

Vaccinovigilance 2020

**Summary of adverse events following immunization
reported in Switzerland during 2020**

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Executive summary

During 2020, the Pharmacovigilance Unit of Swissmedic received 271 new case-reports of suspected adverse events following immunization (AEFI) from Switzerland. This is a quite stable reporting level as compared to the number of case-reports submitted in 2019 (273 reports) and higher compared to 2018 (223 reports). Notably, as the Covid-19 vaccination campaign was starting in Switzerland in late December, only single AEFI-cases were reported in 2020 for the new Covid-vaccines.

Similar to previous year, AEFI-reports submitted during 2020 have been recorded, assessed and analysed in the pharmacovigilance database of Swissmedic. However, no accurate data was available regarding the number of doses administered in Switzerland during 2020 for different vaccine groups or products 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 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 vaccines safety.

Reports of AEFI 2020

Figure 1
Number of AEFI reports per age group and gender, 2020

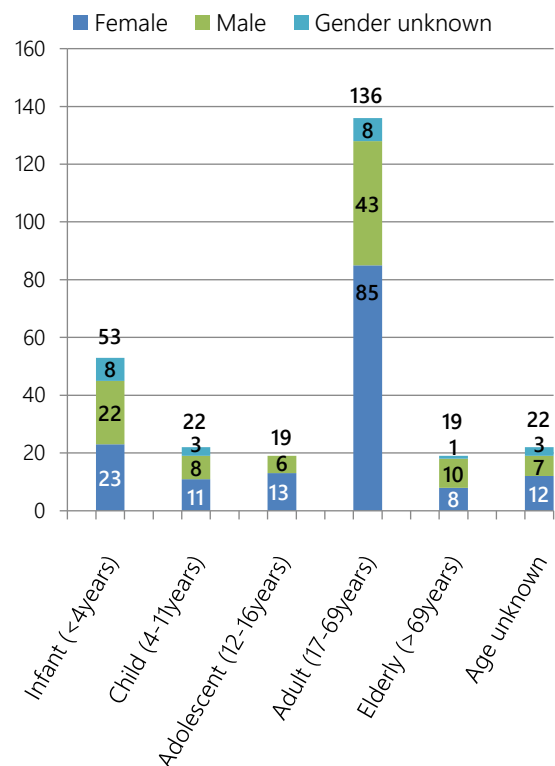


Figure 1 compares the number of reports per age group and gender. The largest number of AEFI reports involved adults (136 reports), followed by infants (53 reports), children (22 reports), elderly (19 reports) and adolescents (19 reports).

Throughout the year 2020, the number of reports concerning females (152 reports; 56.1%) exceeded the number of reports concerning males (96 reports; 35.4%). In 23 AEFI reports (8.5%), the gender of the persons remained unknown. In 22 case-reports (8.1%), the age group of the patients was not recorded.

