Vaers Id: 307829-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Aug-2007	27-Jan-2008	153	17-Mar-2008	02-Apr-2008	FL	WAES0802USA06024	02-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Guillain-Barre syndrome, Upper respiratory tract infection

Symptom Text: Information has been received from a physician concerning a 19 year old female who on approximately 27-AUG-2007 was vaccinated IM with a 0.5 ml first dose of GARDASIL. On approximately 27-JAN-2008 the patient developed an upper respiratory infection. On approximately 13-FEB-2008 the patient developed Guillain-Barre syndrome and was hospitalized. The patient was discharged from the hospital to a rehabilitation center. At the time of the report, the patient had not recovered. The reporting physician felt that GARDASIL vaccination "has nothing to do with the patient's diagnosis." No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 307697-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Mar-2008	02-Apr-2008	FL	WAES0802USA04123	02-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician concerning a female (age and gender unknown), who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently, the patient was diagnosed with guillain-barre syndrome. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Upon internal review, guillain-barre syndrome was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 306721-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Nov-2007	07-Feb-2008	82	10-Mar-2008	11-Mar-2008	FL	WAES0802USA06248	15-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood product transfusion, Cough, Diarrhoea, Dysarthria, Gait disturbance, Guillain-Barre syndrome, Neurological symptom, Paraesthesia, Pyrexia, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician via a company representative concerning a 17 year old who on an unspecified date was vaccinated with Gardasil IM. On approx 07-FEB-2008, "about 3 weeks ago" the patient developed neurological symptoms and was hospitalized for one week. The neurologist at the hospital diagnosed her with Miller Fisher variance of Guillain-Barre syndrome. At the time of reporting the patient "improved but she's undergoing therapy" and has not recovered. No further information was provided. The reporter felt that Miller Fisher variance of Guillain-Barre syndrome was disabling and required hospitalization. Additional information has been requested. 4/8/08-records received for DOS 2/6-2/12/08- DC DX: Guillain-Barre variant. Developed cough and diarrhea week prior to admission. Also had vomiting and fevers. On morning of admission developed tingling in hands and feet and dysarthric speech, blurry vision and difficulty with walking. Treated with IVIG with improvement of ataxia and dysarthria.

Other Meds: Unknown

Lab Data: 4/8/08-records received-LP normal. MRI brain normal. CT head negative. WBC 16.31, absolute neurtrophils 13.6. M. IgG 2.06. Urine cutlure no growth.

History: None 4/8/08-records received-PMH: Depression.

Prex Illness:

Prex Vax Illns:

Vaers Id: 306111-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Jan-2008	26-Jan-2008	1	19-Feb-2008	10-Mar-2008	--	WAES0802USA00019	10-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Guillain-Barre syndrome, Hypoaesthesia, Musculoskeletal stiffness, Paraesthesia

Symptom Text: Information has been received regarding a case in litigation. On 31-JAN-2007 the mother of a 25 year old female reported that on 25-JAN-2008 her daughter was vaccinated IM with 0.5 mL of the second dose of Gardasil (Lot #659657/1487U). No concomitant medications were reported. The patients mother reported that post vaccination on 26-JAN-2008, the patient experienced numbness and tingling in her extremities. That same day the patient reported that on an unspecified date her physician had her get unspecified blood work for the event. She reported that all of the blood tests were normal and that her physician was "ruling out paraesthesis". The patient reported that she did not have any events after her first vaccination with Gardasil (Lot #, dates of vaccination and details were not provided). On 01-FEB-2008 the patient's father reported "my daughter went to the ER (date not provided) and apparently had a low electrolyte level. She is stable now, but her condition has not improved much. My daughter has no other medical conditions". Later that same day the patient's mother reported that her daughter was experiencing what "she believes is Guillain-Barre syndrome." She reported that her daughter experienced numbness from her waist down, back tightening, tingling in her fingers and was extremely tired. She stated "she feels like going to the dentist and coming off anesthesia." At the time of this report the patient had not recovered from these events. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory normal - physician was ruling out "parathesis"; serum electrolytes test 02/01?/08 low value.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 305974-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-Feb-2008	02-Mar-2008	--	WAES0801USA04644	10-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated IM with a dose of GARDASIL. Subsequently the patient "came down with some syndrome", may have been Guillain-Barre syndrome. Medical attention was sought and the patient recovered. The consumer noted in this report was not one of the physician's patients. Upon internal review, Guillain-Barre syndrome was considered to be an other important medical event. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to identify the existence of a patient. Additional information has been requested. 3/10/08 Per FDA contact-DX: Bell's Palsy not GBS. Confirmed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 303555-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Nov-2007	01-Jan-2008	33	25-Jan-2008	28-Jan-2008	FR	WAES0801USA04083	28-Jan-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0482U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aspiration, Dysphagia, Gastrointestinal infection, Guillain-Barre syndrome, Immunoglobulins, Intensive care, Mechanical ventilation, Oxygen supplementation, Paraesthesia, Paralysis, Paresis, Sedation

Symptom Text: Information has been received from a Nurse concerning a 17 year old female who on 29-NOV-2007 was vaccinated IM in the deltoid muscle with a first dose of Gardasil (batch# NE09920). On 07-JAN-2008 the patient experienced paralusis and was hospitalized. On 18-JAN-2008 received further information by the treating internist. The patient experienced ascending paraesthesia and paresis beginning in feet and hands and was hospitalized the same day. Guillain Barre syndrome was diagnosed. Symptoms worsened the following days and on 11-Jan-2008 the patient experienced deglutition disorder. Subsequently the patient aspirated and was transferred to an intensive care unit where she was sedated and ventilated artificially. She was treated with immunoglobulins in high dose (20 g/day) for 5 days and was improving. It was also reported that the patient suffered from a gastro-intestinal infection one week prior to onset of GBS. Serological examination was negative for campylobacter, CMV, Borrelia, Herpes-Virus, mumps-virus, VZV and treponema pallidum. Also lab findings for auto-antibodies (ANA, ANCA, anti-ds-DNA, phospholipid antibodies) were negative. Other business partner numbers included E2008-00284. Additional information has been requested.

