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Vaccinovigilance Annual report 2022

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Vaccinovigilance
Annual report 2022

Summary of adverse events following immunization reported in Switzerland during 2022

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Contents

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Executive summary

During 2022, the Pharmacovigilance Unit of Swissmedic received a high number of case reports of suspected "adverse events following immunization (AEFIs)" from Switzerland. As in the previous year 2021, the vast majority of these reports (> 5,000 cases) were submitted in relation with the COVID-19 vaccines during the vaccination campaign which continued throughout the year 2022. In addition to that, 217 AEFI reports have been submitted in Switzerland for **non**-COVID vaccines during 2022, which is a higher number as compared with the previous year 2021 (159 reports), but lower than in 2020 (271 reports). These figures are not unexpected and are probably still a consequence of the large scale COVID-19 vaccination and information campaign, having the main attention focused on COVID-19 vaccines. However, most of these reports describe well-known reactions following COVID-19 immunisation such as fever, chills or administration site reactions. This summary report has its main focus on the **non**-COVID vaccine AEFIs since several COVID-19 vaccine safety reports have been regularly published as cumulative updates on Swissmedic's website. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2022 is presented in the final section of this document.

Similar to the previous year, AEFI reports submitted during 2022 have been recorded, assessed and analysed in the pharmacovigilance database of Swissmedic. However, no accurate data were available regarding the number of vaccine doses administered in Switzerland during 2022 for different **non**-COVID vaccine groups and therefore a straightforward conclusion regarding AEFI reporting rates cannot be drawn. 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 being 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 per age group and gender, 2022

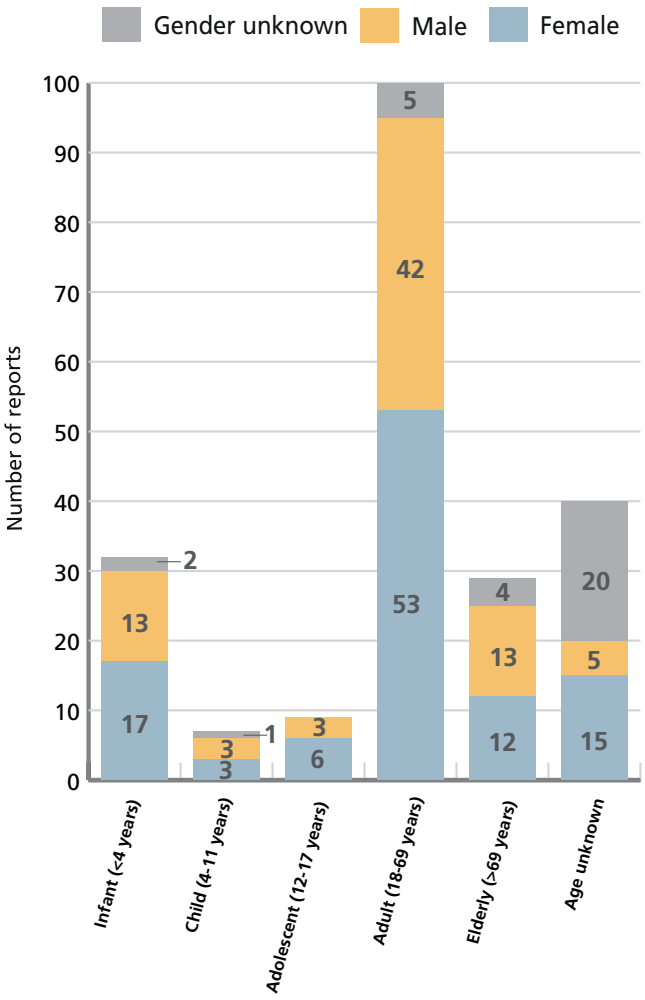

Figure 1 compares the number of reports per age group and gender. The largest number of AEFI reports involved adults (100 reports), followed by infants (32 reports), the elderly (29 reports), adolescents (9 reports) and children (7 reports). Throughout the year 2022, the number of reports concerning females (106 reports; 48.8%) exceeded the number of reports concerning males (79 reports; 36.4%). In 32 AEFI reports (14.7%), the gender of the persons remained unknown. In 40 case reports (18.4%), the age group of the patients was not recorded.