Figure 2
Number of reports per vaccine group (ATC code) and seriousness, 2020

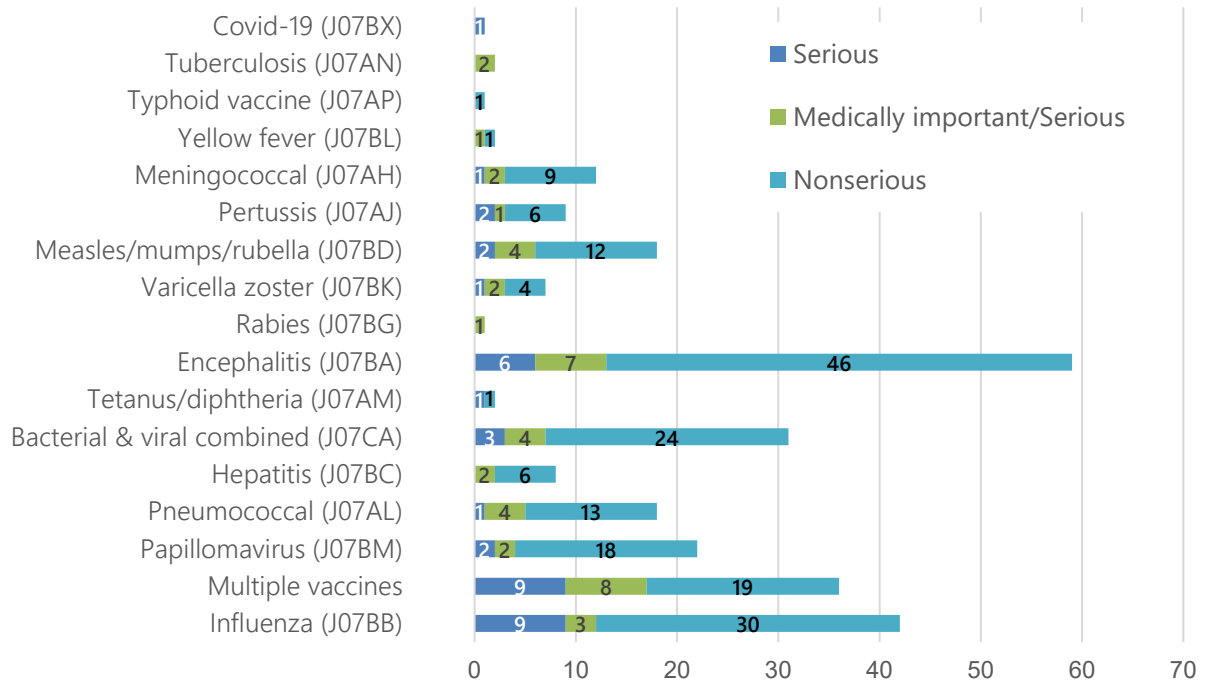


Figure 2 shows the number of spontaneous AEFI reports grouped per vaccine group (ATC code) and seriousness. There are no accurate data available to Swissmedic regarding the number of doses administered in each particular vaccine group in 2020 and therefore this figure does not indicate which vaccine group displayed a higher AEFI rate (e.g. as 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 it involves an event considered to be significant by medical judgement.

All other reports are assessed as 'not serious' (e.g. self-limiting adverse events with good recovering). Of the 271 spontaneous reports received in 2020, 190 (70.1%) were not-serious, 43 (15.9%) included only medically important events and 38 (14%) of the reports involved AEFIs with serious consequences.

Generally, by considering all vaccines in 2020, the relative frequency (percentage) of 'serious' including 'medically important' cases taken together (29.9%) slightly declined as compared to those recorded in the previous year 2019 (35.2%).

During 2020, a higher number of cases was submitted in relation with the tick-borne encephalitis vaccination. However, the majority of these case-reports were assessed as 'non-serious', whereas the number of 'serious' and/or 'medically important' cases regarding encephalitis vaccines (n=13) was comparable with those received for other vaccine groups. Among the serious/medically important reports, some few cases of 'vaccination failure' and consecutive 'tick-borne viral encephalitis' have been received for this vaccine-group.