Other Meds: Unknown

Lab Data: DNA Ab immunoprecipitation Comment: negative; Serum ANA Comment: Negative; serum ANCA Comment: negative; serum Herpes virus Ab Comment: negative; serum Treponema palladium Ab ELISA Comment: negative; serum VZV-specific gpELISA AB Comment: n

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314520-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Feb-2008	06-Feb-2008	1	02-Jun-2008	03-Jun-2008	--	WAES0803USA04942	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Condition aggravated, Drug exposure during pregnancy, Haemorrhage, Herpes virus infection, Ureaplasma infection

Symptom Text: Initial and follow-up information has been received from a certified medical assistant, for the Pregnancy Registry, concerning a 25 year old female with anxiety, herpes, and no drug allergies, and with a history of pyelonephritis (reported as phylonephritis), caesearean section in 2002, chlamydia, 3 previous pregnancies, 1 full term delivery, 2 elective terminations, who on 29-NOV-2007 was vaccinated IM with a first dose of GARDASIL (lot # 659437/1266U) and on 05-FEB-2008 was vaccinated IM with a second dose of GARDASIL (lot # 659653/1448U). Concomitant therapy included EFFEXOR, KLONOPIN, and VALTREX. The patient was pregnant. The patient's last menstrual period was 06-FEB-2008 and her estimated delivery date was 13-NOV-2008. The patient saw her physician for medical attention. On 19-MAR-2008 an ultrasound was performed for viability and the results were viable, the fetal heart tones were positive. On 25-MAR-2008 an ultrasound was performed for a threatened Ab and the results were viable. On 07-APR-2008 an ultrasound was performed due to first trimester bleeding and the results nonviable and a probable spontaneous abortion. On 07-APR-2008 at 8 4/7 weeks from her last menstrual period the patient experienced a spontaneous abortion. The products of conception were not examined. It was unknown if the fetus was normal. The complications during the pregnancy was first trimester bleeding. Illnesses during the pregnancy were Herpes and Ureaplasma urealyticum. The patient's outcome was unknown. A product quality complaint was not involved. Upon internal review the spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: KLONOPIN; VALTREX; EFFEXOR

Lab Data: ultrasound, 03/19/08, reason-viability result-viable; FHT positive; diagnostic laboratory; ultrasound, 03/25/08, reason-viability result-threatened Ab; viable; ultrasound, 04/07/08, spontaneous abortion; nonviable

History: Pyelonephritis; Chlamydial infection; Termination of pregnancy-elective

Prex Illness: Pregnancy NOS (LMP =2/6/2008); Herpes simplex; Anxiety; Herpes virus infection

Prex Vax Illns:

Vaers Id: 311265-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	27-Feb-2008	27-Feb-2008	0	30-Apr-2008	01-May-2008	FR	WAES0803CAN00084	01-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a female who on 27-FEB-2008 was vaccinated with GARDASIL, first dose, lot # not available. On 19-MAR-2008 the patient found out that she was pregnant. The patient reported that the first day of her last menstrual cycle was 17-FEB-2008. The estimated date of delivery is 23-NOV-2008. Additional information was received on 23-APR-2008: the patient suffered a miscarriage on 21-APR-2008. She was about 9 weeks along in her pregnancy at the time. On 21-APR-2008 the patient recovered from pregnant. Upon internal review, miscarriage was considered to be another important medical event. No further information is available.

Other Meds: unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 17Feb08)

Prex Vax Illns:

Vaers Id: 311179-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Dec-2007	01-Feb-2008	51	29-Apr-2008	30-Apr-2008	FR	WAES0804USA05026	30-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck pregnancy registry for GARDASIL from a physician concerning a 19 year old female who on 17-OCT-2007 was vaccinated with a first dose of GARDASIL. On 12-DEC-2007, the patient was vaccinated with a second dose of GARDASIL. In early February 2008, the patient became pregnant. In March 2008, the patient had a spontaneous abortion and was hospitalized. The reporting physician considered spontaneous abortion to be an other important medical event. No further details were provided. Other business partner numbers included E2008-03825.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 310279-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Dec-2007	10-Jan-2008	20	21-Apr-2008	22-Apr-2008	ME	WAES0804USA01762	22-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received through the pregnancy registry, concerning a 20 year old female patient, a non smoker, with a history of one pregnancy and one live birth, who on 23-OCT-2007 and 21-DEC-2007 was vaccinated with the first and second doses of Gardasil, respectively (Lot # first dose 658560/1062U, second dose 569437/1266U). Subsequently, the patient became pregnant. It was reported that the patient's last menstrual period (LMP) was 10-JAN-2008. The estimated delivery date was 17-OCT-2008. On 10-MAR-2008 the patient experienced a spontaneous abortion, eight weeks from LMP (reported as 6 5/7 weeks). Diagnostic testing performed on 10-MAR-2008 to assess dates indicated fetal demise. No product quality complaint was involved. Upon internal review, miscarriage was considered to be an other important medical event. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: ultrasound 03/10/08 fetal demise

History: Pregnancy NOS (LMP= 1/10/2008); Non-smoker

Prex Illness: Pregnancy NOS (LMP= 1/10/2008) Non-smoker

Prex Vax Illns:

Vaers Id: 309234-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Jan-2008	11-Jan-2008	0	10-Apr-2008	11-Apr-2008	CA	WAES0803USA05021	11-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician concerning a 22 year old female with no medical history and no concurrent conditions, who on 11-JAN-2008 was vaccinated with a second dose of Gardasil (Lot# 659653/1448U). Concomitant therapy included prenatal vitamins (unspecified). Subsequently, the patient was pregnant. The estimated conception date was 12-DEC-2007, the patient's last menstrual period was 28-NOV-2007, and the estimated delivery date was 03-SEP-2008. On 11-JAN-2008 an ultrasound was performed and showed one gestational sac, and was positive for yolksac fetal pole. On 31-JAN-2008 and 01-FEB-2008 repeat ultrasounds were performed and showed a single intrauterine pregnancy, crown-rump length (CRL) was approximately 7.9 weeks, there was no fetal heart tones with embryonic demise. The patient did not have any previous pregnancies and no full-term deliveries. On 08-FEB-2008 the patient experienced a spontaneous abortion nine weeks and one day from her last menstrual period. The products of conception were examined and were normal appearing. The fetus was not normal due to chromosomes 69XXY. At the time of the report, the outcome of the patient was unknown. Upon internal review spontaneous intrauterine embryonic demise was considered to be an other important medical event. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 01/11/08, reason-early pregnancy ultrasound results-1 gestational sac, positive yolk sac fetal pole; ultrasound, 01/31/08; ultrasound, 02/01/2008, single, CRL approximately 7.9 weeks, no fetal heart tones with embryonic demise

History:

Prex Illness: Pregnancy NOS (LMP = 11/28/2007)

Prex Vax Illns:

Vaers Id: 308819-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Feb-2008		03-Apr-2008	04-Apr-2008	--	WAES0803USA04326	07-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no medical history and no drug allergies, who, on an unspecified date, was vaccinated with a third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient had a miscarriage "a month and a half ago" in approximately February 2008. The patient sought unspecified medical attention. No laboratory diagnostics were performed. At the time of the report, the outcome of the patient was unknown. Upon internal review miscarriage was considered to be an other important medical event. Additional information is not available.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307054-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Feb-2008	12-Feb-2008	0	14-Mar-2008	17-Mar-2008	--	WAES0803USA01259	17-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received for the Pregnancy Registry for Gardasil from an 18 year old female consumer with Amoxicillin allergy who on 12-FEB-2008 was vaccinated with a first dose of Gardasil (route, site and lot # not reported). There were no concomitant therapies. Her last menstrual period was on 22-JAN-2008 and expected delivery date (EDC) being 28-OCT-2008. She later found out that she had a miscarriage on 06-MAR-2008. The consumer did not report if any laboratory tests were done. No other information was available at this time. Upon internal review "miscarriage" was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/22/2008); Penicillin allergy

Prex Vax Illns:

Vaers Id: 304880-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Jan-2008	31-Jan-2008	0	14-Feb-2008	15-Feb-2008	--	WAES0802USA01815	15-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Ovarian enlargement, Pain

Symptom Text: Information has been received for the Merck Pregnancy Registry for Gardasil from an 18 year old female with no pertinent medical history or drug reactions/allergies who on 31-JAN-2008 was vaccinated with a first dose of Gardasil injection. There was no concomitant medication. On 03-FEB-2008 or 04-FEB-2008 (3 to 4 days) after receiving the first dose of Gardasil the patient miscarried. The patient was approximately 2 weeks pregnant. The patient was unaware she was pregnant until she miscarried. The physician stated to the patient that her left ovary was swollen. The patient was in alot of pain. The patient was scheduled for a CT scan next week. At the time of reporting the patient has not recovered. On approximately 20-JAN-2008 was the patient's date of last menstrual period. The patient's estimated date of delivery was 26-OCT-2008. No additional information was provided. Upon internal review miscarriage was considered to be an other medical event. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP=Unknown)

Prex Vax Illns:

Vaers Id: 303187-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2008		22-Jan-2008	23-Jan-2008	FR	WAES0801AUS00088	23-Jan-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a female who in 2007 was vaccinated with the first and second dose of Gardasil. In approximately January 2008 ("recently"), the patient had a miscarriage after having the second injection of Gardasil. Upon internal medical review a miscarriage after having the second injection of Gardasil was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 302707-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Jan-2008	04-Jan-2008	0	15-Jan-2008	16-Jan-2008	CA	WAES0801USA00959	16-Jan-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cough, Dyspnoea, Pharyngeal oedema, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no medical history and no drug allergies, who on 04-JAN-2008 was vaccinated intramuscularly with a 0.5mL first dose of Gardasil (Lot# 658488/1264U). There was no concomitant medication. On 04-JAN-2008 four or five hours post vaccination the patient experienced difficulty in breathing, shortness of breath, and a swollen throat. The symptoms lasted about 6 hours and then the patient developed a "high fever" and a cough that lasted about 2 days. The patient called the office. The patient was not hospitalized. No laboratory diagnostics were performed. On 06-JAN-2008 the patient recovered. No product quality complaint was involved. The physician considered the difficulty breathing, shortness of breath, swollen throat, "high fever", and cough to be life threatening. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 304571-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jan-2008	23-Jan-2008	14	08-Feb-2008	11-Feb-2008	FR	WAES0802USA00271	11-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0483U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Intensive care, No reaction on previous exposure to drug, Resuscitation, Ventricular fibrillation

Symptom Text: Information has been received from a gynecologist concerning a 22 year old female who on 09-JAN-2008 was vaccinated intramuscularly into the deltoid muscle with her third dose of Gardasil (lot #0483U). On approximately 23-JAN-2008 the patient experienced ventricular fibrillation. Resuscitation was necessary, she was admitted to the hospital and treated in the ICU. At the time of reporting her condition was stable. No detailed information was available and no cause for the event was found so far. The physician didn't see a casual relation to the vaccine. On unspecified dates, previous vaccinations with Gardasil were well tolerated. The ventricular fibrillation was considered to be immediately life-threatening and an other important medical event. Other business partner numbers included: E2008-00699. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **304663-3 (S)** **Related reports:** 304663-1; 304663-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jan-2008	29-Jan-2008	0	26-Feb-2008	28-Feb-2008	CA		10-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Dizziness, Headache, Hypoaesthesia, Pain, Paraesthesia, Pyrexia, Tremor

Symptom Text: numbness, tingling sensation, dizziness, fever, headaches, seizures, tremors, body ache.

