VACCINOVIGILANCE : SUMMARY OF ADVERSE EVENTS FOLLOWING IMMUNIZATION REPORTED IN SWITZERLAND

Executive summary

In 2011, 143 reports of AEFIs were received by Swissmedic, representing a slightly decreased number compared with previous years and also a very low rate of spontaneous reports considering the high number (millions) of immunizations performed. Importantly, no death cases following vaccination were recorded during this year. As previously, Swissmedic continues to actively encourage good quality spontaneous reporting of AEFIs. Since 2010, important topics with regard to AEFIs are discussed in Swissmedic on regular basis during the meetings of the Human Medicines Expert Committee.

Figure 1: Number of AEFI reports per month and gender

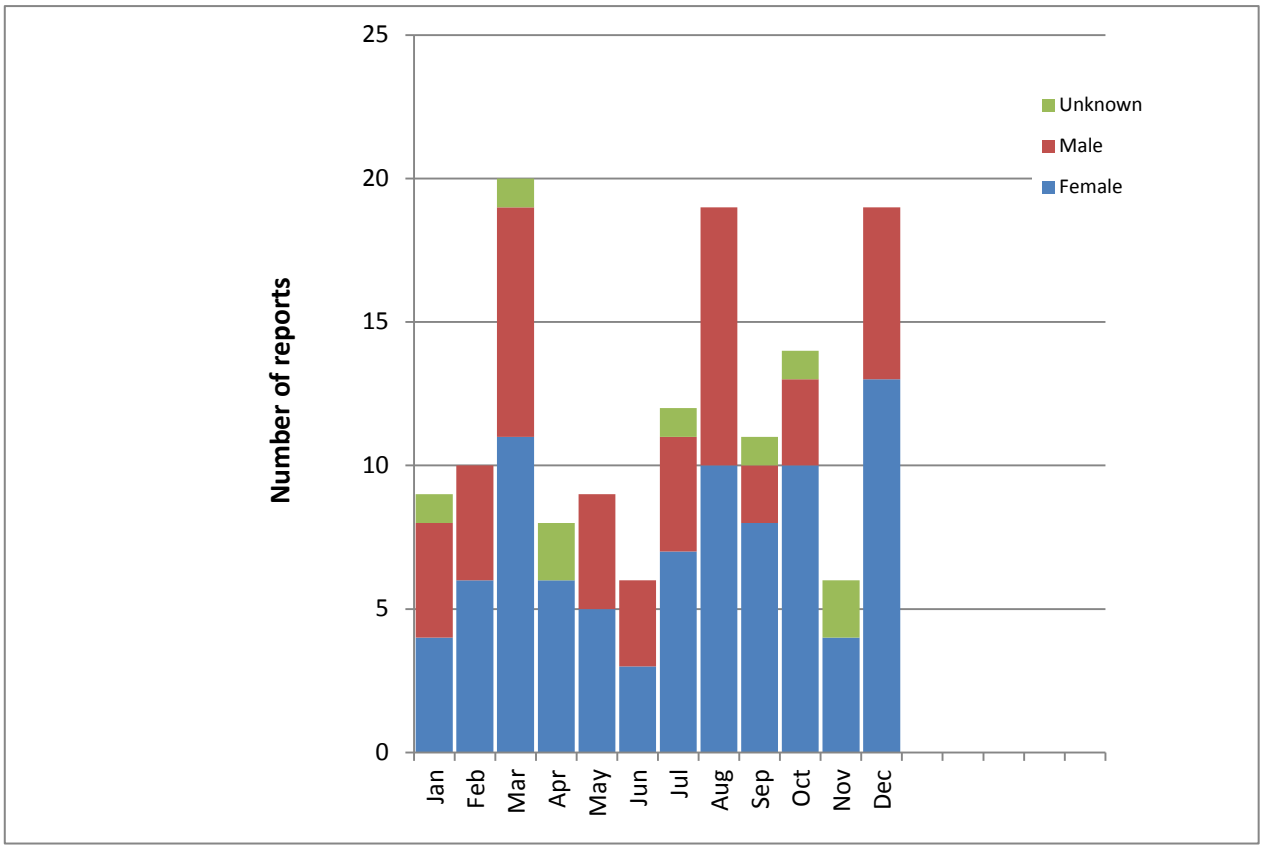

Figure 1 shows the number of AEFI reports received in 2011, as grouped by calendar months and compared by gender. The 3 months with the highest reporting of AEFI were March (20 reports received), August (19 reports) and December (19 reports). Throughout the year, the number of reports concerning females (87 reports) was almost twice as high as the number of reports regarding males (47 reports) and this difference was highest in the last quarter of the year (27 reports of women vs. 9 reports of men). In 9 AEFI reports, the gender of the persons remained unknown.

