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Swiss Agency for Therapeutic Products

Summary of adverse events following immunization reported in Switzerland during 2017

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Introduction
Executive summary

During 2017, Swissmedic received 232 case reports of suspected adverse events following immunization (AEFI) from Switzerland. This is a higher level as the number of cases submitted during 2016 (209 reports) but lower as compared to 2015 (278 reports).

However, in 2015, 80 of 278 reports had been retrospectively submitted cases occurring in previous years. No retrospective reporting occurred during 2017 and hence all 232 case-reports contain recently occurring AEFI.

Notably, there are no accurate data available regarding the total number of vaccines/doses administered during 2017 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. Since 2010, important safety topics concerning vaccines – including potential risks - are being discussed and evaluated by experts of the Swissmedic Human Medicines Expert Committee (HMEC).

An increased AEFI reporting rate followed by a scientific evaluation of relevant cases can lead to risk minimisation measures in order to ensure vaccines safety, if necessary.

Figure 1
Number of AEFI reports per age group and gender, 2017

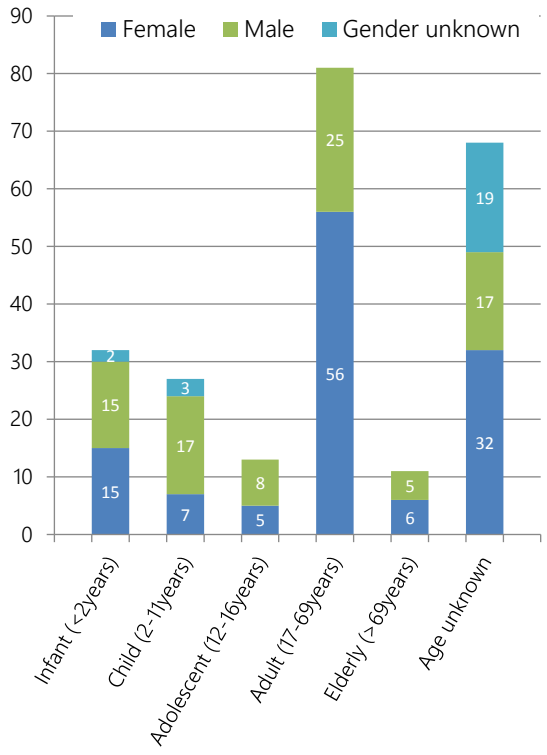

Figure 1 compares the number of reports per age group and gender. The largest number of AEFI reports involved adults (81 reports), followed by infants (32 reports), children (27 reports), adolescents (13 reports) and elderly (11 reports).

Throughout the year, the number of reports concerning females (121 reports) was significantly higher than the number of reports regarding males (87 reports). In 24 AEFI reports, the gender of the persons remained unknown. A higher difference in gender is apparent in the group 'adults' (56 reports of females vs. 25 males). In 68 case-reports, the age of the patients was not recorded.