Other Meds: None

Lab Data: According to some Dr's it is very un-usual what's happening to her. Because they did not find anything medicaly wrong with her. Patient had MRI -Cat scans, blood work and urine test all her test where normal. There saying this could be ph

History: No allegies, no medical condition patient was a perfect healthy child

Prex Illness: No illnesses

Prex Vax Illns: headache, numbness, dizziness, shivers~HPV (Gardasil)~2~14~In Patient

Vaers Id: 304739-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	31-Jan-2008	31-Jan-2008	0	12-Feb-2008	13-Feb-2008	FR	WAES0802USA01143	13-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic shock, Bradycardia, Cyanosis, Gaze palsy, Heart sounds abnormal, Hypotension, Loss of consciousness, Malaise, Pallor, Respiratory arrest, Vision blurred

Symptom Text: Information has been received from a physician concerning a 23 year old female with drug hypersensitivity to PRIMPERAN characterized by sensation of malaise and tingling who on 31-JAN-2008 was vaccinated with her 1st dose of Gardasil (route, site of administration and lot number not reported). Concomitant therapy included HOLGYEME for the treatment of acne. On 31-JAN-2008 the patient experienced anaphylactic shock 2 minutes after vaccination characaterized by a brief loss of consciousness, lasting a few seconds, respiratory arrest, eyes rolled upwards, blurred vision and greyish skin tone. The patient experienced bradycardia at 50bpm and hypotension at 7. She had muffled heart sounds. The patient received an injection of 0.25mg of adrenaline 3 minutes after onset. She had hypotension at 8 for 5 to 6 minutes. The patient subsequently experienced further minor malaise. She recovered within 20 minutes. No oedema was observed. The patient was placed on surveillance for 1/4 hour in the wating room. Anaphylactic shock was considered to be immediately life-threatening. Other business partner numbers include: E2008-00828. No further information is available.

Other Meds: cryproterone acetate/ethinyl estradiol Unk

Lab Data: Total heartbeat count 50 bpm

History:

Prex Illness: Drug hypersensitivity; Acne; Malaise; Tingling

Prex Vax Illns:

Vaers Id: 305007-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Jan-2008	22-Jan-2008	0	15-Feb-2008	18-Feb-2008	FR	WAES0802USA01283	18-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Circulatory collapse, Fall

Symptom Text: Information has been received from a Health Authority (ref. # PEI2008000776) concerning a 13 year old female with a history of previous unspecified vaccinations being well tolerated. On 22-JAN-2008, the patient was vaccinated with a first dose of Gardasil. On 22-JAN-2008, five minutes post vaccination, the patient experienced a circulatory collapse and fell down on her head. She recovered within 10 seconds. The events were considered to be immediately life-threatening by the reporter. Other business partner numbers include: E2008-00848. Further information was expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 305256-1 (S) **Related reports:** 305256-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Dec-2007	05-Feb-2008	61	20-Feb-2008	22-Feb-2008	NJ		14-Mar-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain upper, Abdominal tenderness, Acute lymphocytic leukaemia, Body temperature increased, Chemotherapy, Chest discomfort, Cough, Decreased appetite, Dyspnoea, Ear pain, Fatigue, Feeling abnormal, Headache, Hepatosplenomegaly, Hiccups, Malaise, Nausea, Pallor, Pancytopenia, Petechiae, Pyrexia, Sick relative, Sinus headache, Sinusitis, Somnolence, Transfusion

Symptom Text: Very fatigued since 2.5.2008. Seen by me, pediatrician on 2.8.08 and 2.11.08. Blood work done 2.12.08 showed occasional blasts and patient had blood marrow done. Now DX to have A.L.L. and chemo Rx started. 2/26/08 Reviewed pcp medical records & vax records. FINAL PCP DX: Acute lymphocytic leukemia (pre B-cell). Received HPV #1 0680U on 9/18/07 at GYN office & Menactra U2385BA on 8/7/07 Fluzone U2451AA on 1/4/2008 at pcp office. Seen 11/07 for cough, sinus pressure, fever, tight chest, ear ache, HA; sibling w/similar symptoms 10 days prior. Dx w/sinusitis, otalgia & cough. Tx w/antibiotics. Returned to office 1/4/08 w/o complaints for flu shot. Returned to office 2/8/08 c/o of extreme fatigue beginning approx 2/5/08, stomach pain & intermittent hiccups. Dx w/malaise & fatigue, r/o mono. Referred for labs. Returned to office 2/11/08 w/continued fatigue, pallor, feeling miserable, SOB, nausea, decreased appetite, earache. Temp 100.7 at that time. 2/13/08 notified by lab of abnormal CBC & referred to hospital. 2/18/08 Received call from parent w/dx of ALL (pre-B cell). Admitted 2/13-2/23/08. Placed in study & will receive most tx as outpatient. 3/11/08 Reviewed hospital medical records for admission 2/13-2/23/2008. FINAL DX: acute lymphocytic leukemia Patient experienced extreme fatigue, excessive sleepiness, SOB, low grade fever, abdominal distention w/tenderness, petechiae on LEs, pancytopenia & hepatosplenomegaly. Consults done by heme/onc. Transfused x 2.

