports). Of the 256 cases, 134 (52.3%) were submitted directly to Swissmedic by reporters, whereas 122 (47.7%) case reports were received from marketing authorisation holders of the vaccines. The focus of this report is on **non-**COVID vaccines. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2025 is presented in the final section.

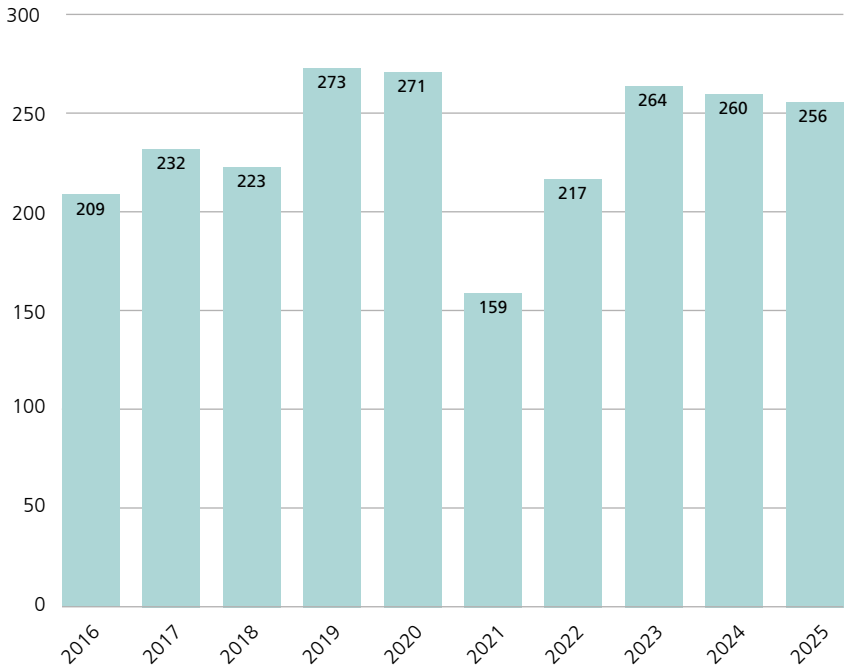


Figure 1: Number of non-Covid AEFI reports received between 2016 and 2025

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.

