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Vaccinovigilance
Annual report 2023

November 2024

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Summary of adverse events following immunization reported in Switzerland during 2023

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Credits

Publisher
Swissmedic, Swiss Agency for Therapeutic Products
Divison Safety of Medicines
Pharmacovigilance
Hallerstrasse 7
3012 Bern
Switzerland
www.swissmedic.ch

Editors/contacts
Swissmedic, Divison Safety of Medicines

Layout and typesetting
Swissmedic, Communication Department

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Summary of adverse events following immunization reported in Switzerland during 2023

During 2023, the Pharmacovigilance Unit of Swissmedic received a considerable number of case reports of suspected "adverse events following immunization (AEFIs)" from Switzerland. Although lower in number than in 2022, the majority of these reports (>700 cases) were still submitted in relation to COVID-19 vaccines. Overall, these figures are a consequence of continuing COVID-19 vaccination in Switzerland and most of these reports describe well-known reactions following COVID-19 immunisation such as fever, chills or administration site reactions. In addition, 264 AEFI reports were submitted in Switzerland for **non**-COVID vaccines during 2023, which is a higher number compared with 2022 (217 reports) and 2021 (159 reports). The main focus of this summary report is on **non**-COVID vaccine AEFIs, since COVID-19 vaccine safety reports have been published as **cumulative** updates on Swissmedic's website. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2023 is presented in the final section of this document.

AEFI reports submitted during 2023 were recorded, assessed and analysed in the pharmacovigilance database of Swissmedic. As previously, Swissmedic is encouraging spontaneous reporting of AEFIs in high quality, which enables early detection of new safety signals. Important safety issues concerning vaccines are evaluated in international collaboration with other foreign agencies and/or with the participation of the Human Medicines Expert Committee (HMEC) of Swissmedic, if necessary. An increased AEFI reporting rate within the Swiss database, followed by an assessment of relevant cases, can lead to risk minimisation measures in order to ensure vaccine safety.

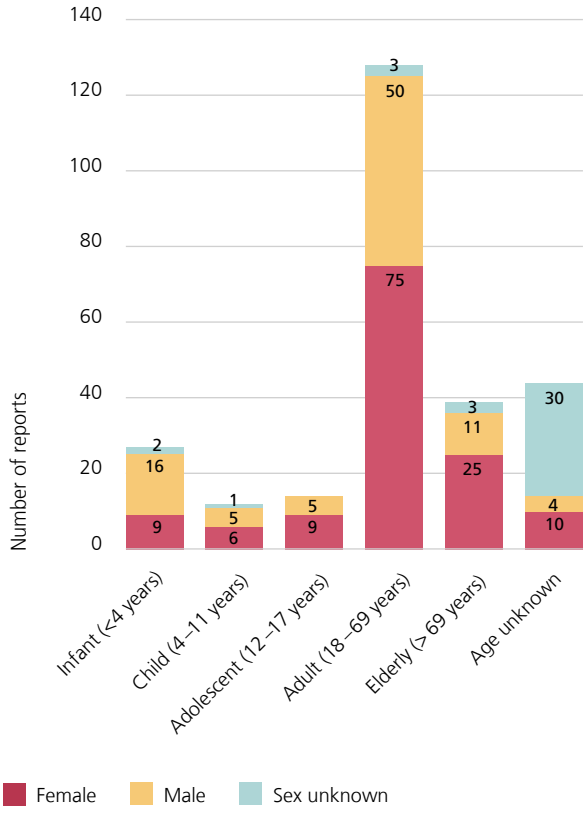


Figure 1: Number of AEFI reports by age group and sex, 2023

Figure 1 compares the number of reports by age group and sex. The largest number of AEFI reports involved adults (128 reports), followed by the elderly (39 reports), infants (27 reports), adolescents (14 reports) and children (12 reports). Throughout 2023, the number of reports concerning females (134 reports; 50.8%) exceeded those concerning males (91 reports; 34.4%). In 39 AEFI reports (14.8%), the sex of the persons remained unknown. In 44 case reports (16.6%), the age group of the patients was not recorded.