Other Meds: Seasonique since 12.13.07

Lab Data: 2.12.08, labs, WBC 2.9 (absolute neutrophils 986); platelets 60,000; occasional blasts; bone marrow LABS from PCP: 2/12/08 abso lymphs 986 (L) w/occasional blast seen. Plts 60 (L)Urine w/+ RBCs. Hospital LABS: Initial WBC 2.6 (L), se

History: None except allergic to ibuprofen & penicillin PMH: on BCP from GYN for heavy periods & anemia w/improvement. Allergies: ibuprofen, PCN. PMH: mennorhagia. Hospitalizations: IDA @ 1yo, FUO @ 5yo. Bone marrow biopsy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **305256-2 (S)** **Related reports:** 305256-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Sep-2007	05-Feb-2008	142	29-Feb-2008	03-Mar-2008	NJ	WAES0802USA04680	13-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0680U	1	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U2451AA		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute lymphocytic leukaemia, Fatigue

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with heavy menstruation periods, drug hypersensitivity to ibuprofen, and penicillin allergy who on 18-SEP-2007 was vaccinated IM with a first dose of 0.5 mL of Gardasil (lot # 658219/0680U). On 06-DEC-2007 she received her second dose of Gardasil (lot# 659437/1266U). Concomitant therapy included FLUZONE and SEASONIQUE. The physician reported that the patient was diagnosed with Acute Lymphoblastic Leukemia (ALL) after blood work on 12-FEB-2008 which showed "blasts in her smear". Her symptoms began two months after she received her second dose of Gardasil. On 05-FEB-2008 symptoms were described as feeling tired for a few days. It was reported that the patient sought medical attention on 08-FEB-2008. The patient was hospitalized for worsening symptoms. On 19-FEB-2008 she had started unspecified antineoplastic chemotherapy. The reporter considered Acute Lymphoblastic Leukemia (ALL) to be disabling and life threatening. The reporter considered ALL to be other important medical event. Additional information has been requested.

Other Meds: SEASONIQUE

Lab Data: laboratory test 02/12/08 - blasts in smear

History:

Prex Illness: Heavy periods; drug hypersensitivity; penicillin allergy

Prex Vax Illns:

Vaers Id: 305259-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Feb-2008	12-Feb-2008	0	20-Feb-2008	22-Feb-2008	CA		27-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	1	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cold sweat, Fall, Foaming at mouth, Grand mal convulsion, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope, Tongue biting

Symptom Text: Pt received vaccine, took 6 steps, fell to the ground unconscious and had a 60 sec grand mal seizure then regained consciousness. BP after seizure 60/40 pale clammy skin. Pt had bit her tongue and had foam around her mouth. BP raised in 7 mins. Benadryl at 1500 25mg. 2/25/08-records receivedfor DOS 2/12/08-Impression: Syncopal episode. Presented to ED after experiencing syncopal episode immediately upon injection of vaccine. PE: unremarkable.

Other Meds:

Lab Data: All labs normal; EKG normal; 1700 BP 60/41, pulse 52; 1708 80/52; 1716 100/58 2/25/08-records received-EKG right bundle branch block with intraventricular conduction delay.

History: No hx seizure

Prex Illness:

Prex Vax Illns:

Vaers Id: **305606-3 (D)** **Related reports:** 305606-1; 305606-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a "17 year old" female who on an unspecified date was vaccinated with GARDASIL. In April 2008, approximately 6 weeks ago the patient died. The physician reported that one of the patient's mother did not want to agree to the vaccine because her friend's daughter died after receiving it. The 17 year old patient was found dead on the floor by her mother. The autopsy was performed and the outcome was unspecified. The physician only has information on the patient that refused the vaccine. No further information was provided. The reporter felt that the event was disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 306812-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jan-2008	18-Feb-2008	20	11-Mar-2008	12-Mar-2008	FR	WAES0803USA00889	12-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anorexia, Haemolytic uraemic syndrome, Nausea, Oliguria, Renal failure acute, Thrombocytopenia, Vomiting

Symptom Text: Information has been received from the Health Authority Agency (ref. # PEI2008002016) concerning a 15 year old female who on unspecified dates was vaccinated with a first and second dose of Gardasil which were well tolerated. On 29-JAN-2008, the patient was vaccinated with Gardasil (lot # 0352U; batch # NG00320) IM (site not reported). Concomitant suspect therapy included corticosteroids (unspecified) (dose, duration and indication not reported). On 10-FEB-2008, the patient complained about increasing nausea, vomiting, and inappetence. On 18-FEB-2007, she developed oliguria and was admitted to the hospital. Acute renal failure was diagnosed and the patient was transferred to a university hospital. A diagnosis of haemolytic uraemic syndrome was established. Laboratory results showed elevated kidney values, thrombocytopenia and LDH elevation. Relevant laboratory tests revealed thrombocyte count 70/microL, serum lactate dehydrogenase (LDH) test 700 U/L, serum creatinine 10 mg/dL, and urea 240 mg/dL. The patient was treated with plasmapheresis and corticosteroids. At the time of reporting, symptoms were ongoing. The patient's haemolytic uraemic syndrome was considered to be immediately life-threatening. Other business partner numbers included: E2008-01988. Additional information has been requested.

Other Meds: corticosteroids (unspecified)

Lab Data: platelet count 70/microL 150-400/nL; serum LDH 700 U/L 90-270; serum blood urea 240 mg/dL 18-45; serum creatinine 10 mg/dL 0.6-1.1

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 307193-1 (S) **Related reports:** 307193-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Nov-2006	14-Mar-2008	476	17-Mar-2008	21-Mar-2008	NC		21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Dry skin, Hodgkins disease, Hodgkins disease nodular sclerosis stage II subdiaphragmatic, Lymphadenopathy, Mediastinal mass, Pruritus, Upper respiratory tract infection, Weight decreased

Symptom Text: Pt. received series of 3 vaccinations - 11/06, 05/07, 01/08. Pt. noted sl. weight loss - 10 lbs, and enlarged supraclavicular lymph nodes around 2/1/08. Node grew slightly larger by 3/11/08. Pt was seen by fam. phys. - cbc done,+ cxr. Cxr abnormal - 4 x 7.4 cm mediastinal mass noted. CT showed grossly enlarged lymph nodes. Biopsy performed on lymph node - positive for Hodgkin's lymphoma. Pt. awaiting appt. with Duke oncology for staging and plan of care. Component HHV-6 known causative agent of Hodgkin's lymphoma contained in recombinant HPV vaccine. 5/19/08-records received-Oncology visit 3/25/08-presented with no significant PMH. C/O enlargement of left cervical lymph node at end of 1/08 and upper respiratory symptoms. Four weeks later seen by PCP, C/O pruritus in legs and arms since January as well as patches of dry skin. Chemotherapy.