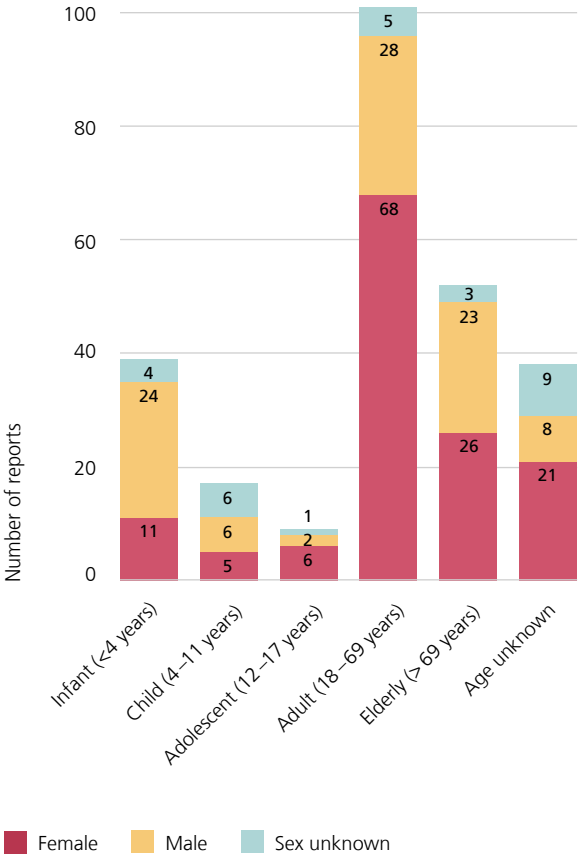


Figure 2: Number of AEFI reports by age group and sex, 2025

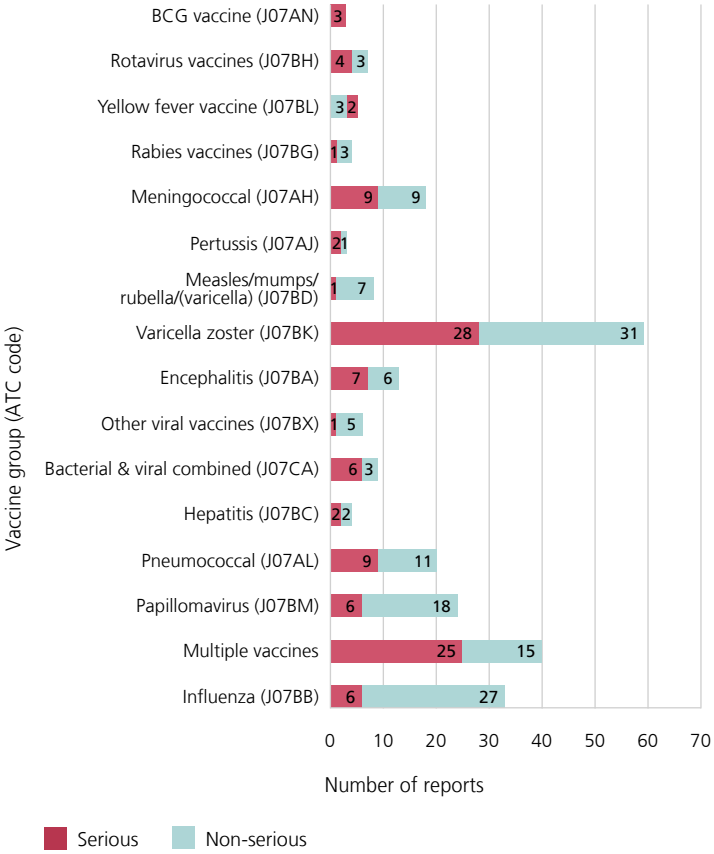


Figure 3: Number of reports by vaccine group (ATC code) and seriousness, 2025

Figure 2 compares the number of reports by age group and sex. The largest number of AEFI reports involved adults (101 reports), followed by the elderly (52 reports), infants (39 reports), children (17 reports) and adolescents (9 reports). Overall, in 2025 the number of reports concerning females (137 reports; 53.5%) exceeded those concerning males (91 reports; 35.6%). In 28 AEFI reports (10.9%), the sex of the persons remained unknown. In 38 case reports (14.8%), the age group of the patients was not recorded.

Figure 3 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 256 spontaneous reports received in 2025, 143 (55.8%) were "non-serious", 88 (34.4%) included only medically important events and 25 (9.8%) of the reports involved AEFIs with serious consequences.

Generally, considering all vaccines in 2025, the relative frequency (percentage) of "serious", including "medically important", cases taken together (113 reports; 44.1%) was slightly higher than 2024 (37.7%) and 2023 (36%).

Cases where several (n >1) vaccines were reported as suspected in relation to AEFIs are shown in Figure 3 as "Multiple vaccines". Many of these cases concerned multiple immunizations in children.

As in 2023 and 2024, during 2025 a higher number of cases relating to the herpes zoster vaccination were submitted, and these are included in Figure 3 as ATC code "Varicella zoster (J07BK)". The majority of these case reports were assessed as "non-serious" (31 of 59 cases; 52.5%), which was a similar percentage to 2023 (54.8%) and 2024 (55.4%).