Figure 2: Number of AEFI reports per age group and gender

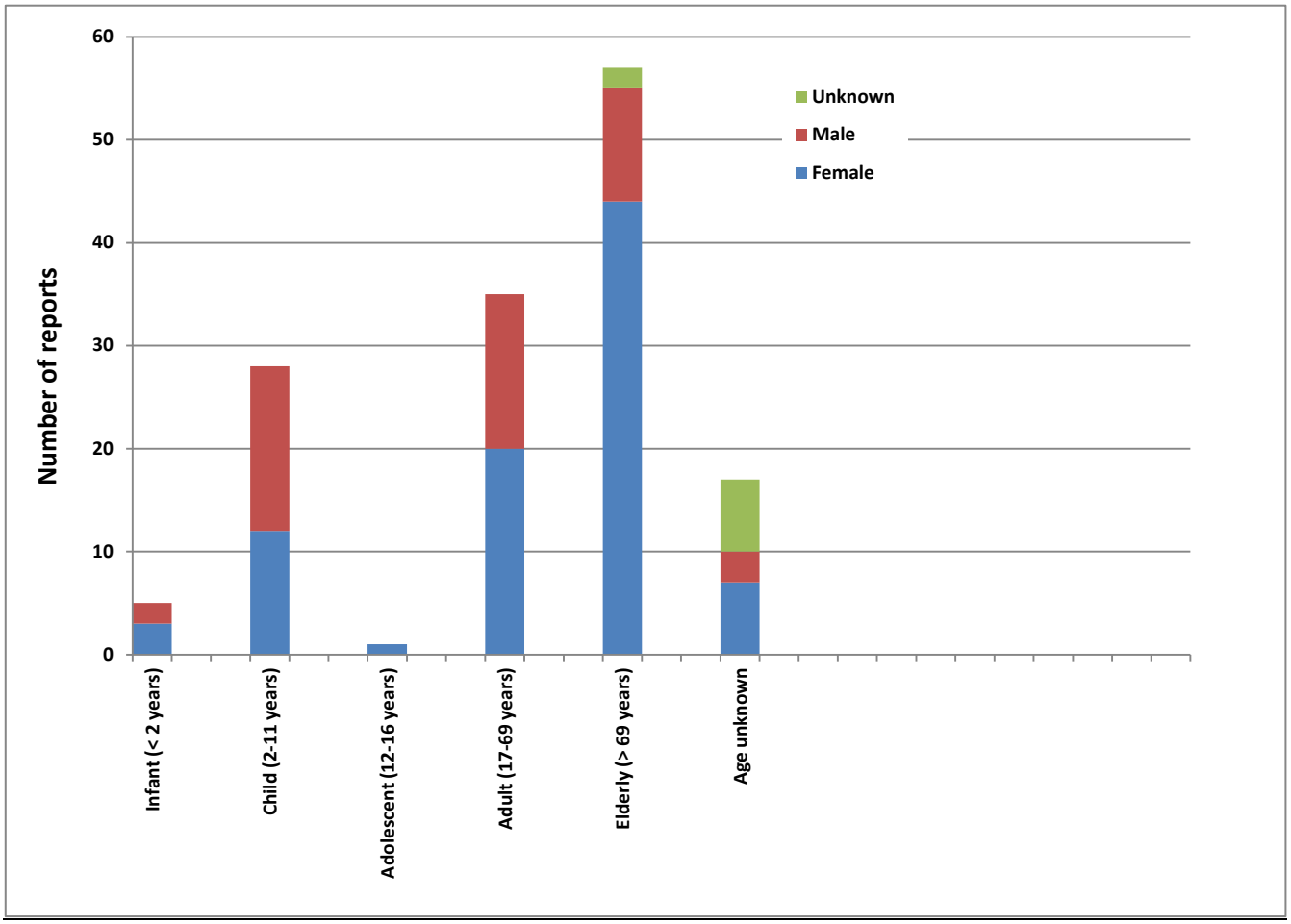

Figure 2 compares the number of reports between age groups and gender. The largest number of AEFI reports involved elderly persons (57 reports), followed by adults (35 reports) and children (28 reports). The difference in gender is apparent in this view as well, the largest discrepancy being recorded in the elderly group (44 reports of females vs. 11 males). In 9 cases (reports), the age of the patients was not recorded.