Figure 3
Number of AEFI reports per reporter qualification and seriousness, 2020

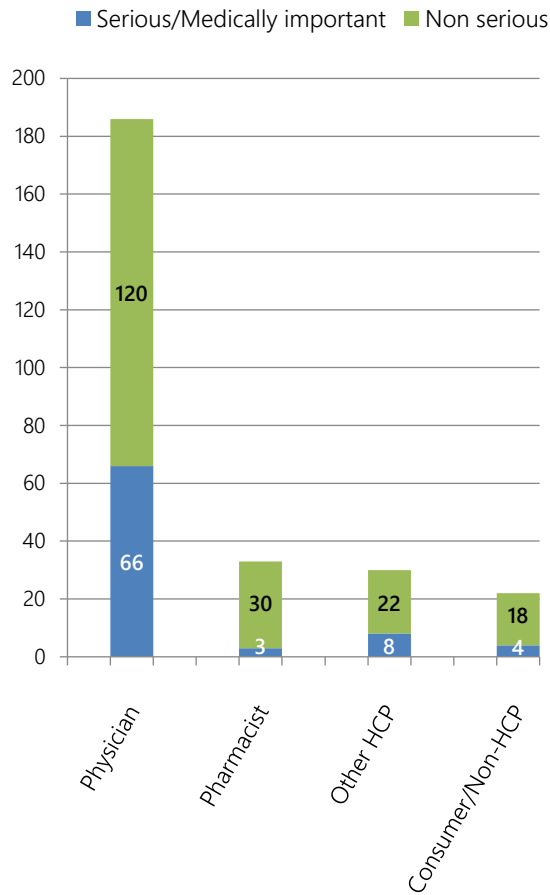


Figure 3 shows the number of Swiss AEFI reports in 2020 grouped by primary reporter and seriousness. Health care professionals - generally providing medically confirmed data and good quality of individual AEFI reports - have been primary reporters in the vast majority of cases. Physicians reported the largest group of AEFI reports (186 of 271), also comprising a higher number of reports assessed as serious or medically important (66 of 186 reports).

Figure 4
Number of AEFI reports per age group and seriousness, 2020

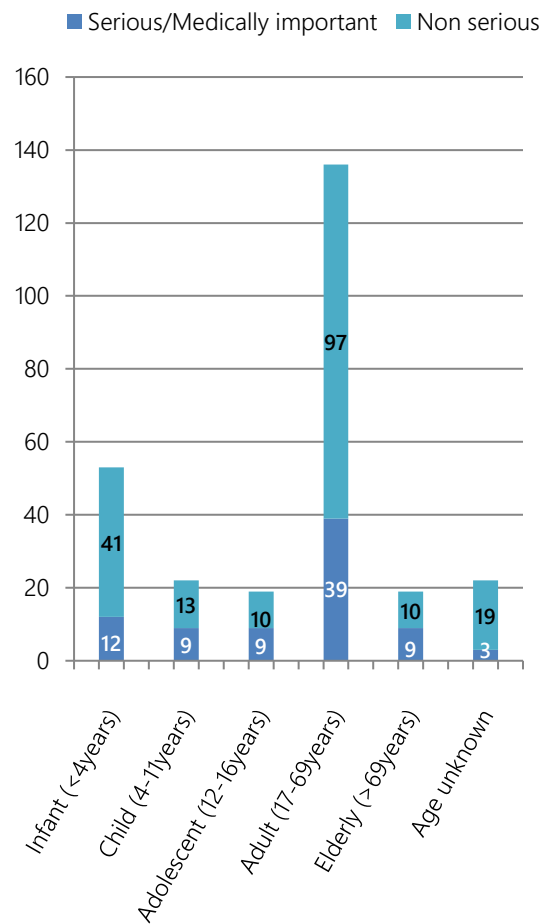


Figure 4 shows the number of spontaneous AEFI reports grouped by age group and seriousness. It becomes apparent that the highest number of 'serious' or 'medically important' (39 AEFI-reports in total) have been recorded in the age group 'adults'.

However, during 2020 the age groups 'elderly' as well as 'adolescents' totalise the highest percentage of 'serious' or 'medically important' cases taken together (with each 9 of 19 reports, 47.4%) as compared with the other age groups specifically recorded: 'children' (9 of 22 reports, 40.9%), 'adults' (39 of 136 reports, 28.7%), and 'infants' (12 of 53 reports, 22.6%).