Figure 2

Number of reports per vaccine group (ATC code) and seriousness, 2017

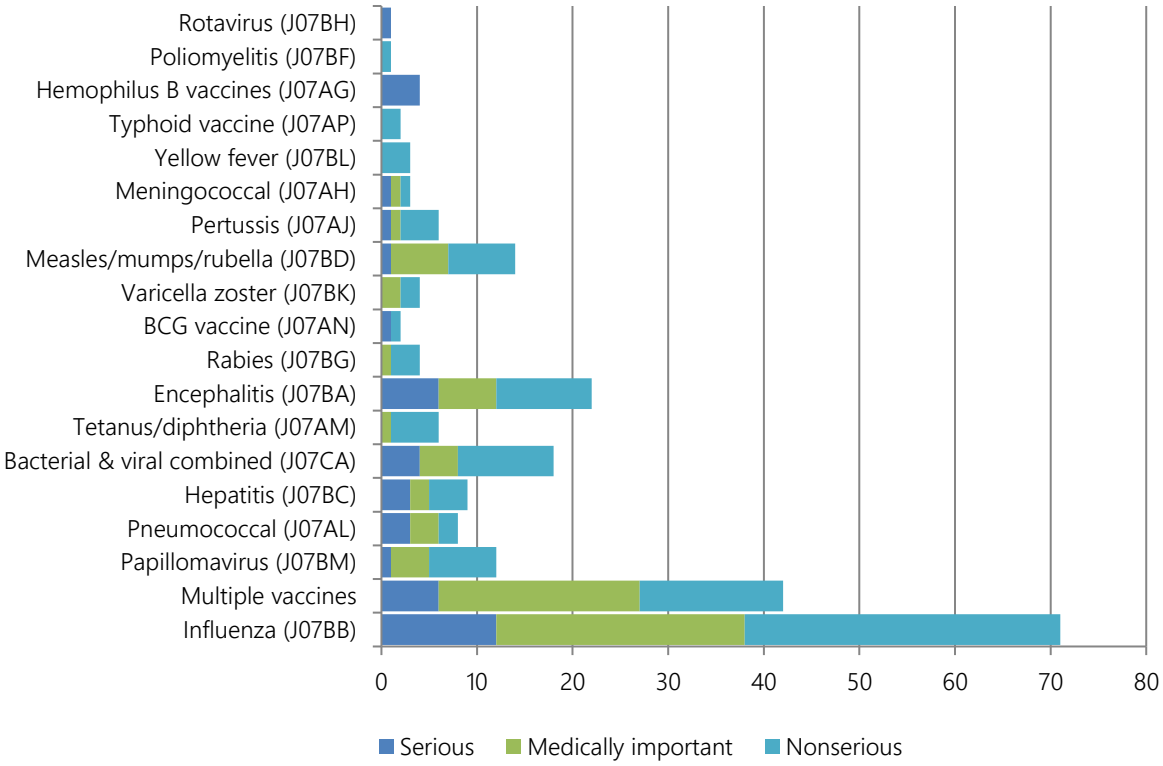

Figure 2 shows the number of spontaneous AEFI reports grouped per vaccine group (ATC code) and seriousness. There are no data available regarding the number of doses administered in each particular vaccine group and therefore this figure does not indicate which vaccine group displayed a higher AEFI rate (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 hence 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 232 spontaneous reports received in 2017, 110 (47.4%) were not-serious, 77 (33.2%) included medically important events and 45 (19.4%) of the reports involved AEFIs with serious consequences. Notably, the relative frequency (percentage) of 'serious' reports (i.e. reports containing AEFIs with serious consequences) remained nearly on the same level as compared to those recorded during the previous year (19.4% in 2017 vs. 18.7% in 2016).

Figure 3

Number of AEFI reports per reporter qualification and seriousness, 2017

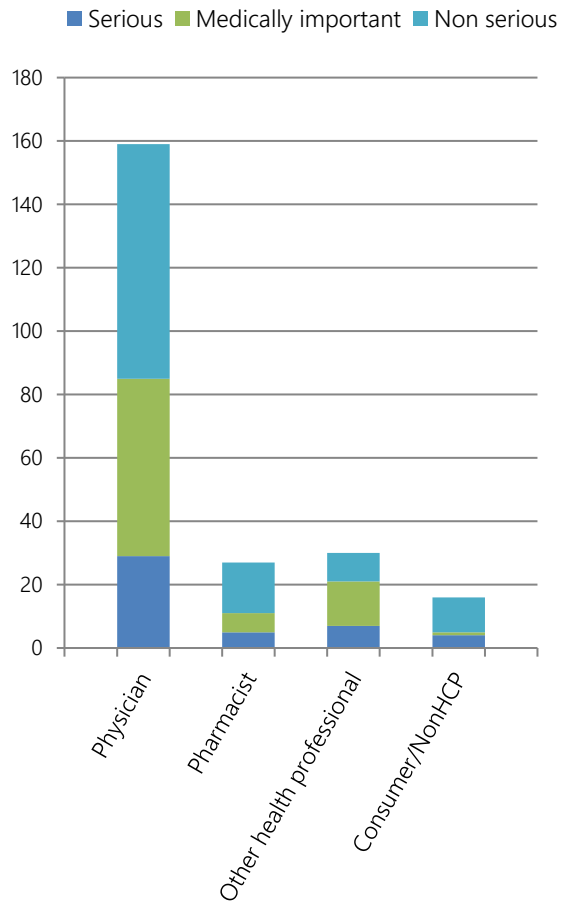

Figure 3 shows the number of Swiss AEFI reports in 2017 grouped by primary reporter and seriousness. Health care professionals - generally providing medically confirmed data and good quality of individual AEFI reports - have been primary reporters in the vast majority of cases.