Figure 3: Number of reports per vaccine group (ATC code) and seriousness

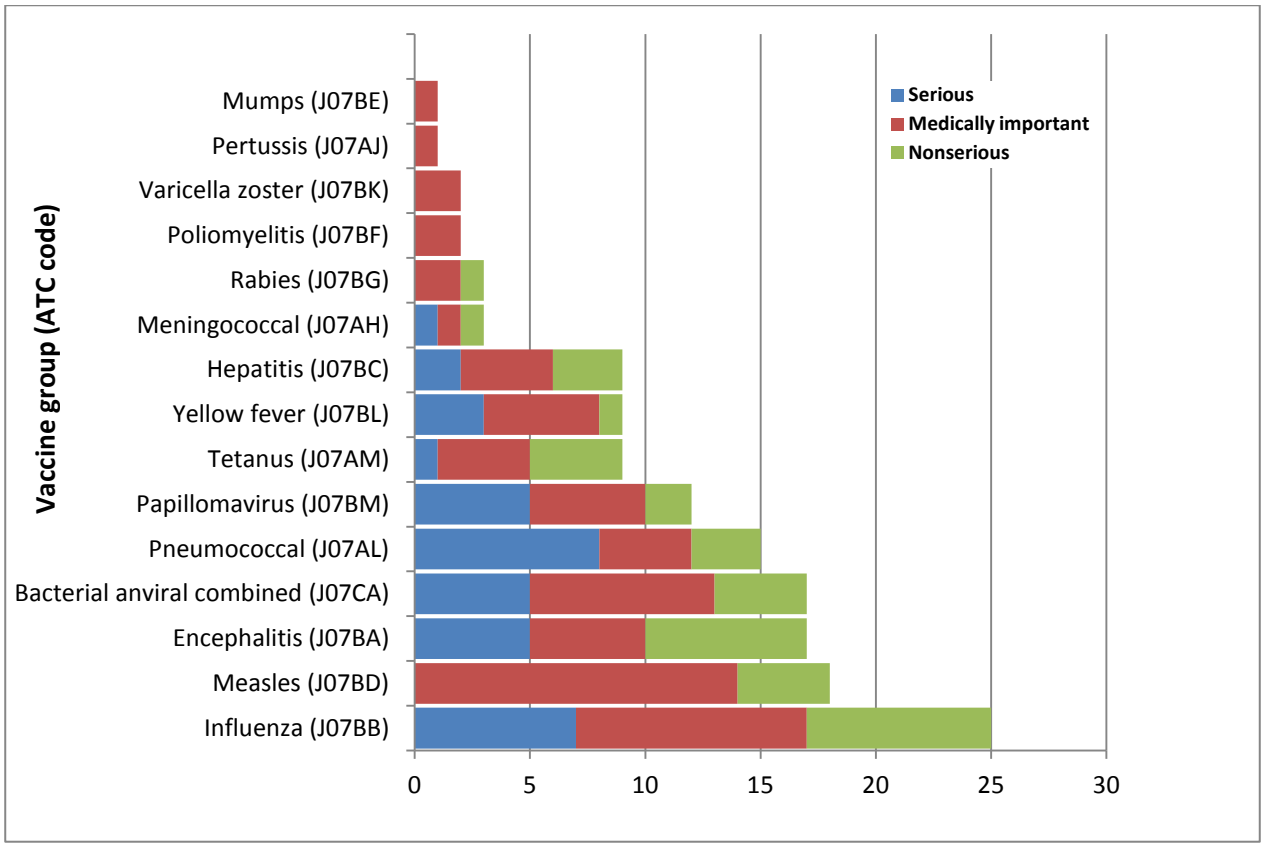

Figure 3 shows the number of spontaneous AEFI reports grouped per vaccine group (ATC code) and seriousness. There are no data available regarding the number of doses administered in each vaccine group and therefore this figure does not show which vaccine group displayed a higher AEFI rate (as number per 100'000 doses). Generally, a safety report is assessed as "serious" if it involves an adverse event leading to death, to hospitalization or to prolongation of an existing hospitalization, if it was life threatening or resulted in a significant or persistent disability or a congenital anomaly. A report is assessed as "medically important" if it does not fulfill the criteria for "seriousness" but it involves a medically significant event. All other reports are assessed as "not serious" (e.g. expected or self-limiting adverse events with good recovering). Of the 143 spontaneous reports, 26.6% were not-serious, 47.6% were medically important events and 25.9% of the AEFIs included events with serious consequences.