Figure 5

Number of AEFI reports in Switzerland by System Organ Classes, 2020

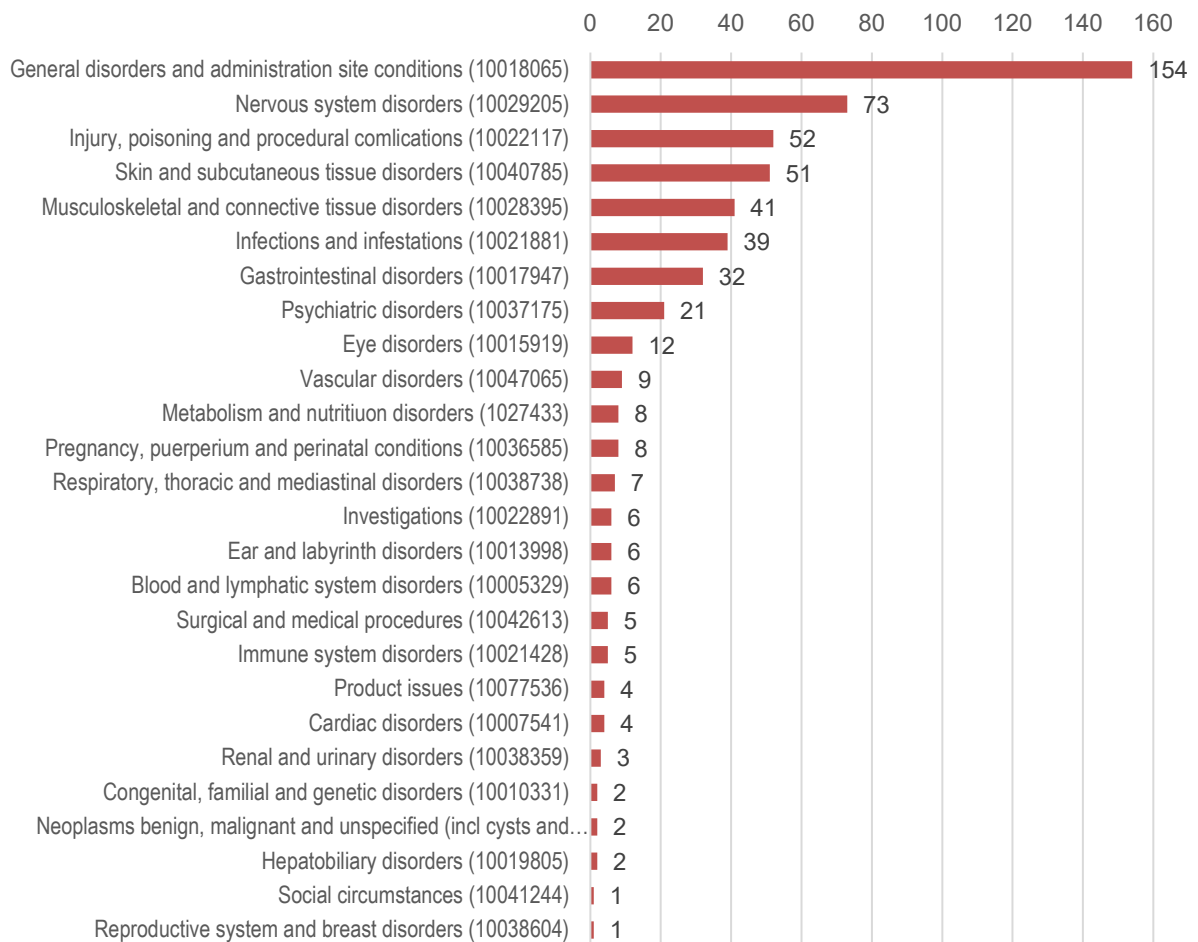


Figure 5 provides an overview on the AEFI reports received during 2020, as grouped by the MedDRA System Organ Classes (SOCs) concerned, i.e. regarding all AEFIs of each report. The following six organ classes were most frequently involved:

- General disorders and administration site conditions (in 154 reports);
- Nervous system disorders (in 73 reports);
- Injury, poisoning and procedural complications (52 reports);
- Skin and subcutaneous tissue disorders (51 reports);
- Musculoskeletal and connective tissue disorders (41 reports);
- Infections and infestations (39 reports).