Figure 2.
Number of reports by vaccine group (ATC code) and seriousness, 2022

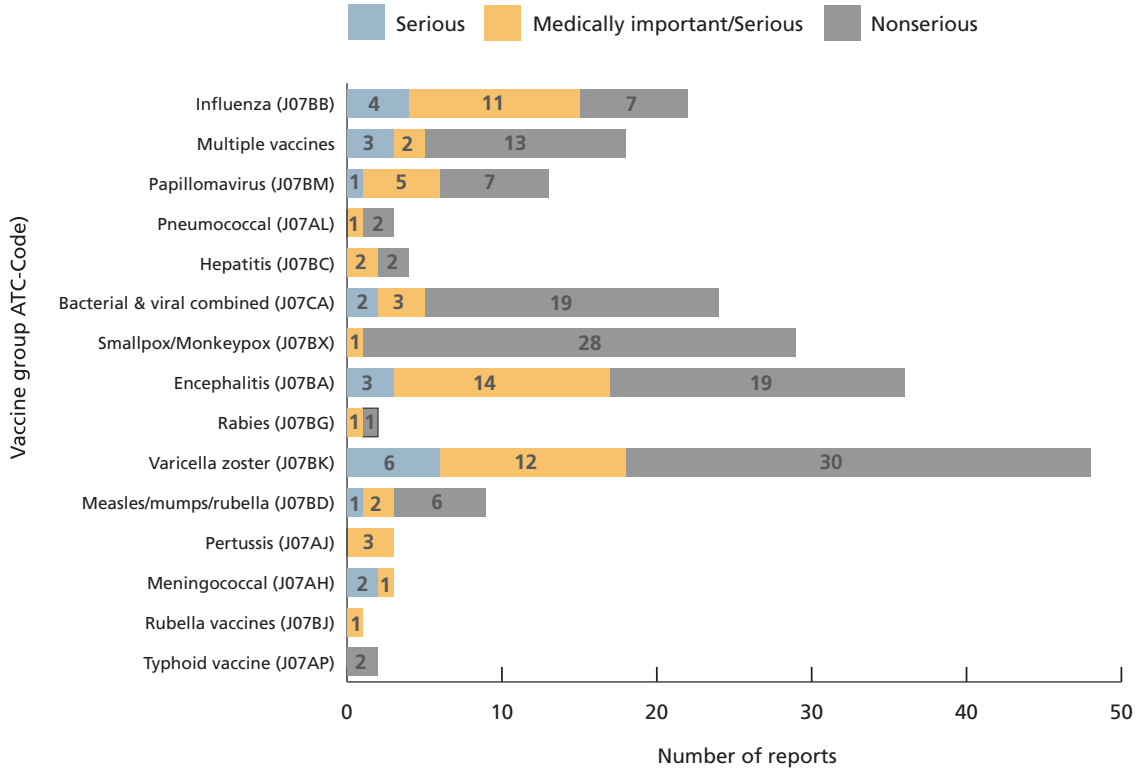

Figure 2 shows the number of spontaneous AEFI reports by vaccine group (ATC code) and seriousness. There are no accurate data available to Swissmedic regarding the number of doses administered in each particular non-COVID 19 vaccine group in 2022 and therefore this figure does not indicate which vaccine group displayed a higher AEFI rate (e.g., as the number per 100,000 doses). 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 217 spontaneous reports received in 2022, 136 (62.7%) were "non-serious", 58 (26.7%) included only medically important events and 23 (10.6%) of the reports involved AEFIs with serious consequences.

Generally, by considering all vaccines in 2022, the relative frequency (percentage) of "serious" including "medically important" cases taken together (81 reports; 37.3%) was higher as compared to previous years 2021 (32.1%) and 2020 (29.9%).

Case reports where several (n >1) different vaccines have been administered and have been reported in relation with suspected AEFIs are shown in **Figure 2** as «Multiple vaccines».