Physicians reported the largest group of AEFI reports (159 of 232), comprising also a higher number of reports assessed as serious or medically important (85 of 159 reports).

Figure 4

Number of AEFI reports per age group and seriousness, 2017

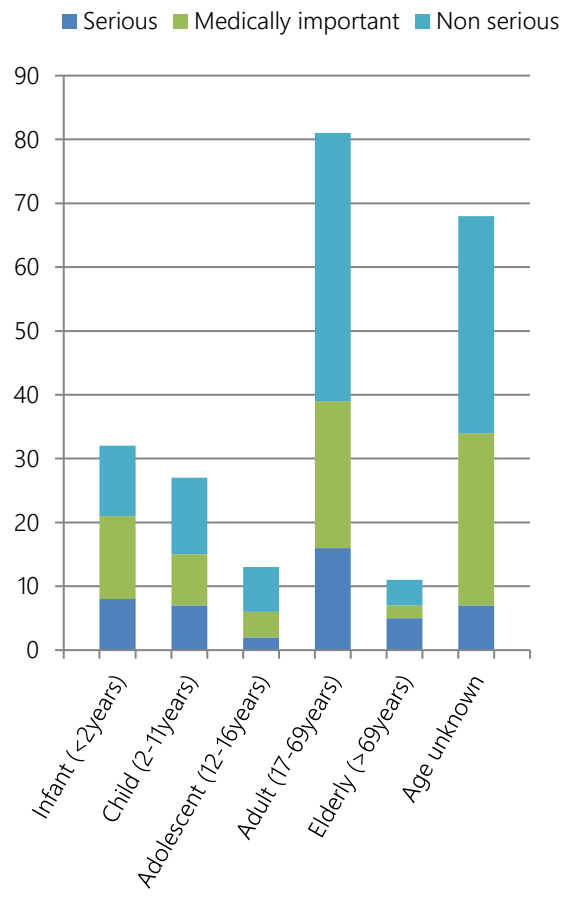

Figure 4 shows the number of spontaneous AEFI reports grouped by age group and seriousness. It becomes apparent that the highest numbers of 'serious' (16 reports) or 'medically important' (23 reports) have been recorded in the age group 'adults'.

However, during 2017, the age group 'infants' totalises the highest percentage of 'serious' or 'medically important' cases taken together (21 of 32 reports, 65.6%) as compared with the other age groups analysed: children (15 of 27 reports, 55.5%), adults (39 of 81 reports, 48.1%), and adolescents (6 of 13 reports, 46.1%).