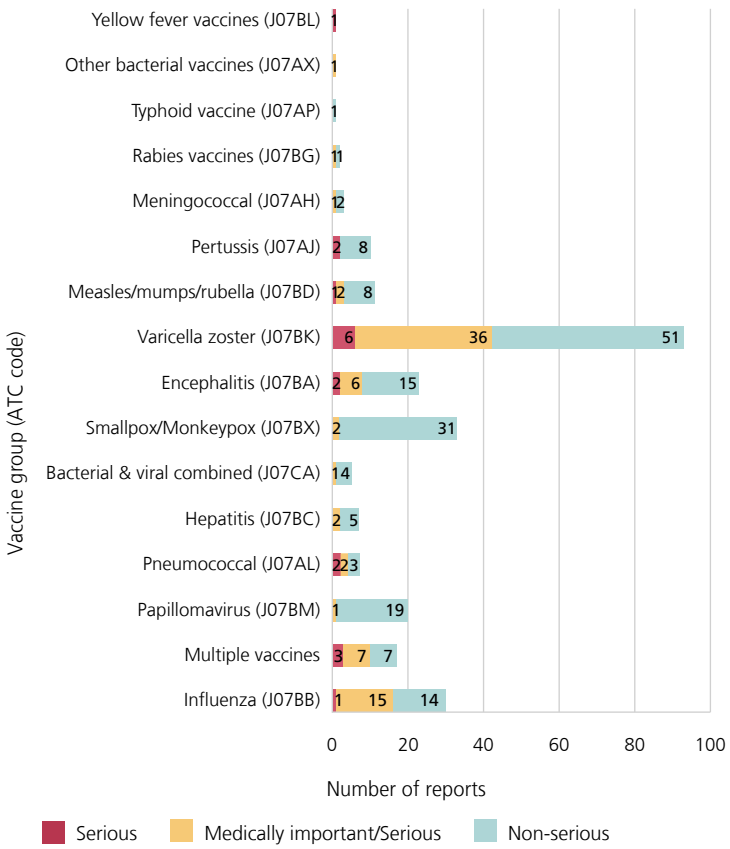


Figure 2: Number of reports by vaccine group (ATC code) and seriousness, 2023

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 was life threatening or resulted 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 criteria for "seriousness" mentioned, 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 264 spontaneous reports received in 2023, 169 (64%) were "non-serious", 77 (29.2%) included only medically important events and 18 (6.8%) of the reports involved AEFIs with serious consequences.

Generally, by considering all vaccines in 2023, the relative frequency (percentage) of "serious" including "medically important" cases taken together (95 reports; 36%) was quite similar to 2022 (37.3%) and higher than in 2021 (32.1%).

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".

Similarly to 2022, during 2023 a higher number of cases was submitted relating to the herpes zoster vaccination, which are shown in Figure 2 as ATC code "Varicella zoster (J07BK)", and to the new monkeypox vaccination, shown in Figure 2 as "Smallpox/Monkeypox (J07BX)". The majority of these case reports were assessed as "non-serious" for the herpes zoster vaccines (51 of 93 cases; 54.8%), and almost all reports relating to smallpox/monkeypox vaccination (31 of 33 cases in 2023) included only "non-serious" AEFIs.