Figure 4: Number of AEFI reports in Switzerland by System Organ Classes

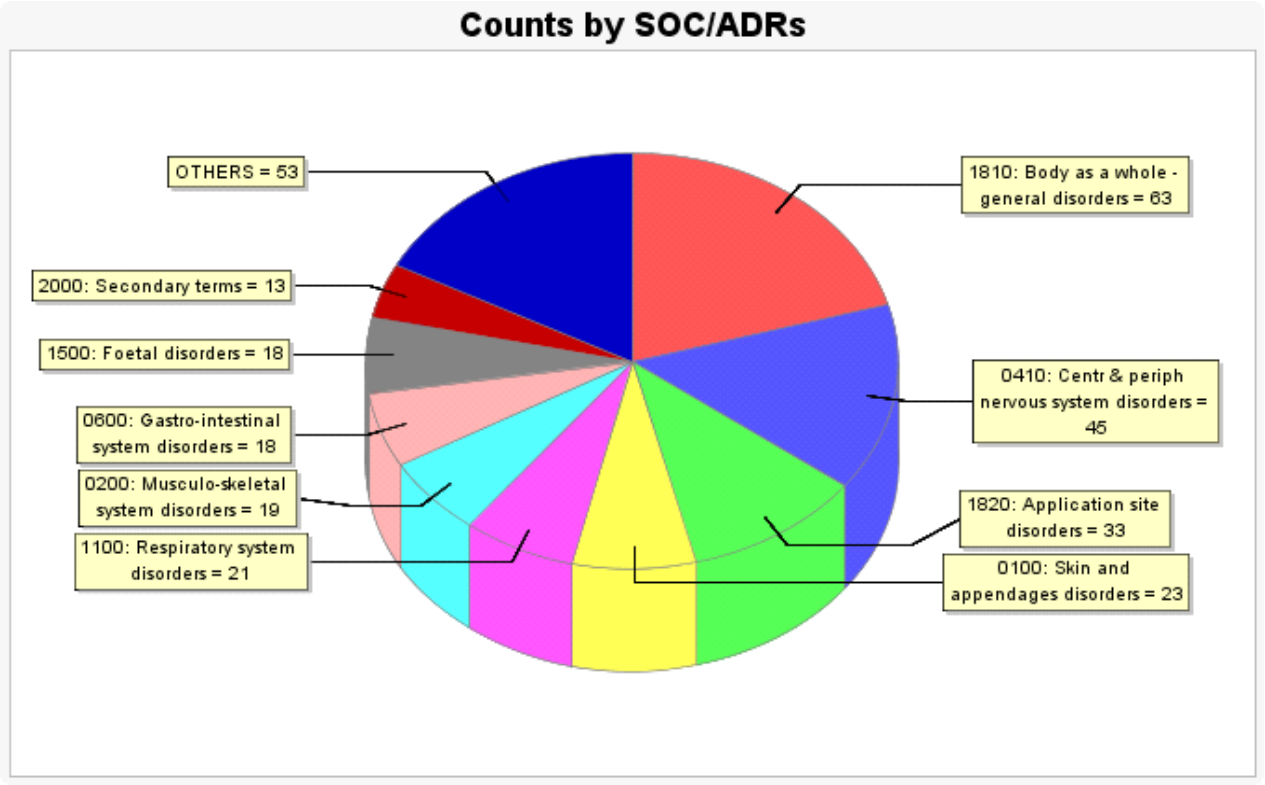

Figure 4 provides an overview on the AEFI reports received during 2011, grouped per System Organ Classes (SOCs) concerned. Following five organ classes were most frequently involved in reports after immunization: Body as a whole – general disorders, Nervous system, Application site disorders, Skin and appendages, and Respiratory system. The group 'Others' is a heterogeneous group of SOCs and is not further described.

Figure 5: AEFI reports by vaccine group (ATC code) and top 3 involved System Organ Classes