Figure 5

Number of AEFI reports in Switzerland by System Organ Classes, 2017

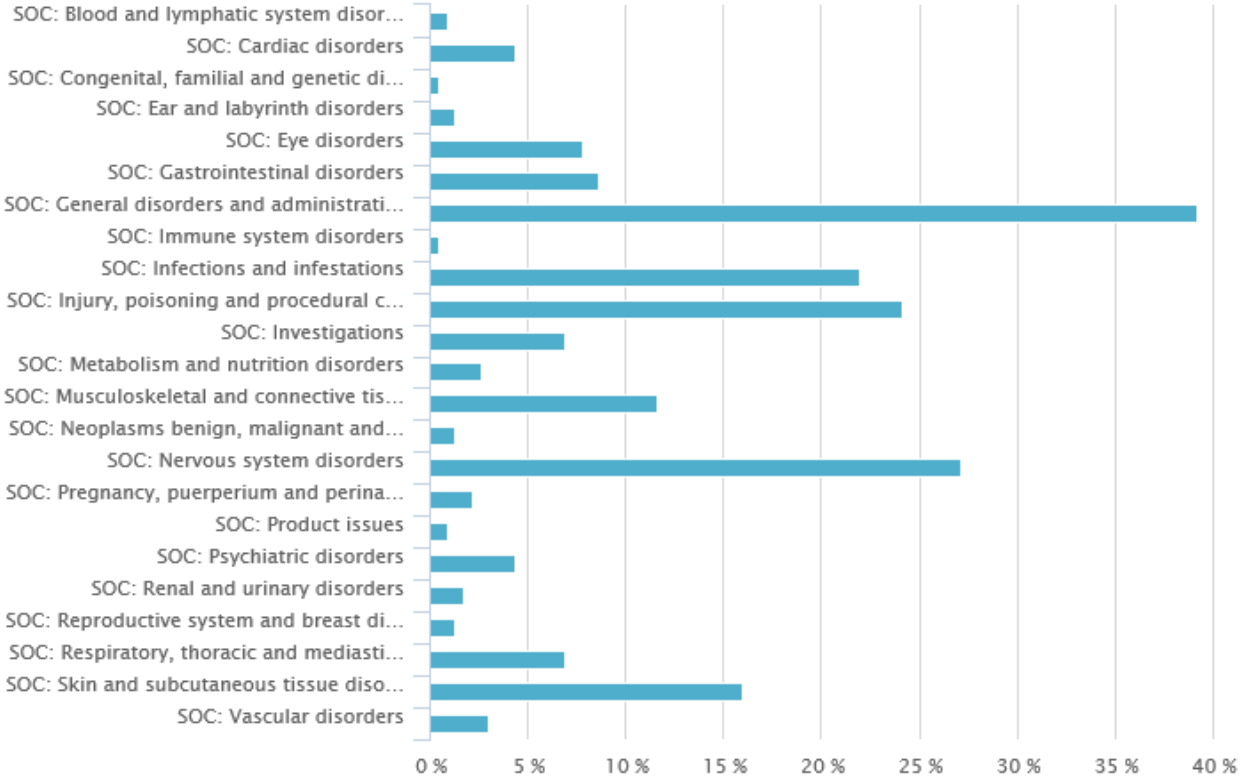

Figure 5 provides an overview on the AEFI reports received during 2017, as grouped by the MedDRA System Organ Classes (SOCs) concerned, i.e. regarding AEFI of each report.

The following five organ classes were most frequently involved in reports after immunization:

- General disorders and administration site conditions (91 reports, 39.2%);
- Nervous system disorders (63 reports, 27.2%);
- Injury, poisoning and procedural complications (56 reports, 24.1%);
- Infections and infestations (51 reports, 22%);
- Skin and subcutaneous tissue disorders (37 reports, 15.9%);
- Musculoskeletal and connective tissue disorders (27 reports, 11.6%).

Figure 6

AEFI reports by vaccine group (ATC code) and top 3 involved System Organ Classes, 2017