As compared to previous years, during 2022 a higher number of cases was submitted in relation with the herpes zoster vaccination, which are shown in **Figure 2** as ATC code «Varicella zoster (J07BK)», and with the monkeypox vaccination, shown in **Figure 2** as «Smallpox/Monkeypox (J07BX)». These reporting figures are not surprising, since a new herpes zoster vaccine had been authorised by Swissmedic toward the end of 2021. Furthermore, during 2022 a new small¬pox vaccine, which was authorised in Europe and the US, could also be administered in Switzerland to high-risk individuals as a preventive measure against infection with the monkeypox virus. The majority of these case reports were assessed as «non-serious» for the herpes zoster vaccines (30 of 48 cases; 62.5%), and almost all reports in relation with the smallpox/monkeypox vaccination (28 of 29 cases in 2022) contained only «non-serious» AEFIs (1).

Figure 3.
Number of AEFI reports by reporter qualification and seriousness, 2022

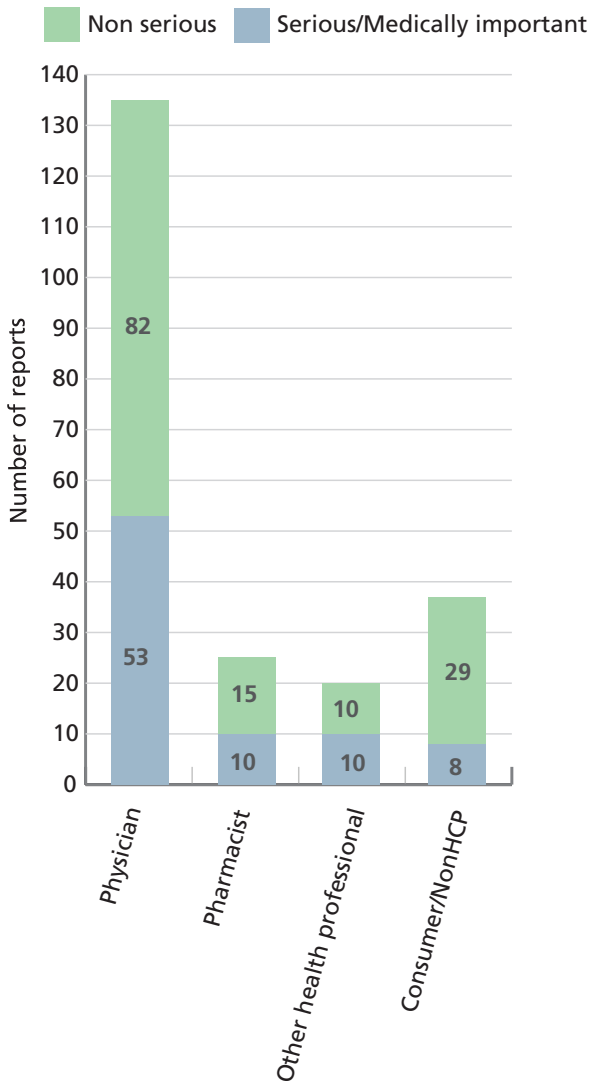

Figure 4.
Number of AEFI reports by age group and seriousness, 2022

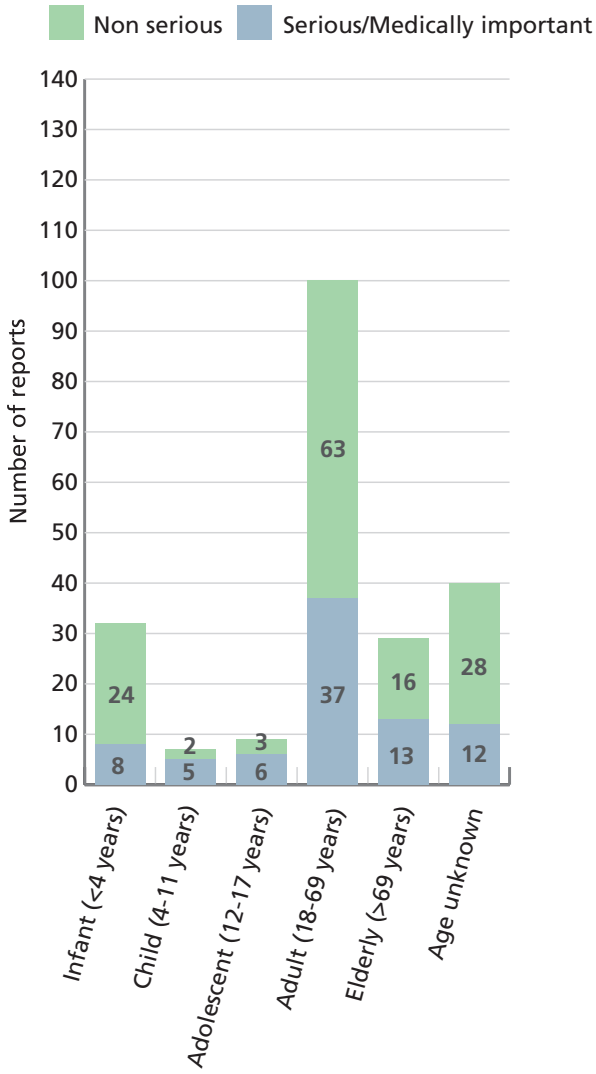

Figure 3 shows the number of Swiss AEFI reports in 2022 grouped by primary reporter and seriousness. Health care professionals – providing medically confirmed data and good quality of individual AEFI reports – have been primary reporters in the vast majority of cases. Physicians reported the largest group of AEFI reports (135 of 217), also comprising a higher number of reports assessed as «serious» or «medically important» (53 of 135 reports). Notably, consumers/patients submitted the second highest number (37) of non-COVID AEFI reports to Swissmedic during 2022.

Figure 4 shows the number of spontaneous AEFI reports by age group and seriousness. It becomes apparent that the highest number of «serious» or «medically important» (37 of 100 AEFI reports in total) have been recorded in the age group of «adults», followed by elderly (13 of 29 reports), infants (8 of 32 reports), adolescents (6 of 9 reports) and children (5 of 7 reports).