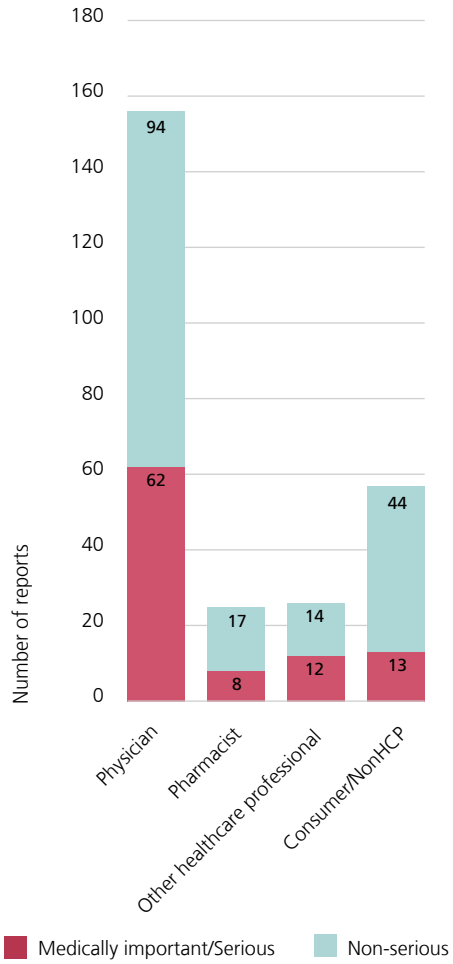


Figure 3: Number of AEFI reports by reporter qualification and seriousness, 2023

Figure 3 shows the number of Swiss AEFI reports in 2023 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 (156 of 264), including a higher number of reports assessed as "serious" or "medically important" (62 of 156 reports). Notably, consumers/patients submitted the second-highest number (57) of non-COVID AEFI reports to Swissmedic during 2023.

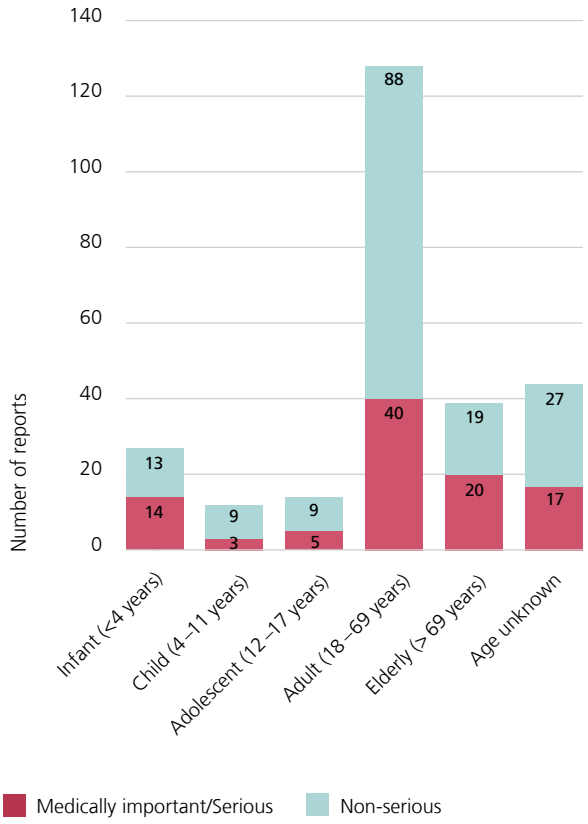


Figure 4: Number of AEFI reports by age group and seriousness, 2023

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 (40 of 128 AEFI reports in total) were recorded in the "adults" age group, followed by the elderly (20 of 39 reports), infants (14 of 27 reports), adolescents (5 of 14 reports) and children (3 of 12 reports).