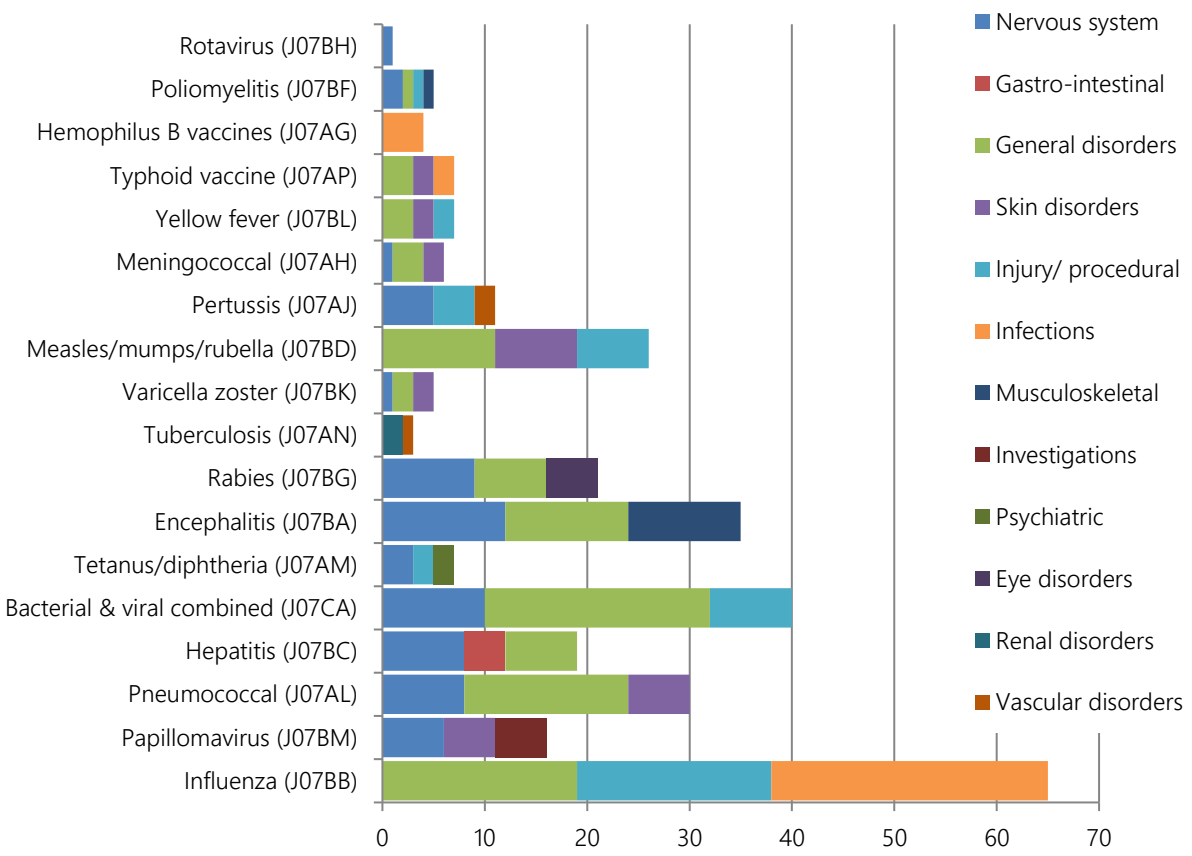

Figure 6 shows the AEFI reports by vaccine group (ATC code) and top 3 MedDRA system organ classes concerned. Notably, most of the vaccines have a significant part of their frequently reported adverse events classified in the SOCs:

- General disorders and administration site conditions;
- Musculoskeletal and connective tissue disorders;
- Skin and subcutaneous tissue disorders;
- Injury, poisoning and procedural complications.

Table 1

Overview on the most frequent AEFIs of all reports, 2017

Adverse event	System Organ Class	Number of reports
Injection site reactions	General disorders and administration site conditions	67
Fever	General disorders and administration site conditions	28
Influenza	Infections and infestations	26
Erythema/ Rash/ Urticaria	Skin and subcutaneous tissue disorders	21
Vaccination failure	Injury, poisoning and procedural complications	18
Headache	Nervous system disorders	16
Myalgia	Musculoskeletal and connective tissue disorders	15
Asthenia/Fatigue	General disorders and administration site conditions	13
Paraesthesia	Nervous system disorders	12
Nausea/ Vomiting	Gastrointestinal disorders	11
Exposure during pregnancy	Injury, poisoning and procedural complications	10
Vertigo/ Dizziness	Musculoskeletal and connective tissue disorders	9
Visual impairment	Eye disorders	7
Arthralgia	Musculoskeletal and connective tissue disorders	7

Table 1 displays the most frequent AEFI as reported during 2017: injection site reactions; fever; influenza; erythema/ rash/ urticaria; vaccination failure; headache; myalgia; asthenia/ fatigue; paraesthesia; nausea/ vomiting; exposure during pregnancy; vertigo/ dizziness; visual impairment; arthralgia.