Figure 5.
Number of AEFI reports in Switzerland by System Organ Classes, 2022

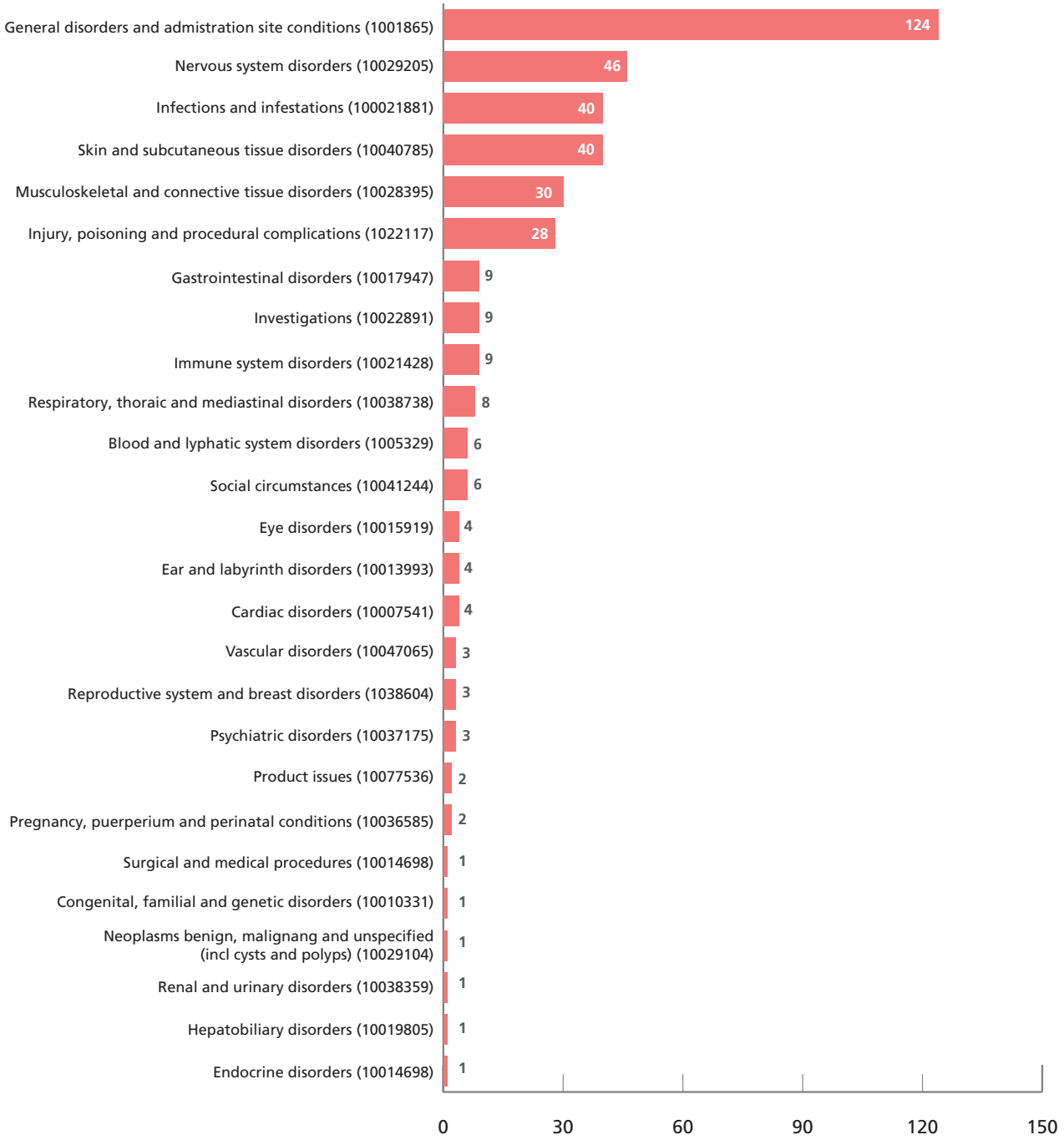

Figure 5 provides an overview of the AEFI reports received during 2022, as grouped by the MedDRA System Organ Classes (SOCs) concerned, i.e., regarding all AEFIs of each report. The following six organ classes were most frequently involved: General disorders and administration site conditions (in 124 reports); Nervous system disorders (in 46 reports); Infections and infestations (40 reports); Skin and subcutaneous tissue disorders (40 reports); Musculoskeletal and connective tissue disorders (30 reports); Injury, poisoning and procedural complications (28 reports).