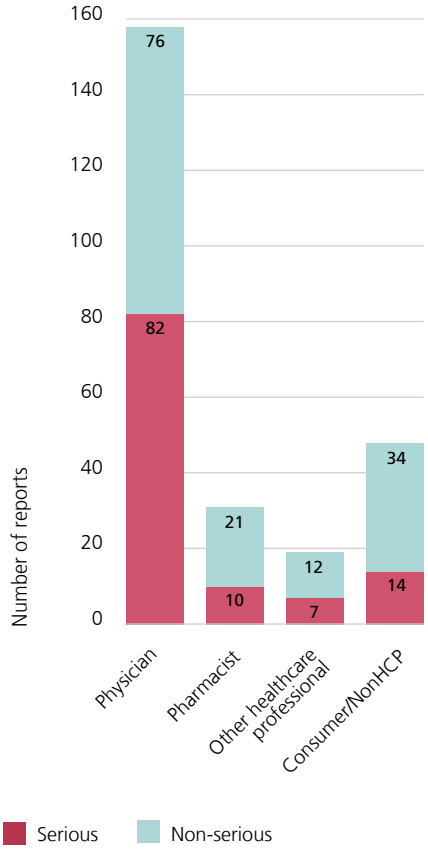


Figure: Number of AEFI reports by reporter qualification and seriousness, 2025

Figure 4 shows the number of Swiss AEFI reports in 2025 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 (158 of 256), including a higher number of reports assessed as "serious" or "medically important" (82 of 158 reports). Consumers/patients submitted the second-highest number (48 AEFI reports), followed by pharmacists (31 reports).

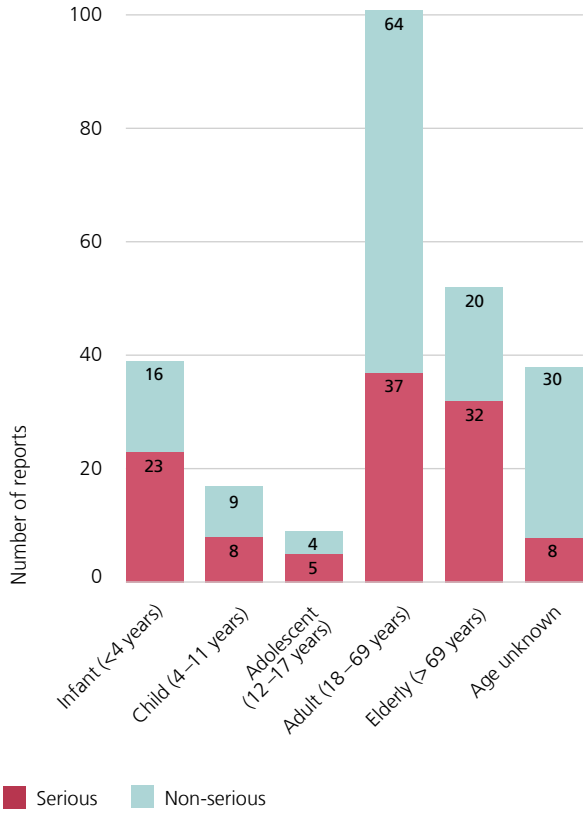


Figure 5: Number of AEFI reports by age group and seriousness, 2025

Figure 5 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 101 AEFI reports in total) were recorded in the adult age group, followed by the elderly (32 of 52 reports), infants (23 of 39 reports), children (8 of 17 reports) and adolescents (5 of 9 reports).