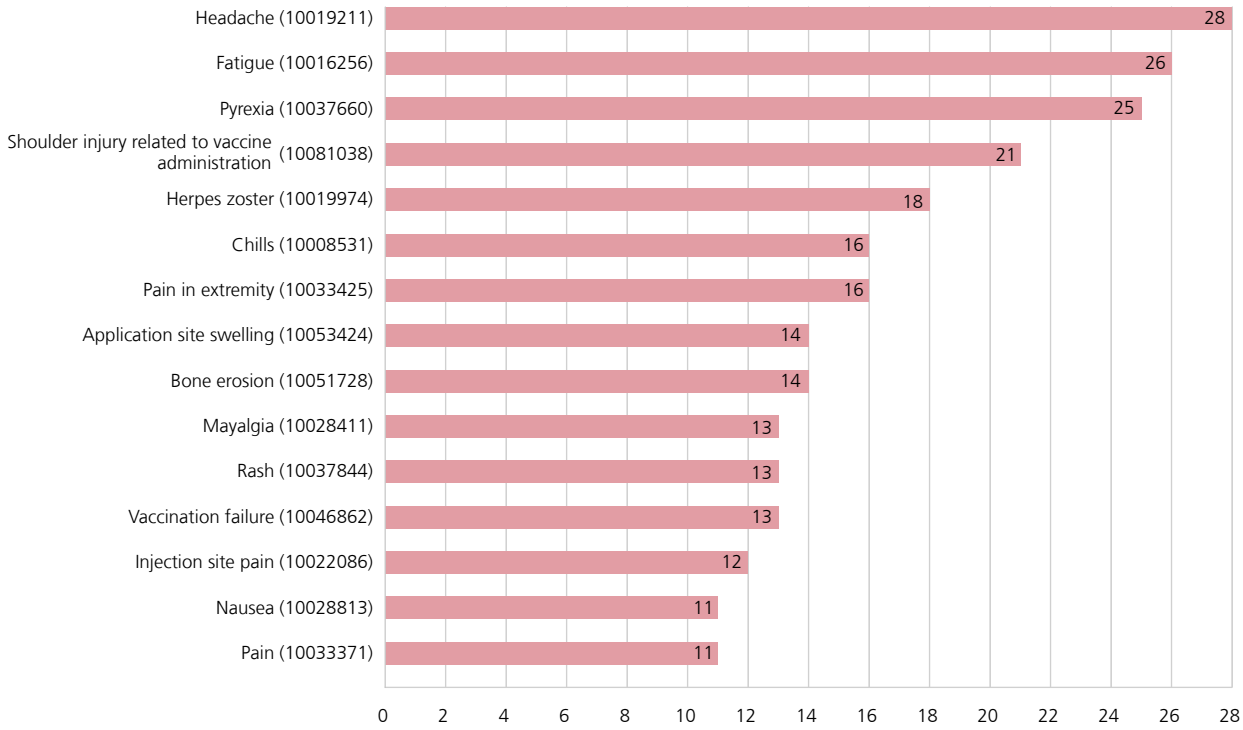


Figure 5: Overview of the most frequent AEFIs of all reports, 2023

Figure 5 shows the most frequent AEFIs reported during 2023 as MedDRA Preferred Terms, such as: headache; fatigue; pyrexia; shoulder injury related to vaccine administration; various injection/vaccination site reactions including injection site erythema; injection site pain; injection site induration; herpes zoster; vaccination failure; and pain. Notably, the cases of "shoulder injury related to vaccine administration" (SIRVA) in Figure 5 include multiple duplicate reports received by Swissmedic from three **different** marketing authorisation holders.

These literature reports refer to n=7 cases from a Swiss study investigating patients by magnetic resonance imaging (1). Furthermore, some reports of herpes zoster were received as suspected cases of vaccination failure following varicella zoster immunisation (see also "serious reports" below).