Figure 6.
Overview of the most frequent AEFIs of all reports, 2022

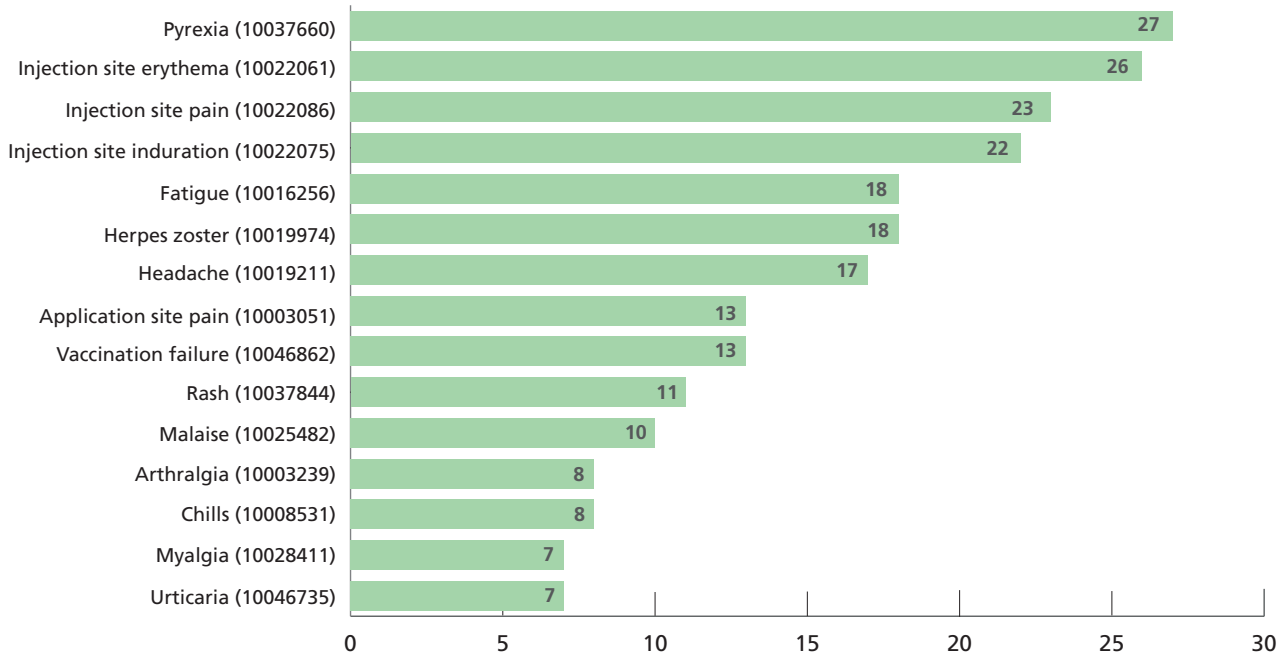

Figure 6 displays the most frequent AEFIs reported during 2022 as MedDRA Preferred Terms, such as: pyrexia; various injection/vaccination site reactions including injection site erythema; injection site pain; injection site induration; fatigue; herpes zoster; headache; and vaccination failure. Notably, some reports of herpes zoster have been received as suspected cases of vaccination failure following varicella zoster immunisation (see also «serious reports» below).