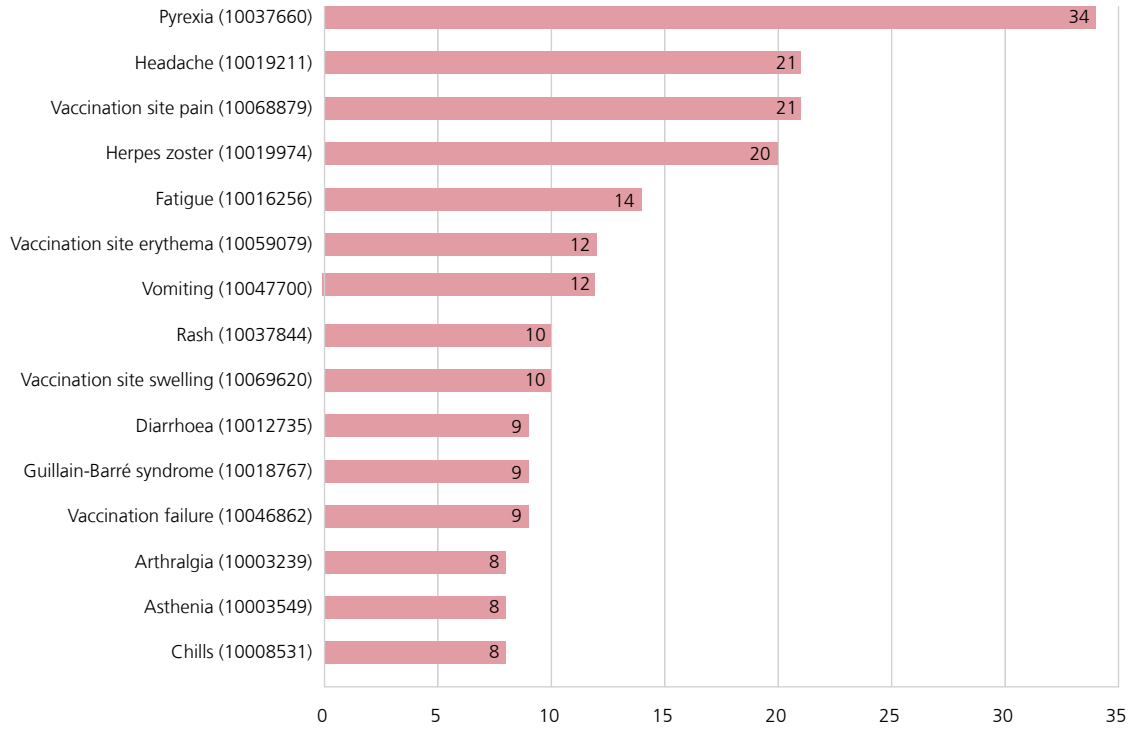


Figure 6: Overview of the most frequent AEFIs of all reports, 2025

Figure 6 shows the most frequent AEFIs reported during 2025 as MedDRA Preferred Terms, including: pyrexia; headache; vaccination site pain; herpes zoster; fatigue; vaccination site erythema; vomiting; rash; vaccination site swelling; diarrhoea; Guillain-Barre syndrome; vaccination failure; arthralgia; asthenia; and chills. Notably, 7 cases of Guillain-Barre syndrome were received as nine reports, some of them being submitted as duplicates from different reporting sources (see also "serious reports" below).

