

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database). Cases in the DAEN are indicated by blue shading. The cases that do not appear in the Database of Adverse Event Notifications (DAEN) may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may be a duplicate of a case included in the DAEN and/or the report may have been received by the TGA within the last 90 days.

Table 1. Cases where death was a reported outcome

Case number	Report entry date	Gender	Age (yrs)	Medicines reported as being taken	MedDRA Reaction terms
244157	26/08/2008	Unknown	<1	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (197 days)	Death neonatal
250015	8/04/2009	Female	23	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Death ; Hypertrophic cardiomyopathy
252796	29/06/2009	Female	16	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (41 days)	Ovarian cancer
377263 (on the DAEN)	11/03/2016	Female	33	Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Cervix carcinoma ; Vaccination failure
388545	23/05/2016	Female	13	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (266 days)	Disease progression ; Motor neurone disease
410426	24/05/2017	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Death
416488	18/08/2017	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Ovarian cancer
449183	30/10/2018	Female	30	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Vaccination failure
449563	2/11/2018	Female	33	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Vaccination failure
450890	20/11/2018	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Cervix carcinoma ; Vaccination failure
468362	14/06/2019	Male	11	Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Glioblastoma ; Pyrexia

Table 2. Cases where abortion (miscarriage) was a reported adverse event

Case number	Report entry date	Gender	Age (yrs)	Medicines reported as being taken	MedDRA Reaction terms
237456 (on the DAEN)	31/01/2008	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Abortion spontaneous
238695 (on the DAEN)	7/03/2008	Female	26	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (49 days)	Abortion spontaneous complete
251437	25/05/2009	Female	22	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Abortion induced ; Exposure during pregnancy
263979 (on the DAEN)	19/03/2010	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Abortion spontaneous ; Systemic lupus erythematosus
291131 (on the DAEN)	31/10/2011	Female	-	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)	Abortion spontaneous ; Anaphylactic reaction