Figure 7.
The most frequent AEFIs in „serious“ reports, 2022

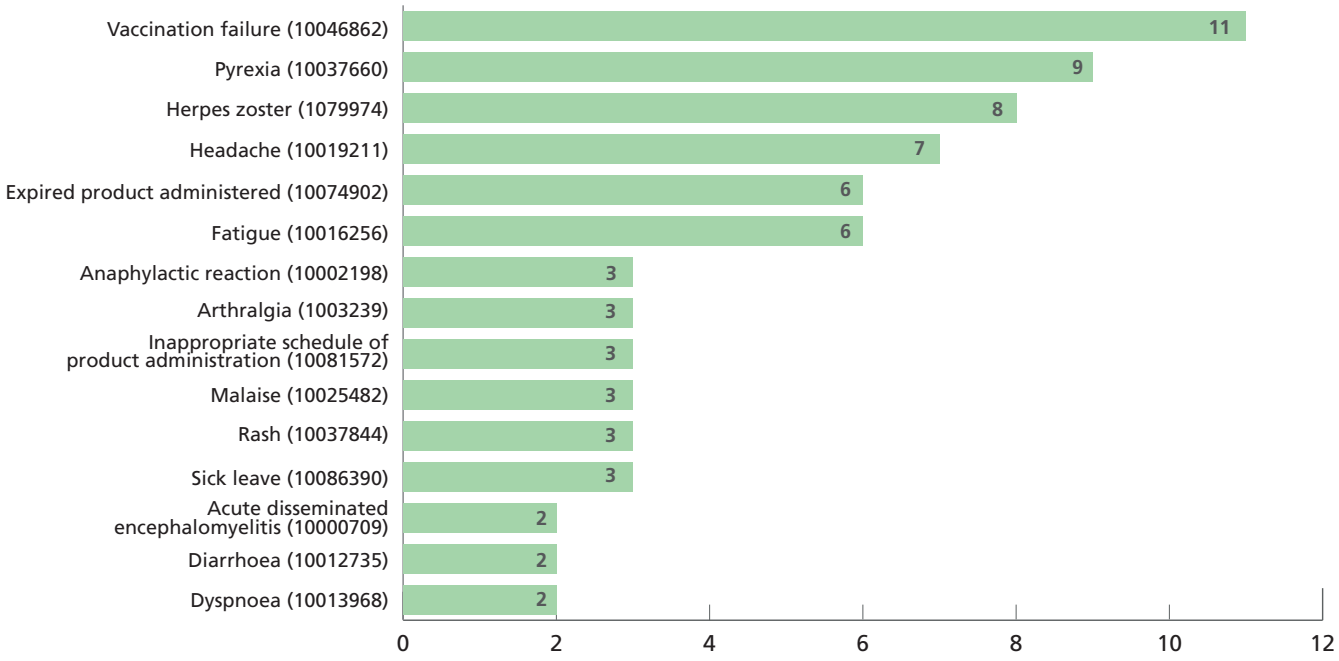

Figure 7 summarises the most frequent AEFIs submitted as MedDRA Preferred Terms in reports assessed as «serious» or «medically important», such as: vaccination failure; pyrexia; herpes zoster; headache; fatigue; anaphylactic reaction; arthralgia; and malaise.

In 2022, 11 «serious» or «medically important» cases of «vaccination failure» were reported following varicella zoster immunisation (5 cases), tick-borne encephalitis vaccination (4 cases); influenza vaccination (one case) and measles/ mumps/ rubella vaccine (one case).

Reports of serious neurological AEFIs occurring in Switzerland during 2022 included:

- One case report of «hypotonic-hyporesponsive episode», which occurred in a 3-month-old female infant following administration of multiple different vaccines; the outcome of the episode was reported as «recovered».

- Two case reports of «encephalitis» and «viral encephalitis»: the case of «encephalitis» occurred in a 48-year-old male adult, following tick-borne encephalitis vaccination, with the outcome «recovering». The second case of «tick borne viral encephalitis» was reported as «vaccination failure» in a 15-year-old male adolescent, following tick-borne encephalitis vaccination, with the outcome «recovering».

- One case of "encephalomyelitis" occurred in a 59-year-old female adult, following "encephalitis vaccines", with the outcome "unknown".

- One case of "encephalitis post immunisation" in a 4-month-old female infant following administration of combined vaccines (diphtheria vaccine/ HIB vaccine/ hepatitis B vaccine / pertussis vaccine / polio vaccine / tetanus vaccine), with the outcome "unknown".

- Two cases of "acute disseminated encephalomyelitis": one case in a 23-year-old female following typhoid/yellow fever vaccination, with the outcome "recovered". The second case occurred in a 56-year-old male following influenza vaccination, with the outcome "not recovered" at the time of reporting.