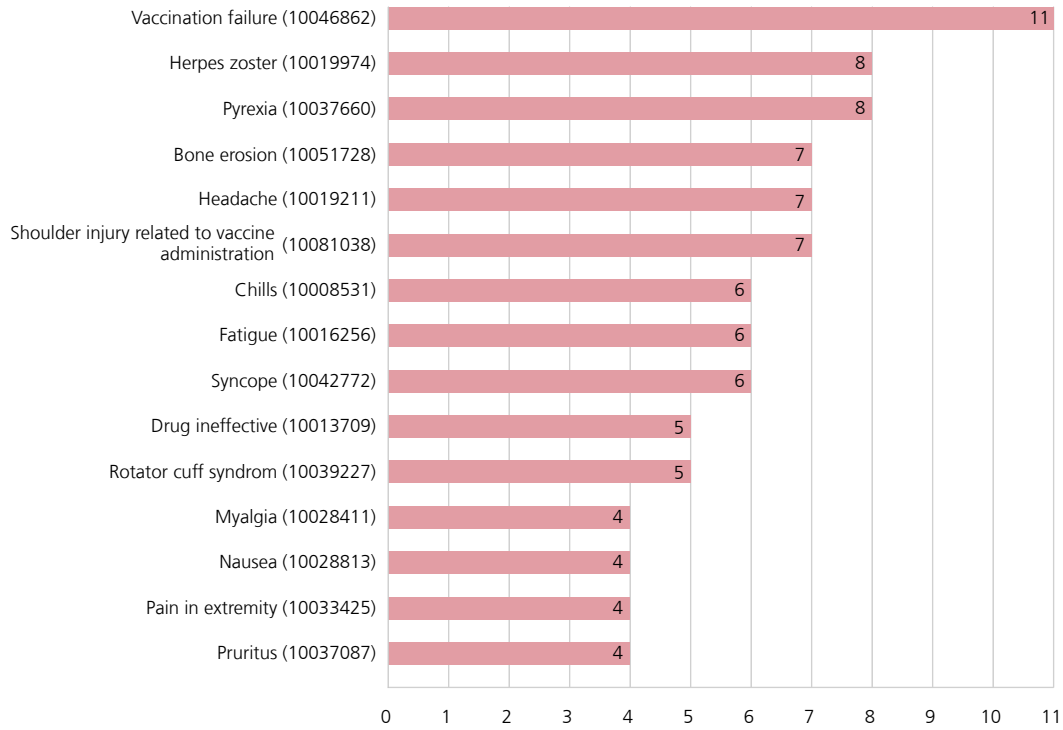


Figure 6: The most frequent AEFIs in "serious" reports, 2023

Figure 6 summarises the most frequent AEFIs submitted as MedDRA Preferred Terms in reports assessed as "serious", such as: vaccination failure; herpes zoster; pyrexia; headache; fatigue; bone erosion (1); and shoulder injury related to vaccine administration (SIRVA) (1).

In 2023, 11 "serious" reports of "vaccination failure" were received, including six cases following herpes zoster vaccination, two cases after HPV immunisation and one case of reported varicella following varicella 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 2023 included:

- One case report of "hypotonic-hyporesponsive episode", which occurred in a 4-month-old male infant following administration of multiple different vaccines; the outcome of the episode was reported as "recovered".
- Two cases of "facial paralysis"; one case in a 15-year-old female adolescent following administration of combined vaccines (diphtheria vaccine / HIB vaccine / hepatitis B vaccine / pertussis vaccine / polio vaccine / tetanus vaccine), with the outcome "not recovered". The second case occurred in a 48-year-old female adult after the varicella zoster vaccine, with the outcome reported as "recovering".
- One case of "unilateral deafness" in a 15-year-old male adolescent following administration of HPV vaccine and hepatitis B vaccine, with the outcome reported as "not recovered".
- One case of "neuralgic amyotrophy" in a 75-year-old male following administration of pneumococcal vaccine, with the outcome "not recovered" at the time of reporting.
- One case of "cerebellitis" in a 16-month-old female infant after administration of live measles vaccine / live mumps vaccine / live rubella vaccine / live varicella zoster vaccine, with the outcome "not recovered".

- Two cases of "tick-borne viral encephalitis", both reported as "drug ineffective" following tick-borne viral encephalitis immunisation: one case in an adult male patient in the context of an inappropriate vaccine administration schedule, with the outcome "recovered" and a second case of "tick borne viral encephalitis" in a male patient (age not specified), with the outcome "unknown".

- Five cases of "syncope" were received as serious (including medically important) AEFI reports: one case in a 3-year-old male infant following live varicella zoster vaccine, with the outcome reported as "resolving". The second case was reported in a 47-year-old male adult following influenza vaccination, with the outcome "recovered". A third case was reported in a 63-year-old male adult after the varicella zoster vaccine, with the outcome "recovered". The fourth case occurred in a 91-year-old female patient after the varicella zoster vaccine, with the outcome "recovered". The fifth case of syncope was reported in a patient of unknown sex and age, following influenza vaccination, with the outcome "unknown".

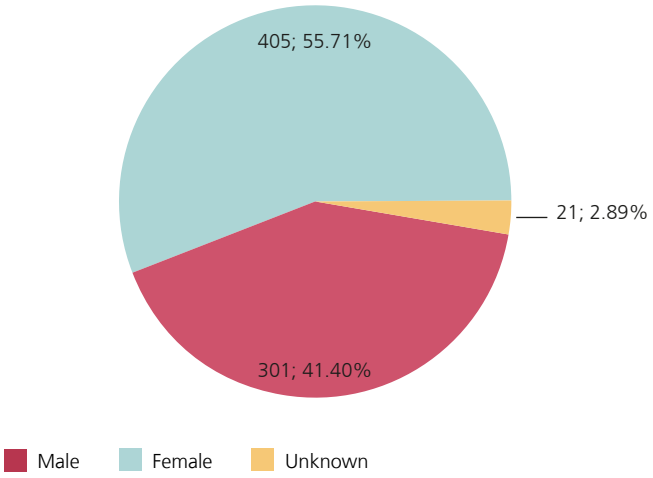
Only one report with a fatal outcome was received by Swissmedic in 2023 in association with non-COVID-19 vaccines. However, this was a case of decompensated cor pulmonare and pulmonary oedema in a 69-year-old male patient with underlying idiopathic pulmonary fibrosis and other severe comorbidities, being treated with nintedanib. Three months before the fatal outcome of his serious conditions, the patient received the varicella zoster vaccine and developed the AEFI "exanthema", which was considered not serious.