Figure 6
Overview on the most frequent AEFIs of all reports, 2020

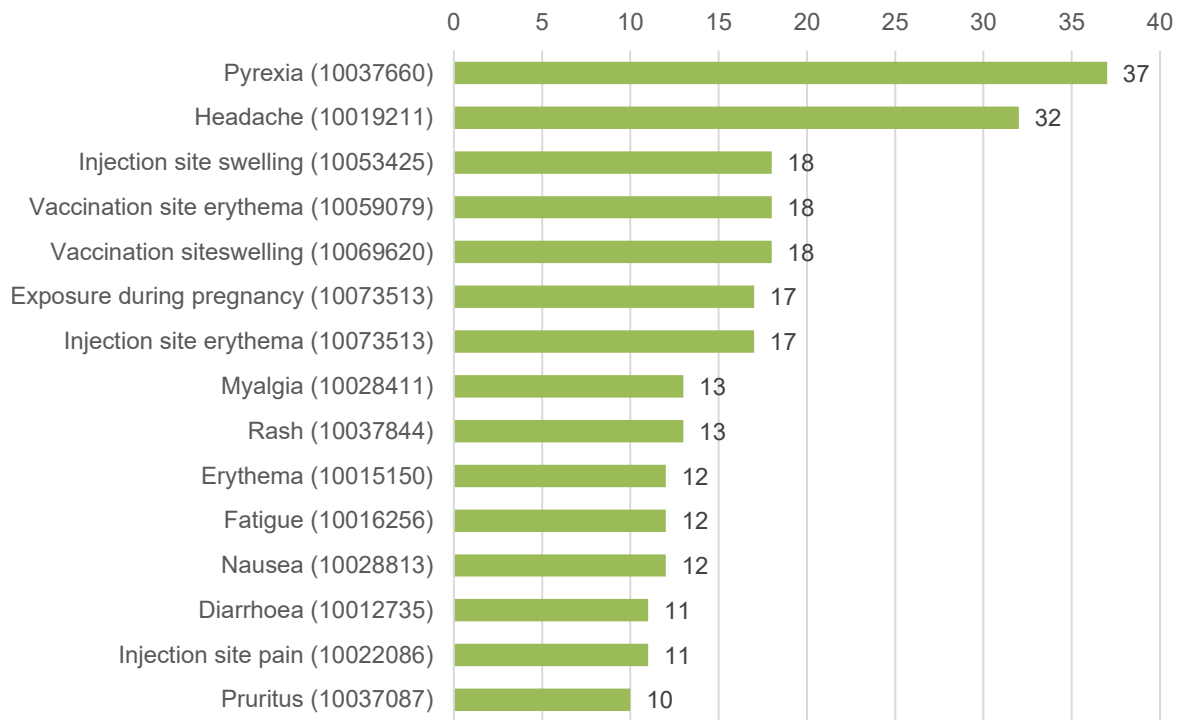


Figure 6 displays the most frequent AEFI reported during 2020 as MedDRA Preferred Terms, such as:

- pyrexia; headache;
- different injection/vaccination site reactions;
- erythema/rash;
- vaccination during pregnancy;
- myalgia;
- fatigue;
- nausea;
- diarrhoea.