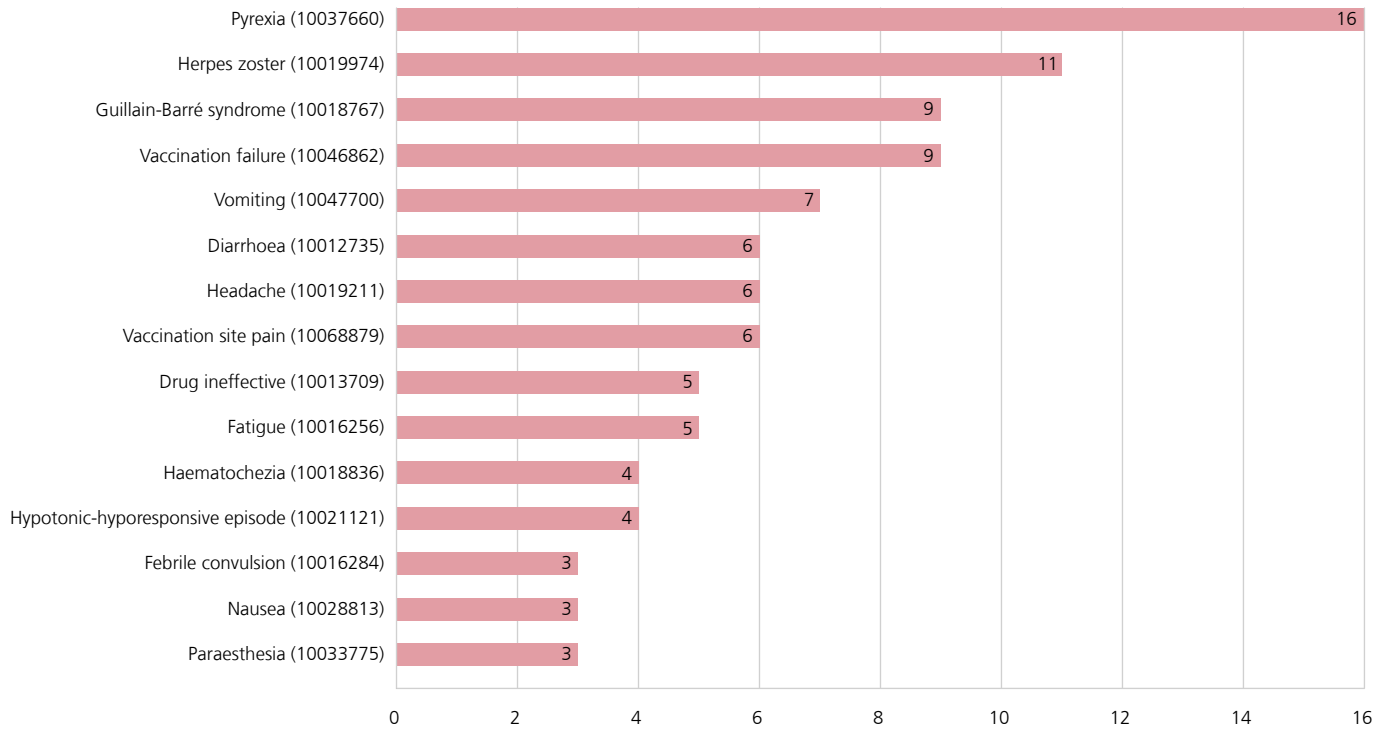


Figure 7: The most frequent AEFIs in "serious" reports, 2025

Figure 7 summarises the most frequent AEFIs submitted as MedDRA Preferred Terms in reports assessed as "serious", including: pyrexia; herpes zoster; Guillain-Barré syndrome; vaccination failure; vomiting; diarrhoea; headache; vaccination site pain; drug ineffective; fatigue; haematochezia; hypotonic-hyporesponsive episode; febrile convulsion; nausea; and paraesthesia.

In 2025, nine "serious" reports of "vaccination failure" (MedDRA-PT) were received, all of them following herpes zoster vaccination.

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 2025 included:

- Seven cases of Guillain-Barré syndrome: two of these cases occurred in females after the varicella zoster vaccine (one of them a 57-year-old and the other of unknown age who also received an influenza vaccine), with the outcomes reported as "not recovered" and "unknown", respectively; one case occurred in a 57-year-old male following the varicella zoster vaccine, with the outcome reported as "recovering"; two other cases occurred following the tick-borne encephalitis vaccine, one in a 56-year-old female with outcome "recovered" and the second in a 59-year-old female who also received combined vaccines (diphtheria vaccine / pertussis vaccine / tetanus vaccine) with outcome "not recovered"; another case occurred in a 63-year-old female following the influenza vaccination, with the outcome reported as "recovering"; the seventh case occurred in a 73-year-old male after the yellow fever vaccine, with the outcome reported as "not recovered".

Guillain-Barré syndrome is a known and very rare adverse reaction of the suspected vaccines in the respective cases (varicella zoster vaccine, influenza vaccine, tick-borne encephalitis vaccine and yellow fever vaccine) (1).

- Four cases of "hypotonic-hyporesponsive episode" in infants aged < 1 year, two males and two females, following administration of multiple different childhood vaccines in all cases (such as diphtheria / hepatitis B / HIB / pertussis / pneumococcal / polio / rotavirus / tetanus); the outcome of all four episodes was reported as "recovered".

  Hypotonic-hyporesponsive episode is a well-known and very rare adverse reaction of the childhood vaccinations administered in these cases. It is considered to be a benign, self-limiting adverse effect following immunization and is not a contraindication for further vaccination (1), (2).

- One case of "autoimmune encephalitis" in a 63-year-old female after the varicella zoster vaccine, with the outcome reported as"recovered".

- Two cases of "encephalitis", one case in a 38-year-old male following administration of multiple vaccines (diphtheria / pertussis / tetanus and tick-borne encephalitis), with outcome "recovered". The second case occurred in a 59-year-old male after the varicella zoster vaccine, also with outcome "recovered".

- One case of "acute disseminated encephalomyelitis" in an 11-year-old male after the meningococcal vaccine, with the outcome reported as "recovering" at the time of reporting.

- Three cases of "drug ineffective" and "tick-borne viral encephalitis" in a 75-year-old male and in two children of unknown age and sex, all three cases following the tick-borne encephalitis vaccination and with outcome reported as "unknown".

- One case of "blindness" in a 59-year-old male following administration of combined vaccines (diphtheria / pertussis / polio / tetanus), with the outcome reported as "recovering" at the time of reporting.