- One case of "facial paralysis" in a 54-year-old male following influenza vaccination, with the outcome "not recovered" at the time of reporting.

- One case of "facial paresis' in a 50-year-old male following tick-borne encephalitis vaccination, with the outcome "recovered".

- One case of "loss of consciousness" in a 20-year-old female following papillomavirus vaccination, with the outcome "recovered".

- One case report of "seizure" in a 29-year-old female following influenza vaccination, with the outcome "recovered".

- Two cases of "deafness": one case in a 55-year-old female following tick-borne encephalitis vaccination, with the outcome "not recovered". The second case occurred in a 71-year-old male following varicella zoster vaccination, with the outcome also reported as "not recovered".

- One case of "acute polyneuropathy", "tick-borne viral encephalitis" and "vaccination failure", in a 71-year-old patient following tick-borne encephalitis vaccination, with outcome reported as "recovering".

- One case of "axonal and demyelinating polyneuropathy" and "radiculopathy", in a 71-year-old female following tick-borne encephalitis vaccination, with outcome reported as "not recovered".

- One case of “radiculopathy”, in a 76-year-old male following varicella zoster vaccination, with outcome reported as “recovering”.

- One case of “autism spectrum disorder”, in a male infant following concomitant administration of multiple different vaccines, with outcome reported as “not recovered”.

- One case of “post herpetic neuralgia” and “vaccination failure” in a female patient following varicella zoster vaccination, with outcome reported as “unknown”.

No case reports with fatal outcome have been received by Swissmedic in 2022 for **non**-COVID-19 vaccines.

AEFI reports received by Swissmedic in 2022 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccine rollout continued during 2022 and the AEFI reports received (>5,000 cases) are reflecting the spontaneous reporting on COVID-19 vaccines in the second year of the national immunisation campaign.