Figure 7
The most frequent AEFIs in 'serious' reports, 2020

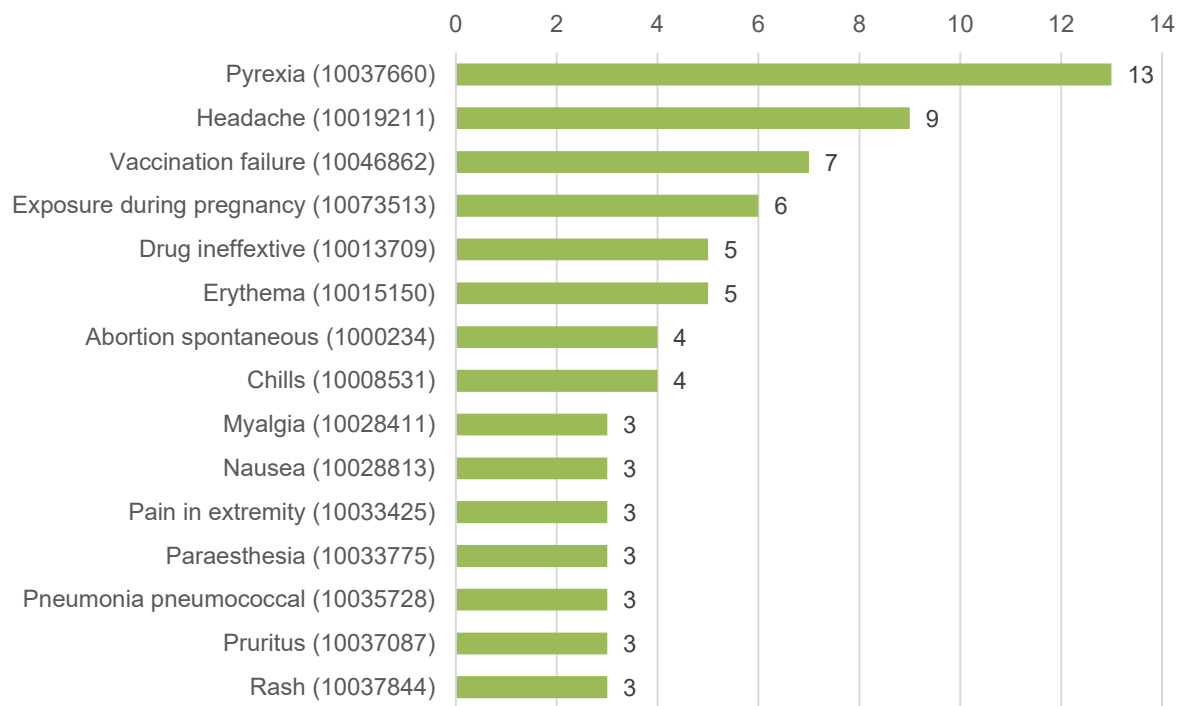


Figure 7 summarizes the most frequent AEFIs submitted as MedDRA Preferred Terms in reports assessed as 'serious' or 'medically important'. The two figures (Figure 6 and Figure 7) are displaying quite similar reported AEFIs.

Several serious cases of immunisation failure have been reported either by the Preferred Term 'vaccination failure' (7 cases) or as 'drug ineffective' (5 cases). In three of these cases, 'pneumococcal pneumonia' occurred as consequence of an ineffective vaccination.

Four cases of 'spontaneous abortion' following vaccination have been reported during 2020:

- one case-report following immunisation with measles/ mumps/ rubella vaccine and combined diphtheria/ tetanus/ pertussis/ polio vaccine
- one case-report following measles/ mumps/ rubella vaccine
- one case-report following administration of combined diphtheria/ tetanus/ pertussis/ vaccine

- one case-report following immunisation with hepatitis B vaccine, typhoid vaccine and yellow fever vaccine

The immunisation with the measles/ mumps/ rubella vaccine during pregnancy is contra-indicated by the Swiss product information for healthcare professionals (Ref. 1).

According to the Swiss product information of the combined diphtheria/ tetanus/ pertussis/ polio vaccine, as well as of the combined diphtheria/ tetanus/ pertussis vaccine, these products can be used in the third trimester of pregnancy. As with other inactivated vaccines, it is not expected that vaccination harms the foetus at any trimester of pregnancy (Ref. 1).