AEFI reports received by Swissmedic in 2023 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccine rollout continued during 2023; however, Swissmedic received far fewer reports of suspected adverse reactions in this year (727 cases) compared to the first two years of the immunisation campaign.

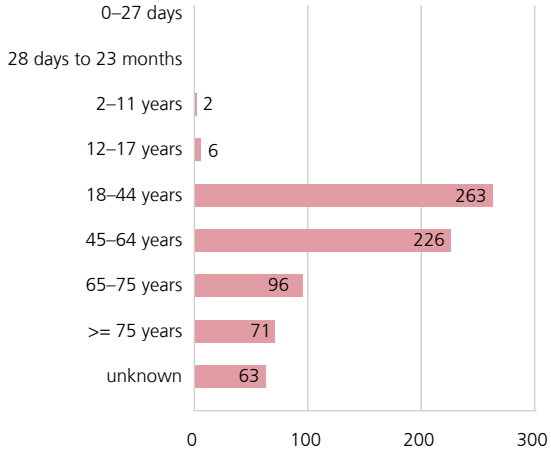
Sex of persons affected

Among the 727 COVID-19 AEFI reports received in 2023, 405 (55.7%) referred to women and 301 (41.4 %) to men. The sex was not specified in some of the reports.



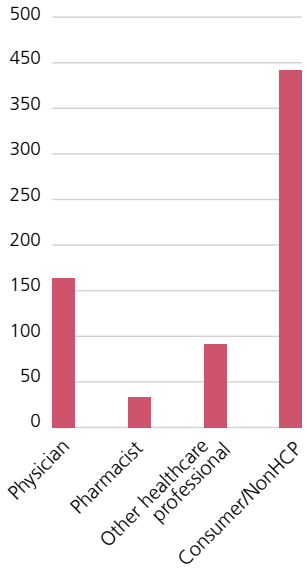
Age of persons affected

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 more than 60 cases. The reported age ranged between 10 and 102 years, with an average of 50.3 years.



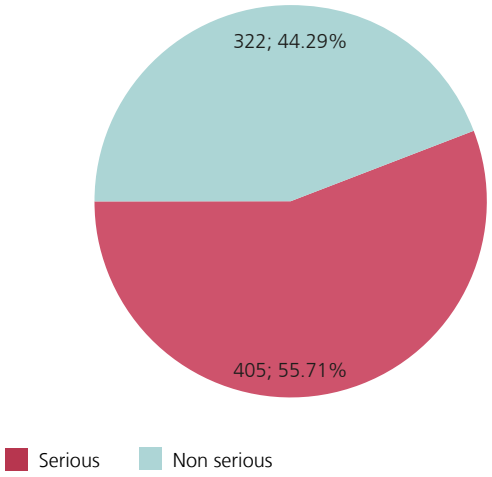
Primary reporters of COVID-19 AEFI in 2023

The primary reporters of the highest number of cases in 2023 were consumers/patients (438 of 727 cases; 60.2%), followed by physicians (167 reports; 23%).



