Table 1: Adverse events of special interest (unsolicited AE potentially associated with hypersensitivity/allergy) with onset within 14 days after vaccination

Adverse Event	IXIARO®, 0.25 mL 2 vaccinations	IXIARO®, 0.5 mL 2 vaccinations	Prevnar® 2-3 vaccinations	HAVRIX® 720 1 vaccination
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
N	871	540	64	394
Subjects with any AESI total	16 (1.8) [1.1, 3.0]	3 (0.6) [0.1, 1.6]	4 (6.3) [1.7,15.2]	6 (1.5) [0.6, 3.3]
Related to study vaccine	*2 (0.2) [0.0, 0.8]*	*0 (0.0) [0.0, 0.7]*	*0 (0.0) [0.0, 5.6]*	*2 (0.5) [0.1, 1.8]*
Conjunctivitis	6 (0.7) [0.3, 1.5]	1 (0.2) [0.0, 1.0]	3 (4.7) [1.0,13.1]	3 (0.8) [0.2, 2.2]
Asthma [1]	1 (0.1) [0.0, 0.6]	2 (0.4) [0.0, 1.3]	0 (0.0) [0.0, 5.6]	1 (0.3) [0.0, 1.4]
Bronchial Hyperreactivity [1]	2 (0.2) [0.0, 0.8]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	0 (0.0) [0.0, 0.9]
Dyspnea	0 (0.0) [0.0, 0.4]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	1 (0.3) [0.0, 1.4]
Dyspnea considered related to vaccination	*0 (0.0) [0.0, 0.4]*	*0 (0.0) [0.0, 0.7]*	*0 (0.0) [0.0, 5.6]*	*1 (0.3) [0.0, 1.4]*
Cutaneous Reaction	9 (1%)	0 (0%)	1 (1.6%)	1 (0.3%)
Cutaneous reaction considered related to vaccination	2	0	0	1
Cases with reaction to further dose / N subjects administered further dose(s)	0/5	0/0	0/1	0/0
Rash [2]	3 (0.3) [0.1, 1.0]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	1 (0.3) [0.0, 1.4]

Rash considered related to vaccination	*1 (0.1) [0.0, 0.6]*	*0 (0.0) [0.0, 0.7]*	*0 (0.0) [0.0, 5.6]*	*1 (0.3) [0.0, 1.4]*
Rash maculo-papular	1 (0.1) [0.0, 0.6]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	0 (0.0) [0.0, 0.9]
Rash papular	1 (0.1) [0.0, 0.6]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	0 (0.0) [0.0, 0.9]
Rash papular considered related to vaccination	*1 (0.1) [0.0, 0.6]*	*0 (0.0) [0.0, 0.7]*	*0 (0.0) [0.0, 5.6]*	*0 (0.0) [0.0, 0.9]*
Hypersensitivity	2 (0.2) [0.0, 0.8]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	0 (0.0) [0.0, 0.9]
Urticaria	2 (0.2) [0.0, 0.8]	0 (0.0) [0.0, 0.7]	0 (0.0) [0.0, 5.6]	0 (0.0) [0.0, 0.9]
Contact dermatitis	0 (0.0) [0.0, 0.4]	0 (0.0) [0.0, 0.7]	1 (1.6) [0.0, 8.4]	0 (0.0) [0.0, 0.9]

Abbreviations: n, number of subjects who experienced each event; N, number of subjects in the Safety Population in the indicated vaccine group.

Note 1: Percentages are based on the number of subjects in the treatment group. The confidence interval is an exact confidence interval for a percentage.

Note 2: Related refers to the opinion of the treating study investigator

[1]None of the subjects with asthma or bronchial hyperreactivity experienced any other adverse events indicative of a hypersensitivity reaction.

[2]All three subjects with rash in the IXIARO group received a second dose without reaction.