- One case of "unilateral blindness" in an 80-year-old male after the varicella zoster vaccine, with the outcome reported as "recovered" at the time of reporting.

- One case of "autism spectrum disorder" in a male child of unknown age, after the administration of measles / mumps / rubella / varicella zoster vaccine and pneumococcal vaccine, with outcome "not recovered".

- One case of "facial paralysis", "amnesia" and "aphasia" in a 65-year-old male after the influenza vaccination, with the outcome reported as "recovering" at the time of reporting.

- One case of "epilepsy", in a 93-year-old female after the varicella zoster vaccination, with the outcome reported as "unknown" at the time of reporting.

- One case of "status epilepticus", in a 2-year-old female infant after the meningococcal vaccine, with the outcome reported as "recovered" at the time of reporting.

One AEFI case report with fatal outcome was received by Swissmedic in 2025 following meningococcal vaccination. Despite extensive investigations including forensic medical assessment, the cause of death could not be definitively established.

AEFI reports received by Swissmedic in 2025 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccinations continued during 2025 with updated vaccines; Swissmedic received far fewer reports of suspected adverse reactions in this year (100 cases) compared to the previous years (2024: 244 reports; 2023: 727 reports; 2022: > 5,000 reports). Of these 100 cases, 80 were submitted directly to Swissmedic and 20 were received from marketing authorisation holders of COVID-19 vaccines.

Sex of persons affected

Among the 100 COVID-19 AEFI reports received in 2025, 45 (45%) referred to women and 55 (55%) to men.

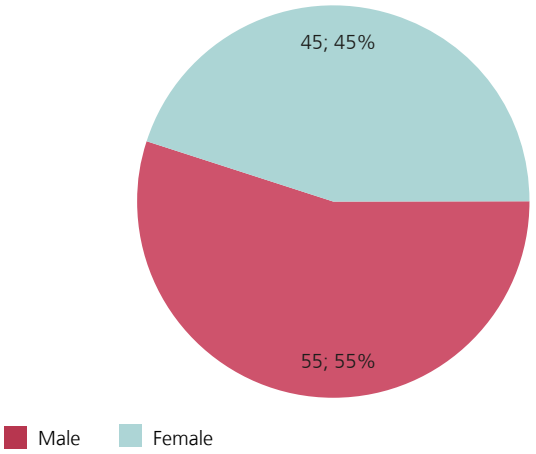


Figure 8: Sex of persons in COVID-19 AEFI reports, 2025

Age of persons affected

AEFI reports from COVID-19 vaccines were most frequent in the 18-44 age group, followed by the 45-64 age group. No age was specified in 11 cases. The reported age ranged between 15 and 86 years, with an average of 48.4 years.

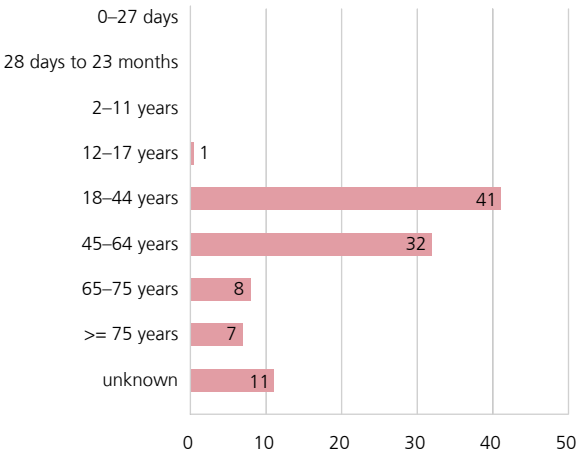


Figure 9: Age of persons in COVID-19 AEFI reports, 2025

Seriousness of COVID-19 AEFI reports in 2025

Of the 100 spontaneous reports received in 2025, 38 (38%) were "non-serious", whereas 62 (62%) involved "serious", including "medically important", AEFIs.