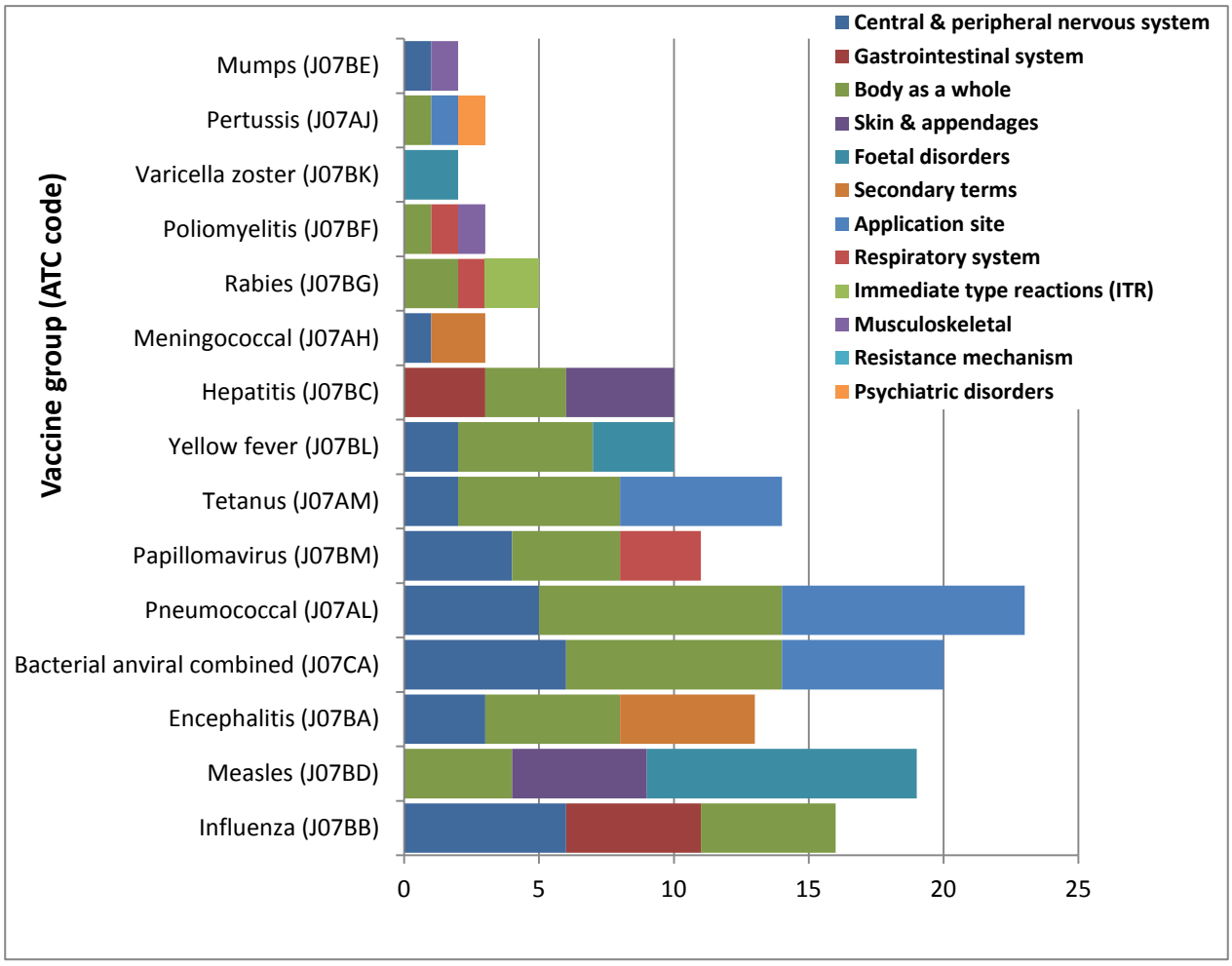

Figure 5 shows the AEFI reports by vaccine group (ATC code) and top 3 system organ classes. Notably, drug exposures during pregnancy or before pregnancy are coded and counted under Foetal disorders. Thus, in figure 5 they are 13 exposures in pregnancy (8 with measles vaccine, 3 with yellow fever vaccine, 2 with varicella zoster vaccine) and 2 cases of exposure before pregnancy (1 with measles vaccine, 1 with MMR vaccine). No congenital anomalies were reported/recorded following immunization in 2011.