Reports of serious neurological AEFIs occurring in Switzerland during 2020 included:

- One case of 'polyneuropathy', 'paraesthesia' and 'delusional perception' in a 49-year-old male, following influenza vaccination, with outcome reported as 'recovered'. This case was concerning an oncology patient with advanced metastatic colorectal adenocarcinoma and concomitant chemo- and immunotherapy.
- One case of 'vestibular neuronitis' in a 14-year-old woman following HPV vaccination, with outcome 'recovered' at the time of reporting.
- One case of 'visual impairment' in a 25-year-old male following rabies vaccination, with outcome 'not recovered'.
- One case of 'vaccination failure' and consecutive 'tick-borne viral encephalitis' in a male of unknown age, following tick-borne encephalitis vaccination. The outcome of the AEFI was not reported.
- One case of 'seizure' in a 4-year-old girl following tick-borne encephalitis vaccination, with outcome 'recovered'.
- One case of 'vaccination failure' and 'tick-borne viral encephalitis' in a 51-year-old woman following tick-borne encephalitis vaccination, with outcome 'recovering' at the time of reporting.
- One case of 'meningoencephalitis', 'nephrotic syndrome' and 'acute renal failure' in a 56-year-old male following tetanus vaccination. The outcome of 'encephalitis' was 'recovered'.
- One case-report of 'ataxia' in an one-year-old infant, following administration of multiple bacterial and viral combined vaccines, with outcome 'not recovered' at the time of reporting.
- One case of 'paralysis' in a female of unknown age, following seasonal influenza vaccination, with outcome 'recovered'.
- One case of 'encephalitis' in a 74-year-old female following influenza vaccination, with outcome 'recovered'.
- One case of 'neurosensory deafness' in an 81-year-old women following influenza vaccination, with outcome 'not recovered'.
- One case of 'visual impairment' and 'photophobia' in a 27-year-old male following HPV vaccination, with outcome 'recovered'.
- One case of 'Guillain-Barre syndrome' in an 83-year-old male following influenza vaccination, with outcome 'recovering' at the time of reporting.
- One case of 'optic neuritis' and 'paraesthesia' in a 28-year-old female following influenza vaccination, with outcome 'recovering' at the time of reporting.
- One case of 'vaccination ineffective' with 'meningitis' and 'quadriplegia', in a 59-year-old female following tick-borne encephalitis vaccination. The outcome was reported as 'recovering'.

Fatal case-reports received by Swissmedic in 2020 included:

- A case reported in a literature article describing the occurrence of vaccination failure (vaccine ineffectiveness) of the Haemophilus type B (HIB) vaccine in a 14-year-old male patient. The teenager developed a severe HIB infection leading to acute respiratory failure and cardio-respiratory arrest shortly after hospital admission. Despite all intensive-care measures and treatments provided, the patient died 72 hours after the onset of symptoms. The authors comment that, despite the good overall immunogenicity of the HIB vaccine, rare cases of infection are still described as vaccination failure may occur (Ref. 2).
- A further report presents a fatal case in a 71-year-old male patient, three days after receiving a refresh immunisation with the combined tetanus/ diphtheria/ pertussis vaccine. 'Headache' and 'nausea' also occurred shortly before the sudden fatal outcome. Other possible factors, such as a cerebrovascular accident, could not be totally excluded since no autopsy has been performed. Hence, in this case the ultimate cause of the fatal outcome could not be definitely established.
- Another fatal case occurred following a Covid-19 vaccination in a 91-year-old male patient with underlying prostatic carcinoma, grade I atrioventricular heart block, arterial hypertension, diabetes mellitus, dementia and urinary incontinence. He also developed a urinary infection and possibly an acute septic state, leading to a rapid general deterioration and finally to the death of this very old and polymorbide patient. No autopsy was performed, since the fatal outcome in this case was assumed to be of natural causes.

References

1. AIPS (www.swissmedicinfo.ch)
2. Casaleiro. R et al. Acute Respiratory failure in a Teenager. Portuguese Pediatric Act. 2013;44

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