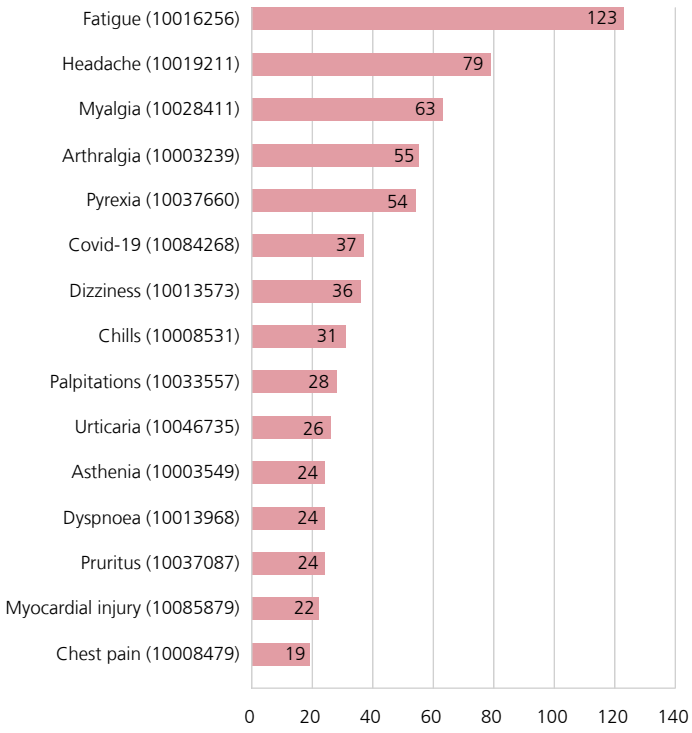
Seriousness of COVID-19 AEFI reports in 2023

Of the 727 spontaneous reports received in 2023, 322 (44.3%) were "non-serious", whereas 405 (55.7%) involved "serious", including "medically important", AEFIs.



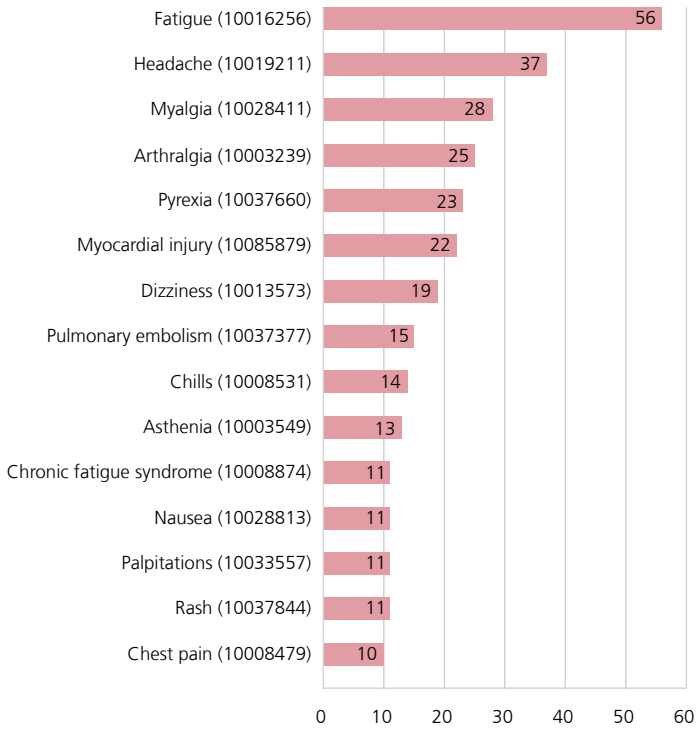
The following suspected reactions were reported most frequently for all COVID-19 vaccines in 2023:

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 22 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 (2). Notably, "myocarditis/pericarditis" is a well-known safety topic, which is listed in the Swiss product information texts of several COVID-19 vaccines (4).

On 24 February 2023, Swissmedic published a new **"Update Report of suspected adverse reactions to COVID-19 vaccines in Switzerland"**, ("Update 29"); (3). Similarly to previous editions, this report presents in a **cumulative** manner a summary of the suspected adverse drug reactions following COVID-19 immunisation in the time period from 1 January 2021 to the publication of the respective report by Swissmedic.

This Update Report includes statistical data (overall figures), the presentation and ranking of suspected reactions by individual vaccines and by vaccination doses, as well as updated information from Swissmedic on particular safety aspects of COVID-19 vaccines (3).

Altogether, the reports of 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 side effects profile. Known side effects of COVID-19 vaccines are listed in the continually updated, published Swiss product information texts (4).

The most recent (additional) cumulative safety update on COVID-19 vaccines was published online by Swissmedic on 5 July 2024 (5). 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.

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3
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4
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5
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