Table 2

The most frequent AEFIs in 'serious' or 'medically important' reports, 2017

Adverse event	System Organ Class	Number of reports
Injection site reactions	General disorders and administration site conditions	28
Fever	General disorders and administration site conditions	21
Influenza	Infections and infestations	20
Vaccination failure	Injury, poisoning and procedural complications	17
Paraesthesia	Nervous system disorders	9
Myalgia	Musculoskeletal and connective tissue disorders	9
Headache	Nervous system disorders	8
Nausea/ Vomiting	Gastrointestinal disorders	8
Visual impairment	Eye disorders	6
Arthralgia	Musculoskeletal and connective tissue disorders	5

Table 2 summarizes the most frequent AEFIs in reports assessed as 'serious' or 'medically important'. The two tables (Table 1 and Table 2) are displaying similar distributions of reported AEFIs. New AEFI appearing in these two tables as compared with previous year 2016 are: 'influenza' – occurring in 26 reports of which 20 were assessed as 'serious'; 'visual impairment' – reported in 7 ICSRs cases of which 6 were considered 'serious'.

Medically confirmed and serious neurological AEFIs reported during 2017 also contained:

- Three case-reports of central nervous system demyelination, including 'transverse myelitis', as published in a literature article (see Ref. 1), in a family with suspected genetic predisposition for autoimmune disorders. The three patients (mother, daughter and son) were part of a clinical and immunological study that aimed to decipher the environmental, genetic and immunologic mechanisms underlying myelin oligodendrocyte glycoprotein antibody-associated autoimmune demyelination in a family after vaccination. These cases occurred following vaccination with several different vaccines, for prophylaxis: tetanus vaccine/ diphtheria vaccine/ pertussis vaccine/ polio vaccine and rabies vaccine. In all three cases, the authors have not provided the outcome of the autoimmune demyelinating diseases.
- Three cases of 'hypotonic-hyporesponsive episode': one case in a 2-month-old female infant following the administration of several different vaccines: tetanus vaccine/ diphtheria vaccine/ pertussis vaccine and pneumococcal vaccine, with outcome 'recovered'. The second case occurred in a 2-month-old male infant, also following the administration of several different vaccines: tetanus vaccine/ diphtheria vaccine/ hepatitis b vaccine/ pertussis vaccine/ polio vaccine/ haemophilus influenza type B vaccine and pneumococcal vaccine, with outcome also 'recovered'.

The third case occurred in a 16-month-old male infant, also following the administration of several different vaccines: measles vaccine/ mumps vaccine/ rubella vaccine and meningococcal vaccine. The outcome was also 'recovered'.

- Two cases of 'myelitis': one case of subacute myelitis in a 30-year-old female, following the administration of rabies vaccine, with outcome 'recovering'. The second case of myelitis, which was associated with 'polyradiculitis' and 'paraplegia', occurred in a 16-year-old male following vaccination with multiple vaccines: tetanus vaccine/ diphtheria vaccine/ pertussis vaccine and hepatitis a vaccine/ hepatitis b vaccine. The outcome was 'not recovered' at the time of reporting.
- Three case-reports of 'narcolepsy' and 'cataplexy', as reported in a scientific publication (see Ref. 2): one case in a patient of unknown age and gender following the administration of influenza vaccine. The second case occurred following tetanus vaccination and the third case occurred after administration of hepatitis B vaccine. In each of these three cases, the outcome of the AEFIs has not been reported.
- One case of 'Guillain-Barré syndrome' in a 71-year-old male patient, following the administration of influenza vaccine, with outcome reported as 'not recovered'.
- One case of 'multiple sclerosis' in a 29-year-old female patient, following the administration of combined hepatitis A/ hepatitis B vaccine, with outcome 'not recovered'.
- One case of 'half paralysis' with 'visual disturbances' in an adult female, following administration of tick-borne encephalitis vaccine, with outcome 'recovered'.
- Two cases of 'convulsive syncope': one case in a 12-year-old male after HPV-vaccination (outcome 'recovered'); the second case in an adolescent female, also following HPV-vaccination (with outcome also 'recovered').

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