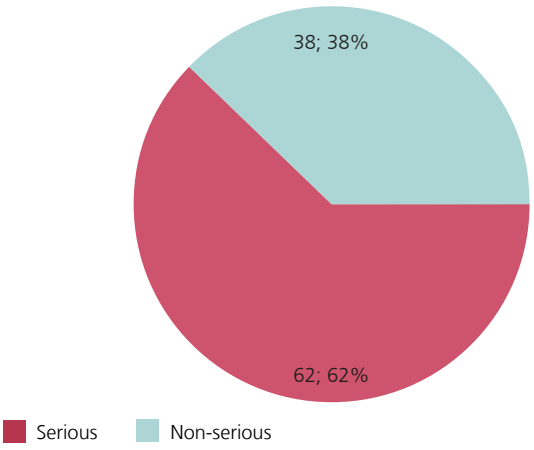


Figure 10: Seriousness of COVID-19 AEFI reports in 2025

Primary reporters of COVID-19 AEFIs in 2025

The primary reporters of the highest number of cases in 2025 were consumers/patients (72 of 100 cases; 72%), followed by physicians (17 reports; 17%).

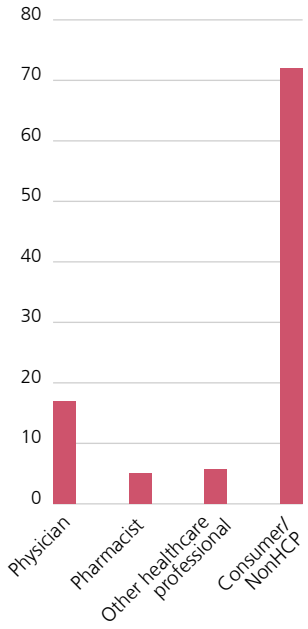


Figure 11: Primary reporters of COVID-19 AEFIs in 2025

The following suspected reactions were reported most frequently for all COVID-19 vaccines in 2025:

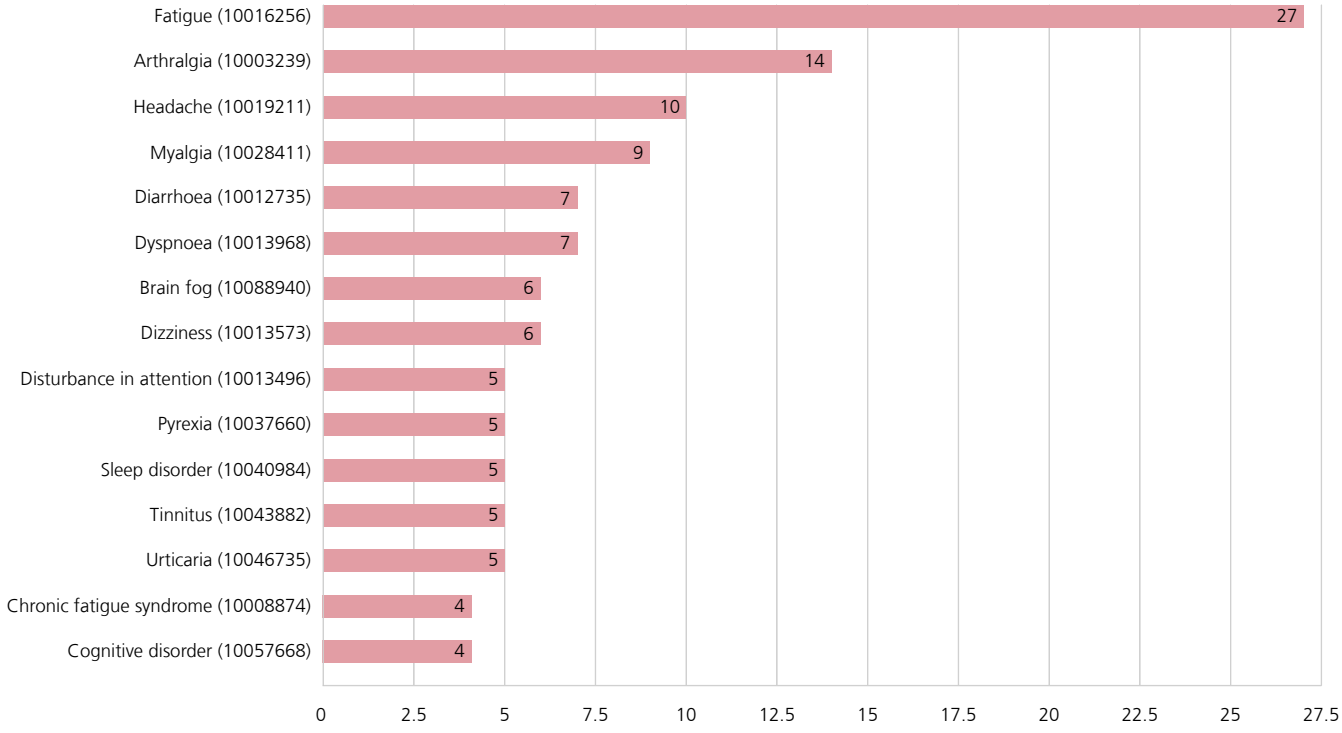


Figure 12: Ranking of the most frequent AEFIs in COVID-19 reports, 2025

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

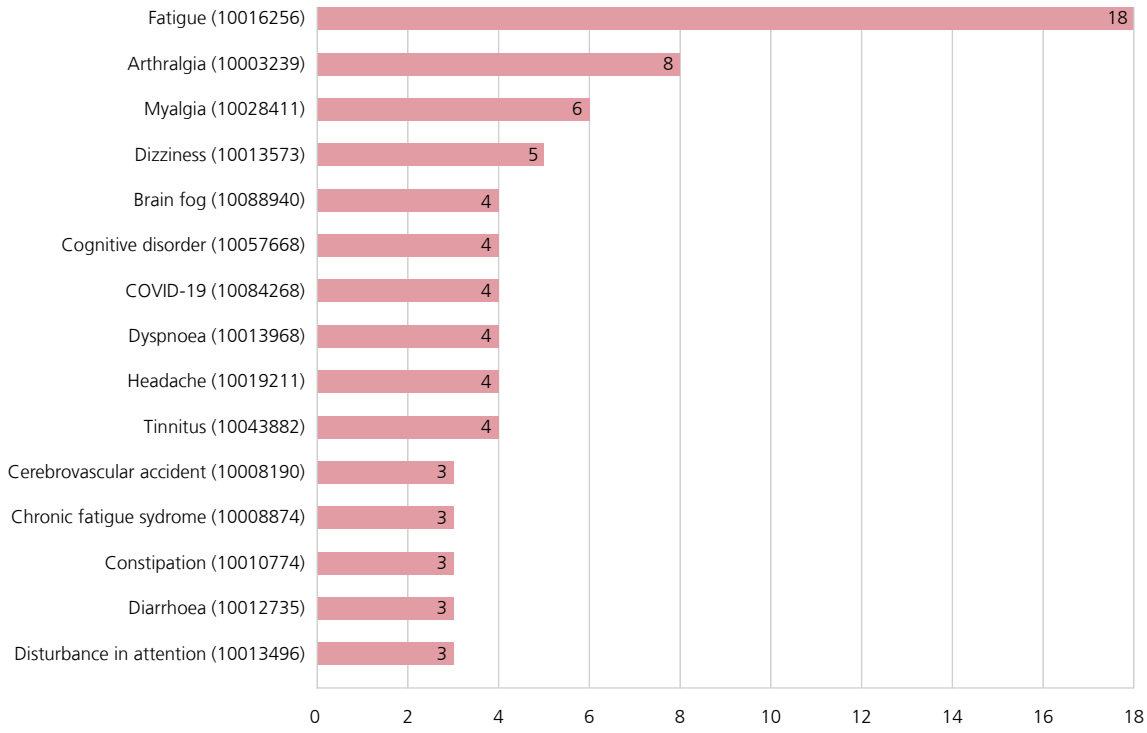


Figure13: The most frequent AEFIs in "serious" COVID-19 reports, 2025

Some of the AEFI listed above (such as "cognitive disorder", "brain fog", "cerebrovascular accident", "chronic fatigue syndrome") were reported as occurring in temporal association with the COVID-19 immunisation; however vaccine-related causality has not been established so far.

No case report with fatal outcome was reported in 2025 for COVID-19 vaccines.

Swissmedic evaluates COVID-19 vaccine 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 (1).

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References

1
AIPS (www.swissmedicinfo.ch)

2
Swissmedic Website: Hypotonic-hyporesponsive episode and basic immunisation in infants

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Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
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