Figure 6: Number of reports per vaccine group (ATC code) and labelling

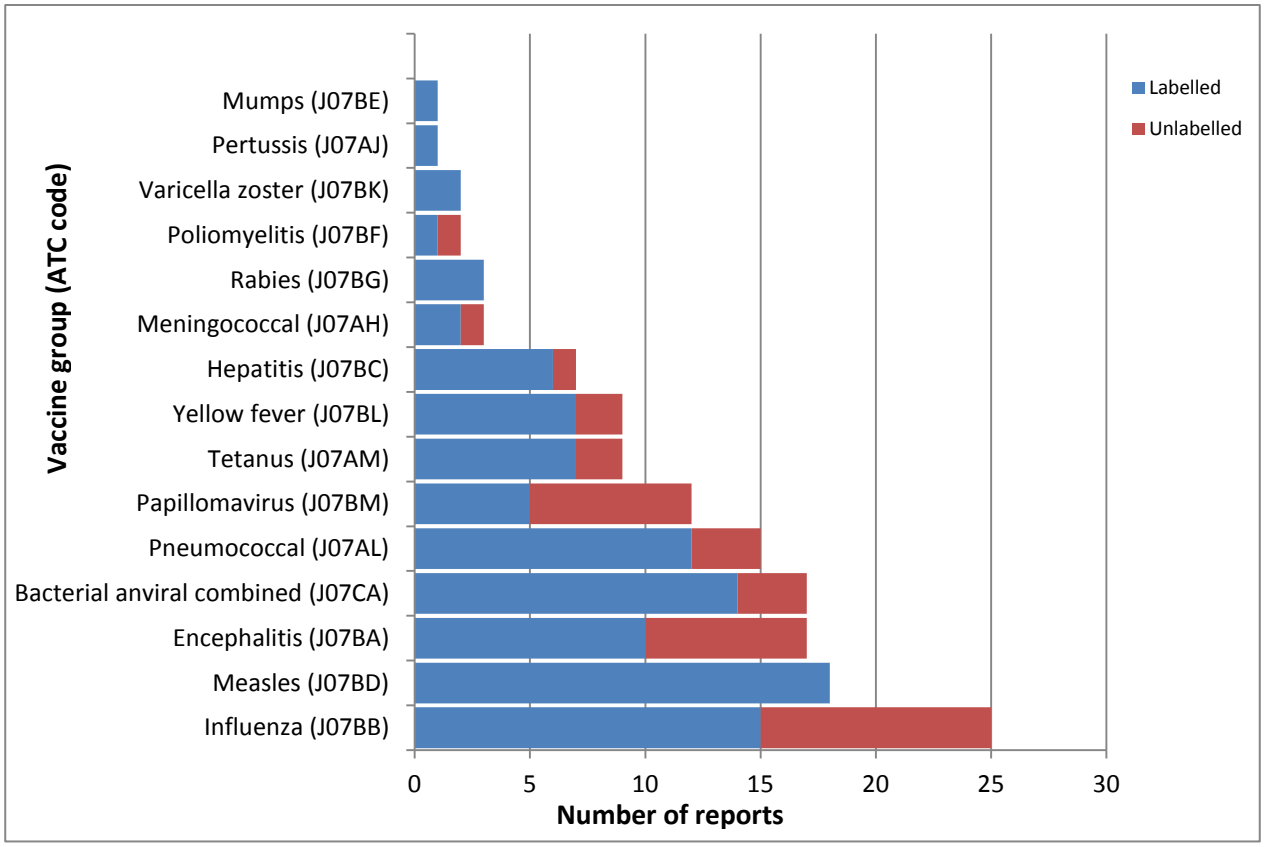

Figure 6 shows the number of AEFI reports per vaccine group (ATC code) and labelling status. Vaccine groups with higher numbers of reports containing unlabelled AEFIs were Influenza (10 of 25 reports), Encephalitis (7 of 17 reports) and Papillomavirus (7 of 12 reports).

Table 1: Overview on the 10 most frequent AEFIs of all reports

Adverse event	System Organ Class	Number of reports
Injection site reaction	Application site disorders	53
Fever	Body as a whole – general disorders	27
Drug exposure in pregnancy	Foetal disorders	16
Headache	Central and peripheral nervous system disorders	10
Exanthema (Rash)	Skin and appendages disorders	10
Nausea	Gastro-intestinal system disorders	7
Myalgia	Musculo-skeletal system disorders	7
Vaccine failure	Resistance mechanism disorders	6
Diarrhoea	Gastro-intestinal system disorders	5
Dyspnoea	Respiratory system disorders	5

Table 1 displays the 10 most frequently adverse events following immunization as reported during 2011: injection site reactions, fever, drug exposure in pregnancy, headache, exanthema (rash), nausea, myalgia, vaccine failure, diarrhoea and dyspnoea.

Table 2: The most 10 frequent AEFIs classified as "Serious" or "Medically Important"

Adverse event	System Organ Class	Number of reports
Injection site reaction	Application site disorders	36
Fever	Body as a whole – general disorders	21
Drug exposure in pregnancy	Foetal disorders	15