Other Meds: adderall, topamax, nuvaring

Lab Data: abnormal cxr, abnormal ct scan, biopsy + for Hodgkin's lymphoma. Cbc within normal limits 5/19/08-records received-Alkaline phosphatase elevated 209, sed rate 58. Echocardiogram normal. Chest-xray mediastinal mass. CT of neck 3/12/08 two

History: allergic to pcn, septra, ceclor 5/19/08-records received-Six month history of headaches diagnosed as migraine headaches.

Prex Illness: none

Prex Vax Illns: prolonged crying~DTP (no brand name)~1~0~In Patient

Vaers Id: 307193-2 (S) **Related reports:** 307193-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jan-2008	01-Feb-2008	31	25-Apr-2008	28-Apr-2008	--	WAES0804USA02746	28-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Hodgkins disease, Lymphadenopathy, Weight decreased

Symptom Text: Information has been received on request from an agency regarding a 20 year old female with no previous illnesses and allergies to penicillin, sulfamethoxazole (+) trimethoprim (SEPTRA), and cefaclor (CECLOR), who on 24-NOV-2006 was vaccinated with a first dose of GARDASIL. In May 2007 the patient was vaccinated with a second dose of GARDASIL. In January 2008 the patient was vaccinated IM in the right arm with a third dose of GARDASIL (Lot# 659055/1522U). Concomitant therapy included amphetamine aspartate/amphetamineS04/dex (ADDERALL TABLETS), topiramate (TOPAMAX) and ethinyl estradiol (+) etonogestrel (NUVARING). Subsequently, it was noted that the patient experienced a weight loss of 10 pounds, and enlarged supravlavicular lymph nodes around 01-FEB-2008. The lymph nodes grew slightly larger by 11-MAR-2008. The patient was seen by the family physician. A complete blood count and chest x-ray were performed. The patient's chest x-ray was abnormal, a 4 x 7.4cm mediatinal mass was noted. A computer axial tomography (CT) showed grossly enlarged lymph nodes. A biopsy was performed on the lymph nodes and was positive for Hodgkin's lymphoma. The patient was awaiting an appointment with oncology for staging and plan of care. It was reported that component HHV-6 was a known causative agent for Hodgkin's lymphoma and was contained in recombinant HPV vaccine. It was also reported that the patient had been previously vaccinated with a dose of diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid and subsequently experienced prolonged crying. At the time of the report, the outcome of the patient was unknown. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the lab and was released. Additional information is not expected.

Other Meds: Adderall tablets; Nuvaring; Topamax

Lab Data: Chest X-ray abnormal - 4 x 7.4cm mediatinal mass; computed axial grossly enlarged lymph nodes; biopsy lymph nodes - positive for Hodgkin's lymphoma; complete blood cell within normal limits.

History:

Prex Illness: Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 307886-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Sep-2007	06-Mar-2008	185	24-Mar-2008	25-Mar-2008	FR	WAES0803USA02574	25-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Pancreatitis acute

Symptom Text: Information has been received from a physician concerning a 15 year old female, who on 03-SEP-2007 was vaccinated with a first dose of Gardasil (Lot# 655127/0575F; Batch# NF23310). On 08-SEP-2007 was vaccinated with a second dose of Gardasil (Lot# 1358F; Batch# NG01520). The first and second doses were well tolerated. On 07-FEB-2008 the patient was vaccinated IM in the upper arm with a third dose of Gardasil (Lot# 0467U; Batch# NG14290). Concomitant therapy included THYRONAJOD. On 06-MAR-2008 the patient experienced acute pancreatitis. At the time of the report, the outcome of the patient was unknown. The physician considered acute pancreatitis to be life threatening. Additional information was not available.

Other Meds: THYRONAJOD, Unk - Unk

Lab Data: Unknown

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: 308895-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Nov-2007	01-Jan-2008	35	04-Apr-2008	07-Apr-2008	FR	WAES0804USA00535	07-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Ataxia, Encephalopathy, Mental disorder due to a general medical condition, Myoclonus, Pleocytosis

Symptom Text: Information has been received from a health authority concerning a 16 year old female who on 27-NOV-2007 was vaccinated IM with a first dose of GARDASIL. On 01-JAN-2008 the patient experienced encephalopathy with myoclonus opsoclonus syndrome. It was reported that the clinical picture was described as encephalopathy with myoclonus, opsoclonus, ataxia and organic brain syndrome. The patient was hospitalized. A cerebrospinal fluid examination showed pleocytosis, oligoclonal bands positive. At the time of this report, the patient has no recovered. Encephalopathy and myoclonus opsoclonus were considered to be immediately life-threatening. Other business partner numbers include: E200802621 and PEI2008002769. No further information is available.

Other Meds: Unknown

Lab Data: cerebrospinal fluid culture 01Jan08 Comment: pleocytosis, oligoclonal bands positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 309168-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Mar-2008	21-Mar-2008	0	09-Apr-2008	10-Apr-2008	--	WAES0803USA04969	24-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Body temperature increased, Depressed level of consciousness, Headache, Intensive care, Lethargy, Meningitis, Ventricular tachycardia

Symptom Text: Information has been received from a a registered pharmacist concerning a 21 year old female who with no pertinent medical history who "7-8 days ago" on approximately 21-MAR-2008 was vaccinated with a dose of GARDASIL (lot number, route and site of administration not specified). There was no concomitant medications. On an unspecified date the patient presented with bacterial meningitis and the only medication she was given was GARDASIL before this occurred. The patient was hospitalized on an unspecified date for an unspecified amount of time. At the time of reporting the patient was recovering. The reporter felt that bacterial meningitis was life threatening. Additional information has been requested. 4/24/08-records received for DOS 3/25-3/31/08-DC DX: meningitis, resolved. Presented with frontal headache. Progressive headache and at ER lethargic and obtunded. ICU- One episode ventricular tachycardia. Temperature 100.4.