During 2022, Swissmedic published eight **«Update Reports of suspected adverse reactions to COVID-19 vaccines in Switzerland»**; the last one – «Update 28» – was published on 25 November 2022 (2). Each of these reports presents in a cumulative manner the 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.

The Update Reports include 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.

Altogether, the reports of adverse reactions received and analysed by the end of 2022 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 Swiss product information texts published (3).

As an important safety topic, «myocarditis/pericarditis» was particularly addressed in «Update 28», since very rare cases of myocarditis and pericarditis have been reported following vaccination with the COVID-19 mRNA vaccines. These cases generally occurred within 14 days of vaccination and more frequently after the second vaccination dose and in younger men. «Update 28» draws the attention of healthcare professionals to the signs and symptoms of myocarditis and pericarditis in order to inform vaccinated persons that they should seek immediate medical advice and assistance in the event of chest pains, shortness of breath or palpitations. Strong physical exertion should be avoided if such symptoms occur until the cause of the symptoms has been ascertained.

By 22 November 2022 (date of data lock for «Update 28»), 416 cases of myocarditis and/or pericarditis with a suspected link to vaccinations had been reported in Switzerland and evaluated out of a total of around 16.7 million vaccine doses administered. Of these reports, 94 were temporally related with Comirnaty (18 of which were after the third dose) and 306 with Spikevax (25 of which were after the third dose); in 12 cases, the vaccine has not been identified, while 4 cases concerned the COVID-19 vaccine from Janssen. The large majority of cases involved males (n = 300, 72.11%), and the mean age was 36.64 years (median 34, range 14 to 88 years). The persons affected received medical treatment and most have recovered. There was no evidence that the number of reports of myocarditis and/or pericarditis received by Swissmedic would increase following booster shots/third vaccinations (5). Various studies have shown that inflammation of the heart muscle and heart sac in those under 30 years of age was observed more frequently after vaccination with Spikevax than after vaccination with Comirnaty.

Another safety topic occurring in 2022 and published in the «Update 26» on 1 July 2022 (4), refers to reports of urticaria (hives, nettle rash) received by Swissmedic following COVID-19 booster vaccinations. Overall, the profile of the adverse effects reported after a vaccine booster/third dose largely resembled the profile after the first and second vaccine doses. There was, however, an exception: cases of urticaria reported to Swissmedic, mostly after booster vaccinations with Spikevax.

Up to 28 June 2022 (date of data lock for «Update 26»), 1,228 such reports have been received in temporal relation with the vaccination (interval of 0-72 days), most of which (approx. 78%) were sent by the affected persons themselves. The case reports often relate to urticaria that appeared on various parts of the body with a time lag (on average around 11 days after the booster vaccination), and with episodes recurring over a lengthy period. The clinical picture as described in many of the reports corresponds most closely to an acute (< 6 weeks) or chronic (> 6 weeks) spontaneous urticaria. On average, the reports were submitted 32 days after the onset of symptoms and in most of the affected persons the symptoms had not yet resolved by the time of reporting. 60% of the reports were related to women and 40% to men. The mean age was approximately 40 years.

Findings on the occurrence of urticaria following booster vaccination with Spikevax were meanwhile included in the product information (3).

An additional, currently most recent cumulative safety «Update 29» on COVID-19 vaccines was published by Swissmedic on the website on 24 February 2023 (6).

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References

(1) Reports of suspected adverse reactions following monkeypox vaccination; Swissmedic Vigilance-News Edition 30 – May 2023

(2) Reports of suspected adverse reactions to COVID-19 vaccines in Switzerland – Update 28; Swissmedic Website, 25.11.2022

(3) AIPS (www.swissmedicinfo.ch)

(4) Reports of suspected adverse reactions to COVID-19 vaccines in Switzerland – Update 26; Swissmedic Website, 01.07.2022

(5) Reporting rates of myocarditis and/or pericarditis following basis and booster vaccinations with COVID-19 mRNA vaccines in Switzerland; Swissmedic Vigilance-News Edition 28 – May 2022

(6) Reports of suspected adverse reactions to COVID-19 vaccines in Switzerland – Update 29; Swissmedic Website, 24.02.2023

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