Exanthema (Rash)	Skin and appendages disorders	8
Headache	Central and peripheral nervous system disorders	7
Nausea	Gastro-intestinal system disorders	6
Vaccine failure	Resistance mechanism disorders	6
Diarrhoea	Gastro-intestinal system disorders	5
Dyspnoea	Respiratory system disorders	5
Dizziness	Central and peripheral nervous system disorders	4

Table 2 summarizes the 10 most frequent AEFIs assessed as "serious" or "medically important". The two tables are displaying very similar distributions of AEFIs, however more cases of dizziness and less cases of myalgia have been assessed as "serious" or "medically important".

Among other serious or medically important AEFIs during 2011, 2 cases of convulsions were reported (both recovered) and 3 cases of fever convulsions after immunization of children (all recovered).

One case of paralysis was reported after tetanus vaccine (outcome "recovered"), 1 case of facial paralysis after Human papilloma vaccine (outcome "unknown"), 1 case of paresis after vaccination against tick-borne encephalitis (outcome "unknown") and 1 case of paraplegia in a 30-year-old woman immunized with a combination of vaccines – Yellow fever, Hepatitis A, Tetanus, Polio, Diphtheria, Typhoid vaccine (outcome "not recovered"). Two cases of Guillain-Barré syndrome were reported in relation with Influenza vaccines in 2011, a 13-year-old female (outcome "recovered") and an 84-year-old woman ("not recovered").

No fatal cases concerning AEFIs were reported during 2011.