Other Meds: None

Lab Data: None 4/24/08-records received-Lumbar puncture analysis showed strep pneumonia bacteria in cerebrospinal fluid, protein 140, wbc 4831, segs, bands, lymph and monocytes of CSF elevated. . Blood culture strep pneumo bacteremia. EEG showing mo

History: None 4/24/08-records received-PMH: several strep pneumonia manifested as upper respiratory tract infections throughout childhood.

Prex Illness:

Prex Vax Illns:

Vaers Id: 309172-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Apr-2008	03-Apr-2008	0	09-Apr-2008	10-Apr-2008	--	WAES0804USA01368	10-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Oxygen supplementation

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no pertinent medical history and no history of drug reactions/allergies who on 03-APR-2008 was vaccinated with a first dose of GARDASIL (lot # 658219/0755U) 0.5 ml IM. There was no concomitant medication. On 03-APR-2008, within seconds of receiving the vaccination, the patient had a seizure and lost consciousness for 30 seconds. The patient was treated with oxygen. Her blood pressure was 95/56 and pulse 131. The patient was transported to a local emergency room via ambulance. The outcome of the events was not reported. The reporter felt that the seizure and loss of consciousness were immediately life-threatening and required intervention (Other Important Medical Events). Additional information has been requested.

Other Meds: None

Lab Data: blood pressure 04/03/08 95/56; total heartbeat count 04/03/08 131

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 309457-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Apr-2008	07-Apr-2008	0	14-Apr-2008	21-Apr-2008	CT	CT200803	27-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1784U	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2375BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Chest discomfort, Cough, Dyspnoea, Erythema, Eye swelling, Hypersensitivity, Injection site erythema, Injection site swelling, Pruritus, Rhinorrhoea, Swelling face, Throat tightness, Urticaria

Symptom Text: Allergic reaction. Coughing, facial swelling and hives 15 minutes after leaving the office. Epi pen administered by mother en route to medical center. Treated in ED and discharged home same day. 5/20/08 Reviewed ER medical records of 4/7/2008. FINAL DX: allergic reaction Records reveal patient experienced itching, SOB, throat tightness, rhinorrhea, chest tightness & hives approx 2 hours s/p vaccination. Developed redness & swelling at varicella injection site. Used epi-pen & antihistamine at home. Called EMS who found patient SOB w/eye swelling, face red. Tx w/steroids. Improved & d/c to home on continued meds.

Other Meds: Advair, Flovent, Vyvanse, Zoloft, fluoride

Lab Data: none

History: Triple X syndrome, eosinophilic esophagitis PMH: allergies to nuts, shellfish, eggs, ceclor, paprika. Anxiety. ADHD. Family hx of asthma & food allergies.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 309503-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Apr-2008	08-Apr-2008	0	15-Apr-2008	16-Apr-2008	CA	WAES0804USA02247	16-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	
BCG	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypotension, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female who on 08-APR-2008 was vaccinated with GARDASIL (lot#659437/1266U) 0.5mL IM. Concomitant therapy included MENACTRA and "TB" vaccine (manufacturer unknown). On 08-APR-28 the patient fainted after receiving GARDASIL. The medical assistant reported that the patient was rushed to the hospital via ambulance due to severe hypotension after receiving the vaccine. At the time of reporting it was unknown if the patient had recovered. The reporter felt that syncope and severe hypotension were considered to be disabling, life threatening and an other medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 310262-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2008	05-Apr-2008	4	21-Apr-2008	22-Apr-2008	NC	WAES0804USA02336	25-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Unknown	Unknown	

Seriousness: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a 20 year old female with no medical history reported, who on 01-APR-2008 was vaccinated with a dose of Gardasil. On 05-APR-2008, the patient died four days after receiving Gardasil. The patient sought unspecified medical attention. An autopsy was performed which ruled out suicide and anything suspicious. The cause of death is currently unknown and they are performing toxicology tests to try to determine the cause. No product quality complaint was involved. The reportable physician considered death to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: autopsy, 04/??/08, ruled out suicide or anything suspicious; diagnostic laboratory, 04/??/08, toxicology results unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **311079-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jan-2008	25-Apr-2008	100	28-Apr-2008	29-Apr-2008	WY		07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	2	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Blood glucose increased, Diabetes mellitus, Glucose urine present, Otitis media, Visual disturbance

Symptom Text: 4/28/08 random BS 386, urine > 1000 mg/dl glucose 05/05/08-records received-seen in office 3/5/08-C/O LOM. Next visit 4/25/08-feels well however C/O vision problems, 20/40. DX: Diabetes

Other Meds:

Lab Data: 5/5/08-records received-Accucheck 386-4/28/08-A1C >14. krk

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 311176-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Apr-2008	16-Apr-2008	0	29-Apr-2008	30-Apr-2008	OK	WAES0804USA03908	30-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaphylactic shock, Dyspnoea, Swollen tongue, Vomiting

Symptom Text: Information has been received from a physician and with a follow up telephone call concerning a 17 year old female patient with no pertinent medical history who on 16-APR-2008 at 11:30 AM was vaccinated with a first dose of GARDASIL (lot # 659657/1487U) and with a dose of MENACTRA. Concomitant suspect therapy included amoxicillin (dose, duration not indicated) for sinus infection. The physician reported that "patient received her first injection on 16-APR-2008 and left the doctor's office fine. She picked up a prescription for amoxicillin and took it with a bowl of taco soup. Within two hours after she received GARDASIL and MENACTRA at 01:30 PM she had tongue swelling, vomiting and trouble breathing. The ambulance came and the patient went to the emergency room where she was treated with steroid injections. The patient was not admitted to the hospital. She left the emergency room recovered and was placed on oral steroids. The emergency room physician felt amoxicillin was the cause of the anaphylactic shock. The reporting physician was not sure of cause of the anaphylactic shock was either from MENATRA, amoxicillin or GARDASIL. The reporting physician considered anaphylactic shock to be disabling and life threatening. Additional information has been requested.

Other Meds: amoxicillin

Lab Data: Unknown

History:

Prex Illness: Sinus infection

Prex Vax Illns:

Vaers Id: 311459-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Mar-2007	01-Mar-2008	338	02-May-2008	05-May-2008	FR	WAES0804USA05386	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Herpes zoster, Immunodeficiency common variable, Sepsis syndrome, Streptococcal infection

Symptom Text: Information has been received from a health authority, concerning a 16 year old female patient, and recurrent infections with transaminases increased (since 2005), who on 29-MAR-2007 was vaccinated with the first dose, which was well tolerated (lot # 654884/0902F; batch NE24240); on 07-MAY-2007 was vaccinated with the second dose, which was well tolerated (lot # 655671/1024F; batch NE63230); and on 06-DEC-2007 was vaccinated with the third dose in the upper arm, of Gardasil (lot # 0251U; batch NF56480). In January 2008, the patient developed streptococcal infection with sepsis syndrome and herpes zoster. In March 2008, the patient was diagnosed with a common variable immunodeficiency, with decreased IgG and IgG 1. She was hospitalized (date and duration not reported. Common variable immunodeficiency was considered to be immediately life threatening. The reporter (not specified), considered a relation to the vaccine doubtful, as the patient showed recurrent infections with increased transaminases, which occurred for the first time in 2005. Other business partner numbers include: E2008-03745; reference # PEI2008004690.

Other Meds: Unknown

Lab Data: serum immunoglobulin G test, 01Mar08, decreased; serum antiendomysial antibodies test, 01Mar08, IgG 1 decreased

History: No reaction on previous exposure to vaccine; Infection; Transaminases increased

Prex Illness:

Prex Vax Illns:

Vaers Id: 311786-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Apr-2007	25-Apr-2008	385	07-May-2008	08-May-2008	FR	WAES0804USA06287	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0088U	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Type 1 diabetes mellitus, Vision blurred, Weight decreased

Symptom Text: Information has been received from a physician and a medical assistant concerning a 12 year old female patient who on 06-APR-2007 was vaccinated IM with a first dose of Gardasil (lot #655324/0088U) and on 02-AUG-2007 she was was vaccinated with a second dose of Gardasil (lot # 657622/0388U). On 16-JAN-2008 she was was vaccinated her third dose of Gardasil (lot # 657868/0523U). No concomitant therapy was reported. The physician reported that the patient developed diabetes Type 1 after receiving three doses of Gardasil. She was examined in the hospital on 25-APR-2008 and on 28-APR-2008. She was not admitted to the hospital on either occasion. The patient was started on insulin. No further information was provided. The patient's outcome was not recovered. In follow up telephone call the medical assistant reported that the patient began experiencing rapid weight loss and blurry vision (dates not reported). She was diagnosed with Type 1 diabetes. The physician considered patient starting on insulin to be life threatening and disabling and an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum glucose, 25Apr08, 386 mg/dL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312479-1 (S)** **Related reports:** 312479-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Apr-2008	01-May-2008	27	16-May-2008	20-May-2008	TX		03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Malaise, Nausea, Vomiting, Weight decreased

Symptom Text: weight loss, nausea & vomiting, malaise

Other Meds: none

Lab Data: pancytopenia, increased liver enzymes; bone marrow biopsy on 5-5-08 showed acute myelogenous leukemia;Gardasil series: 9-26-07, 11-21-07 & 4-4-08 (#13does not allow Gardasil to be entered)

History: none

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling

Vaers Id: 312648-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jan-2008	18-Jan-2008	2	20-May-2008	21-May-2008	FR	WAES0805USA02809	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575F	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Amnesia, Cyanosis, Disorientation, Fall, Loss of consciousness, Mydriasis, Tetany

Symptom Text: Information has been received from a health authority concerning a 14 year old female with a history of rhinitis and conjunctivitis (with no evidence of true allergy: negative cutaneous test to pneumallergens) and family atopic diathesis, who on 16-JAN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (Batch # NE47400/Lot #655127/0575F). The patient was with her mother and was very anxious because of vaccination. Within a few seconds following vaccination, the patient lost consciousness and fell onto the ground. Examination found mydriasis, incipient cyanosis, and tetany of the upper limbs. Pulse was not measurable. No work-up results were provided and no additional examination was performed concerning ruled out etiologies not related to drugs. The patient's legs were raised and she regained consciousness in a few seconds. The patient had total amnesia of her loss of consciousness and was disoriented. Subsequently, the patient recovered. The physician did not wish to continue vaccination. The events were considered to be immediately life-threatening. Additional information is not expected. The case is closed. Other business partner numbers include E2008-04343.

Other Meds: Unknown

Lab Data: Unknown

History: Rhinitis; Conjunctivitis

Prex Illness:

Prex Vax Illns:

Vaers Id: 312946-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jan-2008	Unknown		21-May-2008	23-May-2008	GA		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Balance disorder, Benign intracranial hypertension, Blindness, Headache, Lumboperitoneal shunt, Neck pain, Vomiting

Symptom Text: One month after vaccine, diagnosed with Pseudo Tumor Cerebri. Major symptoms: headache, loss of vision, vomiting, neck pain, balance off. Lumbar shunt was put from spine to abdomen to drain spinal fluid.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 314524-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a "17 year old" female who on an unspecified date was vaccinated with GARDASIL. In April 2008, approximately 6 weeks ago the patient died. The physician reported that one of the patient's mother did not want to agree to the vaccine because her friend's daughter died after receiving it. The 17 year old patient was found dead on the floor by her mother. The autopsy was performed and the outcome was unspecified. The physician only has information on the patient that refused the vaccine. No further information was provided. The reporter felt that the event was disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: