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: 303189-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jan-2008	08-Jan-2008	2	22-Jan-2008	23-Jan-2008	FL	WAES0801USA02310	23-Jan-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anorexia, Headache, Insomnia, Myalgia, Nausea, Pharyngolaryngeal pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning her 17 year old daughter who on 06-JUL-2007, was vaccinated IM with a first 0.5ml dose of Gardasil. On 12-SEP-2007 and 06-JAN-2008, the patient was vaccinated with a second and third dose of Gardasil (Lot# 657872/0515U), respectively. Concomitant therapy included PROZAC and vitamins (unspecified). On 08-JAN-2008 two days later, the patient experienced nausea. On 09-JAN-2008 the next morning, she vomited. On approximately (09-JAN-2008)since the last vaccination), she experienced myalgia, headache, sore throat, fever, loss of appetite and difficulty sleeping. Unspecified medical attention was sought. Laboratory diagnostic studies included a complete blood cell count which was reported as normal. As of 10-JAN-2008, the patient no longer had a fever or sore throat but she was experiencing an increase in her myalgia. As of 14-JAN-2008, it was reported that the patient started to feel better. It was also reported that the patient had not been able to attend school since 08-JAN-2008. On 15-JAN-2008, the patient returned to school. No product quality complaint was involved. Nausea, vomited, myalgia, headache, sore throat, fever, loss of appetite and difficulty sleeping were considered to be disabling by the reporter. Additional information is not expected.

Other Meds: PROZAC; vitamins (unspecified)

Lab Data: complete blood cell - normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 303190-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jan-2008	04-Jan-2008	2	22-Jan-2008	23-Jan-2008	FR	WAES0801USA02758	23-Jan-2008

VAX Detail:

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Inflammatory pain, Injected limb mobility decreased, Insomnia, Musculoskeletal pain, Oedema, Periarthritis

Symptom Text: Initial and follow up information has been received from a health professional concerning an 18 year old female patient in good health who on 02-JAN-2008 was vaccinated IM in the deltoid with a second dose of Gardasil. It was reported that 48 hours after vaccination, the patient experienced severe pain in the shoulder. No reaction occurred at the site of injection. One week later, the event worsened as the patient could no longer move her arm. Oedema in the shoulder joint was suspected. Pain was reported to prevent the patient from sleeping. Frozen shoulder was the suspected diagnosis. At the time of this report the patient had not recovered. In follow up it was reported that the patient had no relevant medical history and was in good health. The first dose of Gardasil was well tolerated by the patient. The physician confirmed that the patient had nocturnal inflammatory type pain that did not regress on analgesics. No work up was performed. As of 14-JAN-2008, the patient was in better condition. The reporting physician considered that the event had been very disabling for at least 3 days. The other business partner numbers include: E2008-00196. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: The first dose of Gardasil was well tolerated by the patient.

Prex Illness:

Prex Vax Illns:

Vaers Id: 303193-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jan-2008	10-Jan-2008	0	22-Jan-2008	23-Jan-2008	FR	WAES0801USA03064	23-Jan-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG00020	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female with a history of neurodermatitis and urticaria factitia, who on 10-JAN-2008 was vaccinated intramuscularly with a first dose of Gardasil (Batch# NG00020). Immediately post vaccination the patient experienced one injection site hive (12 x 5mm) and injection site redness (12cm diameter). the patient was admitted to the hospital for monitoring. The symptoms were ongoing at the time of the report. It was reported that previous vaccinations were well tolerated. Other business partner numbers included: E2008-00176. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Neurodermatitis; Urticaria; No reaction on previous exposure to vaccine

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: 303836-1 (S) **Related reports:** 303836-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Jan-2008	03-Jan-2008	1	29-Jan-2008	30-Jan-2008	MO	WAES0801USA02867	05-Mar-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1658U		Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1448U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood urine present, Chest pain, Chills, Flank pain, Micturition urgency, Nausea, Pollakiuria, Pyelonephritis, Weight decreased

Symptom Text: Information has been received from a physician concerning a 14 year old female with no medical history, who on 02-JAN-2008 was vaccinated with a first dose of Gardasil (Lot# 659653/1448U). Concomitant suspect vaccinations included Varivax. Other concomitant vaccinations included HAVRIX. On 03-JAN-2008 the patient experienced urinary urgency and frequency. On 03-JAN-2008 a urinary analysis was performed and showed a trace of blood in the urine. The patient improved within 48 hours. The patient then experienced right flank pain, chest pain with chills, and no fever. On 10-JAN-2008 the patient was admitted to the hospital and experienced nausea and loss of weight. The patient was better by 11-JAN-2008 and was released from the hospital. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested. 03/03/2008 MR received for DOS 01/6-10/2008 with DX: Pyelonephritis. Pt presented to ED with c/o sudden onset flank pain (R chest, flank, back). Pt txd x 3 days for UTI sx of frequency and urgency). On abx.

Other Meds:

Lab Data: urinalysis 01/03/08 - trace of blood in urine. Labs and Diagnostics: UA with trace leukocytes, (+) nitrites, trace ketones, 1+ bilirubin, 4.0 urobilinogen, 1-3 WBCs, 2-5 epis. Repeat UA WNL 3 days later. UC (-)x2. CBC WNL. CMP unremarkab

History: None. PMH: tonsillectomy, tendon repair R foot.

Prex Illness:

Prex Vax Illns:

Vaers Id: 303838-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jan-2008	09-Jan-2008	0	29-Jan-2008	30-Jan-2008	PA	WAES0801USA03962	30-Jan-2008

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Immediate post-injection reaction, Injected limb mobility decreased, Pain in extremity, Wound, Wrong technique in drug usage process

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female with no pertinent medical history or drug reactions/allergies who on 12-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil. On 09-JAN-2008 the patient was vaccinated intramuscularly in the left upper arm with a 0.5 ml second dose of Gardasil (659055/1522U). Concomitant therapy included ORTHO TRI-CYCLEN LO. On 09-JAN-2008 the patient developed pain to the arm right after receiving the injection. The pain radiates down the left arm and has gotten worse since the injection. The patient called and was seen by her family physician, who told her that the injection was given improperly into the tendon or ligament causing a puncture wound. The patient last saw the reporting physician on 14-JAN-2008. At that time there was no bruising noted at the site. The patient was not able to lift her left arm. The patient has been using TYLENOL, CELECOXIB, and heat as prescribed by her family physician. The patient's outcome was reported as not recovered. The patient's mother is requesting an MRI of the left arm, it has not been ordered at this time. There was no product quality complaint involved. Follow up information was received from the licensed practical nurse indicating that she would consider the patient to have temporary incapacity of her arm and therefore felt that the events were disabling. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 303974-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Jan-2008	26-Jan-2008	1	30-Jan-2008	01-Feb-2008	TX		01-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Gaze palsy, Muscle twitching, Nausea, Syncope

Symptom Text: Pt's mother presented at clinic reporting possible reaction to Gardasil. States daughter got the Gardasil Friday afternoon. Sat "about 24 hours later" pt was at a dress fitting, states pt hadn't eaten was standing x 20 min and got nauseous and light headed then fainted. States she was out for several minutes and had "some twitching" and "her eyes rolled back". States called emergency line and then went to ER where they spent several hrs, test run there were negative, but they have been advised to get a neuro work up and pt is not to drive. Mother reports no F/H of seizures and the only thing that was different in pt's life was the Gardasil. States she went online and fainting is one of the side effects listed for Gardasil. States doesn't want to have unnecessary testing done if this was caused by the Gardasil. Mother states she is not sure she wants pt to get another Gardasil injection.

Other Meds:

Lab Data:

History: NKDA, Hypothyroid, ADD

Prex Illness:

Prex Vax Illns:

Vaers Id: **304124-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jan-2008	25-Jan-2008	15	01-Feb-2008	04-Feb-2008	FR	WAES0801USA05394	04-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breast cyst, Weight increased

Symptom Text: Information has been received from a health professional concerning a 17 year old female with genetic disease with renal failure and hormonal deficiency who on 10-JAN-2008 was vaccinated with the first primary dose of GARDASIL. Route and site of administration were not reported. Concomitant therapy included TRI-CYCLEN and corticosteroids (unspecified). Within 15 days post vaccination, on approximately 25-JAN-2008, the patient experienced weight increased of 5 kg and developed about 20 cysts in the breast. No exploration was performed at the time of reporting. The patient was hospitalized in the pediatric unit for investigation. Diagnostic ultrasound was scheduled on 29-JAN-2008. The reporter felt that the events were serious for other important medical events. Other business partner numbers include E2008-00585. Additional information has been requested.

Other Meds: TRI-CYCLEN, Unk - Unk; corticosteroids (unspecified), Unk - Unk

Lab Data: ultrasound, 29Jan08

History:

Prex Illness: Renal failure; Hormonal imbalance

Prex Vax Illns:

Vaers Id: 304337-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jan-2008	22-Jan-2008	0	05-Feb-2008	06-Feb-2008	LA		28-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2323AA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1266U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dizziness, Dyskinesia, Gaze palsy, Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: Seizure like episode lasting approx 10 seconds. 2/14/08-records received for DOS 1/22/08- Became light-headed after vaccination, eye began rolling back, unresponsive to voice. Began jerking movements of right and left arm and head. Post ictal state. 5/27/08-DC Summary received for DOS 1/22-1/23/08-DC DX: Reaction to HPV vaccine. Light headed few seconds after vaccination.

Other Meds:

Lab Data: Accu check; CBC; CMP; EEG & EKG 2/14/08-records received-EEG normal awake and drowsy EEG. Labs within normal limits.

History: None 2/14/08-records received-HX of psoriasis.

Prex Illness: None

Prex Vax Illns: ~DTaP (no brand name)~3~1~In Patient

Vaers Id: 304409-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Jan-2008	15-Jan-2008	0	06-Feb-2008	07-Feb-2008	FR	WAES0801USA05863	07-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Erythema, Joint swelling, Osteomyelitis, Pyrexia

Symptom Text: Information has been received from a general practitioner concerning a 12 year old female who on 08-JAN-2008 was vaccinated IM into the upper arm with the third dose of Gardasil. On 15-JAn-2008 the patient experienced arthralgia in the left ankle joint. X-ray of the ankle joint showed normal results. The same date the patient received an IM booster dose into the upper arm of REVAXIS. On 16-JAN-2008, the patient developed fever up to 38.9 C. The patient was treated with anti-inflammatory ointment and ibuprofen tablets. On 17-JAN-2008 a blood sample was taken to determine inflammatory parameters. Symptoms were ongoing at that time. Follow-up on 25-JAN-2008. It was reported that the patient was hospitalized. The case has to be upgraded. Fever increase in the course. The left ankle joint was swollen and reddened. The patient was hospitalized, osteomyelitis was diagnosed, "septic genesis" was assumed. Antibiotic treatment was started. At the time of the report the patient had already recovered from fever. Other symptoms were still ongoing. The reporting physician does not see a relation to the vaccines anymore. Previous vaccinations with Gardasil were well tolerated. Other business partner numbers include: E2008-00327. Additional information has been requested.

Other Meds: Unknown

Lab Data: X-ray 15Jan08 Comment: ankle joint x-ray showed normal results; hematology 17Jan08 Comment: results determine inflammatory parameters

History: Previous vaccinations with Gardasil were well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: 304410-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jan-2008	26-Jan-2008	1	06-Feb-2008	07-Feb-2008	FR	WAES0801USA06083	07-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Meningism, Myalgia, Pain in extremity, Pyrexia, Stupor, Upper respiratory tract infection

Symptom Text: Information has been received from a health care professional concerning a 14 year old female who on 25-JAN-2008 was vaccinated with a third dose of Gardasil (lot # not reported). On 26-JAN-2008 the patient presented at the practice with myalgia and pain in limbs, fever, severe headache, meningism and stupor. She was admitted to the neurological department of a hospital. The hospital reports was forwarded on 29-JAN-2008 where it was reported that exhaustive laboratory examinations were carried out and showed normal results except for increased serum C-reactive protein test (CRP) which was 4.8 mg/dl and decreased leukocytes (3.6 10^3/ul). Electrocardiogram (EEG), magnetic resonance imaging (MRI), electroencephalography (ECG) lumbar puncture Cerebrospinal fluid (CSF) showed normal results. A mild upper respiratory tract infection was diagnosed. She was treated with ROCEPHIN and acetaminophen "paracetamol". The reactions were supposed to be "postvaccinal or parainfectious". Meningism stopped on 27-JAN-2008. In the hospital report "stupor was not mentioned. The patient was discharged on 28-JAN-2008 in a remarkable improved condition. On 29-JAN-2008 the reporter informed the office by phone that she had recovered completely. The file is closed. The other business partner number includes: E2008-00611. Additional information is not expected.

Other Meds: Unknown

Lab Data: electroencephalography 27Jan08 Comment: Normal result; magnetic resonance imaging 27Jan08 Comment: Cranial magnetic resonance imaging normal result; electrocardiogram 27Jan08 Comment: Normal result; spinal tap 27Jan08 Comment: Cerebrospinal

History: Unknown

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: **304637-2 (S)** **Related reports:** 304637-1; 304637-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jan-2008	27-Jan-2008	5	19-Feb-2008	20-Feb-2008	TX	WAES0802USA02092	20-Feb-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	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Joint swelling, Oedema peripheral

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with an amoxicillin allergy who on 20-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil (lot 659437/1266U). On 22-JAN-2008, the patient was vaccinated intramuscularly with a 0.5 ml second dose of Gardasil (lot 659657/1487U) and concomitantly vaccinated with a dose of MENACTRA. On 27-JAN-2008, the patient developed joint pain affecting her hands, elbows, and feet and swelling to her toes, knees and ankles. The patient was seen by the office and was being treated with prednisone. Laboratory evaluations revealed complete blood count, sedimentation rate, and antinuclear antibody test were within normal limits. The patient had not recovered at the time of reporting. The patient's joint pain in hands, elbows, and feet and swelling to her toes, knees, and ankles were considered to be disabling by the reporter as "the patient had difficulty using a pencil and had missed school." Additional information has been requested.

Other Meds:

Lab Data: complete blood cell - normal; erythrocyte - normal; serum ANA - normal

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

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

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	11-Feb-2008	12-Feb-2008	CA	WAES0802USA00767	14-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Ataxia, Conversion disorder, Dizziness, Gait disturbance, Headache, Hypoaesthesia, Muscular weakness, Nausea, Photophobia, Pyrexia, Tremor

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no pertinent medical history and no known allergies who in February 2007, was vaccinated with Gardasil. In May 2007, she received the second dose and on 29-JAN-2008, she received the third dose. There was no concomitant medication. There were no adverse events following the first and second doses. On 29-JAN-2008, four hours after the third dose, the patient experienced numbness in her legs, severe headaches, Dizziness, nausea, fever, muscle weakness and her body would not stop shaking. The patient sought medical attention and has been in and out of the hospital since 29-JAN-2008. The reporter was unsure of the exact amount of time she was hospitalized. As of 04-FEB-2008, the patient had not recovered. Additional information has been requested. 03/13/2008 MR received for DOS 1/31-2/5/2008 with D/C DX: Anxiety NOS with hysterical gait disorder. Pt presented for admission with 2 day hx of shaking episodes which began within hours of HPV vax #3 on 1/29/08. Also c/o photophobia, nausea, and dizziness. Pt has episodic multi-amplitude shivering/shaking type movements of the upper and lower extremities, trunk, and head somewhat decreased when distracted on PE. Neuro and psych consults. Neuro exam (+) for psychogenic wide-based gait with pseudotremor and ataxia. D/C for outpt f/u.

Other Meds: None

Lab Data: diagnostic laboratory - tests and results not provided. Labs and Diagnostics: CT brain scan WNL. EEG normal. MRI brain normal. CXR WNL. CBC with WBC 3.95. ASO titre 416.

History: None. One episode of shaking with anxiety 1 yr ago.

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: 304737-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Nov-2007	01-Jan-2008	61	12-Feb-2008	13-Feb-2008	FR	WAES0802USA00543	13-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chronic myeloid leukaemia, Leukocytosis

Symptom Text: Information has been received from a health professional concerning a 19 year old female who in January 2008 was vaccinated with her second dose of Gardasil intramuscularly. Fifteen days post vaccination she was found to have leukocytosis at 30,000. She was hospitalized in the haematology unit and was diagnosed with chronic myeloid leukemia. At the time of reporting the outcome was not reported. She had received the first dose of Gardasil in November 2007. Other business partner numbers include E200800808. The reporter source was a health professional. No further information is available.

Other Meds: Unknown

Lab Data: WBC count ??Jan08 30,000

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 304738-1 (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	29-Jan-2008	0	12-Feb-2008	13-Feb-2008	--	WAES0802USA00808	13-Feb-2008

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

Seriousness: EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Chills, Headache, Inappropriate schedule of drug administration, Photophobia, Tremor

Symptom Text: Information has been received from a physician concerning a 15 year old female with no known allergies and no pertinent medical history who was vaccinated with three doses of Gardasil. The first dose was administered on 19-FEB-2007 and the second dose was on 02-MAY-2007. On 29-JAN-2008, the patient was by her primary care physician for complaints of increased frequencies of headaches, non radiating pain at the left side of her head and photophobia. While at the primary care office on 29-JAN-2008, the patient also received the third dose of Gardasil. A few hours post vaccination, the patient experienced chills and was shaking while sitting, walking or standing. The patient was hospitalized on 31-JAN-2008. The reporting physician was working with the neurology team at the hospital. Tests performed were MRI of the head and an EEG, both with normal results. Urine pregnancy test was negative for pregnancy. The physician reported the patient had some improvement, but as of 04-FEB-2008, was still hospitalized. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance 01/31/08 - head: normal; electroencephalography 01/31/08 - normal; urine beta-human 01/31/08 - negative

History: None

Prex Illness:

Prex Vax Illns:

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: 304881-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Jan-2008	05-Feb-2008	18	14-Feb-2008	15-Feb-2008	FR	WAES0802USA01968	15-Feb-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 Abdominal pain upper, Back pain, Gastrooesophageal reflux disease, Malaise, Musculoskeletal pain, Oesophagitis

Symptom Text: Information has been received from a gynecologist concerning a 24 year old female with appetite lost and unintended weight decreased (7 kg) who in 18-JAN-2008, was vaccinated with a second dose of Gardasil. On 05-FEB-2008 the patient experienced heavy back pain, pain in both shoulders, stomach pain and felt very ill. She was admitted to the hospital. Following information gathered on 07-FEB-2008, the exams should that she had acute oesophagitis due to gastroesophageal reflux. She was successfully treated and discharged on 07-FEB-2008. A disorder of the gallbladder was also suspected. Further outpatient examinations were scheduled. It was to be noted that the patient had decreased appetite and unintended weight loss of 7 kg since mid 2007 (prior to first dose of Gardasil). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Appetite lost; weight decreased

Prex Vax Illns:

Vaers Id: 304884-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Nov-2007	24-Jan-2008	77	14-Feb-2008	15-Feb-2008	FR	WAES0802USA02228	15-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1340F	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Tremor

Symptom Text: Information has been received from a physician, concerning a 16 year old female who on 08-NOV-2007 was vaccinated IM in the left deltoid, with the first dose of GARDASIL (lot 1340F; batch NF14740). On 24-JAN-2008 the patient developed a tremor in her right arm, and was hospitalized. Subsequently, the patient recovered (duration and date not specified), and was discharged from the hospital on 01-FEB-2008. Other business partner numbers include: E2008-01011.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 304987-1 (S) **Related reports:** 304987-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Feb-2008	09-Feb-2008	2	14-Feb-2008	15-Feb-2008	PA		25-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Anaemia, Arthralgia, Asthenia, Gait disturbance, Hypocomplementaemia, Injection site reaction, Joint stiffness, Joint swelling, Musculoskeletal stiffness, Myalgia, Pyrexia, Systemic lupus erythematosus

Symptom Text: Received Gardasil injection #3 on 2/7/08. Few days later developed neck stiffness and joint pain/stiffness, tightness both legs & L arm where inj./fever on 3rd day x24 hrs. Can barely walk. Sent to ER. 03/17/2008 MR recieved for DOS 2/18-21/2008 with DX: Severe polyarthragia and weakness 2' to SLE. Systemic Lupus Erythematosus. ADD. Anemia. Pt presented with hisory of joint pain and swelling, generalized weakness progressing to the point of having difficulty getting out of bed. PE (+) for tenderness of both feet, ankles and hands. Decreased hand grip. Rheumatology consult with assessment of polyarthralgias, fevers, myalgias and hypocomplementemia.

Other Meds: Strattera

Lab Data: Labs and Diagnostics: CBC with normal WBC and dfferential, Hgb 11.8. Electrolytes WNL. UA with 3-5 WBCs, 3-5 RBCs and few bacteria. Complement C3 and C4 decreased at 63 and 7.2. Parvovirus B19 IgG (+). RF (-). CRP 3.6. dsDNA AutoAb 734.

History: NKA; no birth defects; Hx ADD; ear surg; LGSIL. PMH: ADHD, anxiety, R knee strain. (+) HPV. NKDA.

Prex Illness: No

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: 305111-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2007	01-Jan-2008	92	19-Feb-2008	20-Feb-2008	FR	WAES0802USA03111	20-Feb-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 Nausea, Tachycardia

Symptom Text: Information has been received from a health professional concerning a female (age unknown) in good health, who in October 2007, was vaccinated with a second dose of Gardasil. A few days after the vaccination, the patient experienced slight tachycardia, which lasted a few minutes and spontaneously resolved. In January 2008, the patient presented with a further episode of tachycardia, with a heartbeat of 130-140. The patient was hospitalized in intensive care for work-up. The second episode was associated with nausea, which resolved in 48 hours. The work-up did not find any aetiology in particular, and no thyroid problem was found. However, the troponin level was slightly increased. The patient was given corrective treatment with beta-blockers. During hospitalization, the patient was in good clinical condition. It was noted by the physician that the first dose of Gardasil had been well tolerated and the patient did not experience tachycardia after the first dose as previously reported. Other business partner numbers included: E2008-01050. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test troponin level slightly increased; total heartbeat count 130-140

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: 305129-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Feb-2008	18-Feb-2008	0	19-Feb-2008	22-Feb-2008	MI		10-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Right leg	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Face injury, Fall, Fracture reduction, Mouth haemorrhage, Surgery

Symptom Text: Client received third dose of HPV vaccine. Her brother received vaccines after she did. About ten minutes passed between the time she got her shot and the family was leaving the clinic. While walking down the hall to exit, patient fell forward and collapsed on her face. Bleeding from mouth, scraped chin. Unable to determine source of bleeding because child could not open her mouth more than 1/2 inch. After juice wnd cold compresses were used, parents left to take her to emergency room. Used wheelchair to go to car. 3/25/08 Reviewed hospital medical records of 2/18-2/20/2008. FINAL DX: Multiple mandible fractures, surgically reduced. Records reveal patient experienced syncope s/p vaccination. Seen at outlying ER & transferred to higher level of care.

Other Meds: None

Lab Data: Per father's report during phone call 2/19/08, child was diagnosed with 3 fractures in her jaw - one in front, and one on either side of her face. Is to undergo surgery today - plate, screws, and mouth wired (per father) LABS: CT scan & x

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 305156-2 (S) **Related reports:** 305156-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2008	04-Feb-2008	0	22-Feb-2008	25-Feb-2008	NY	WAES0802USA02908	13-Mar-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Facial pain, Hypoaesthesia, Hypoaesthesia facial, Lethargy, Muscular weakness, Pain in extremity, Pain in jaw

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of guillain-barre syndrome with an electromyogram abnormal from 3 years ago who on 04-FEB-2008 was vaccinated with the first dose of Gardasil IM. On 04-FEB-2008 the physician reported that the patient developed face, jaw and leg pain. The patient also felt lethargic and experienced muscle weakness. The patient was admitted in the hospital but the length and dates of hospitalization is unknown. On an unspecified date the patient had a spinal magnetic resonance imaging (MRI) performed and was negative. The patient is not currently in the hospital and has "improved 95%". The patient still has some pain, muscle weakness and numbness in her face, jaw and legs. No further information was available. The events required hospitalization and were considered to be other medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance - spinal - negative

History: Guillain-Barre syndrome; Electromyogram abnormal

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: 305498-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Feb-2008	11-Feb-2008	0	22-Feb-2008	25-Feb-2008	FR	WAES0802USA04332	25-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Paraesthesia, Tachycardia

Symptom Text: Information has been received from a physician, concerning a female adolescent with a history of infection (5 days prior to vaccination), who on 11-FEB-2008 was vaccinated with the third dose of Gardasil (route, site and lot # not specified). In the evening of the same day, the patient experienced paraesthesia, tachycardia, sweating attacks and felt faint. On 12-FEB-2008, an electrocardiogram (ECG) was normal, blood pressure was 100/60 mmHg, and pulse was 108, and the patient was admitted to the hospital. The physician noted that 5 days prior to vaccination, the patient was seen for an infection, and the vaccination had been postponed. Other business partner numbers include: E200801193.

Other Meds: Unknown

Lab Data: electrocardiogram 12Feb08 normal; blood pressure measurement 12Feb08 100/60 mmHg; total heartbeat count 12Feb08 108

History: Infection

Prex Illness:

Prex Vax Illns:

Vaers Id: 305539-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jul-2007	07-Feb-2008	219	25-Feb-2008	26-Feb-2008	FR	WAES0802USA02229	26-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute tonsillitis, Fatigue, Headache, Nausea, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old female with no medical history reported who was vaccinated with a first and second dose of Gardasil on 03-JUL-2007 and 06-SEP-2007 respectively. On 03-JAN-2008, the patient was vaccinated with a third dose of Gardasil (lot # not reported). On 06-FEB-2008, the patient experienced a headache and fever up to 39 degrees centigrade (C). On 07-FEB-2008, the patient was admitted into a hospital via an ambulance. The reporting physician suspected a trivial viral infection, he just wanted to know if there are some special tests existing to detect a typical reaction, if there is one, after the administration of Gardasil. The outcome of the event was not reported. Follow-up information was received on 13-FEB-2008 from the hospital. The patient was hospitalized due to fever, fatigue, nausea, headache, and heavy sore throat from 07-FEB-2008 to 09-FEB-2008. Due to increased inflammatory parameters (leukocytes 17,270/microL, c-reactive protein (CRP) 6.12 mg/dL) therapy was started with CUROCEF 3x1500 mg intravenously. Examinations performed included: X-ray of the lung: result inconspicuous, and X-ray of nasal sinus revealed regularly ventilated and no secretion. Virology testing on 08-FEB-2008 was negative for adenovirus, influenza A and B, parainfluenzal 2, 3, respiratory syncytial virus (RSV). Quick testing for Streptococcus and mononucleosis was negative. Angina tonsillaris was diagnosed. Due to treatment, the patient's condition improved considerably so she was discharged on 09-FEB-2008. The case is closed. Other business partner numbers included: E2008-01025. No further information is expected.

Other Meds: Unknown

Lab Data: chest X-ray 07Feb08 inconspicuous; nasal sinus X-ray regularly ventilated and no secretion 07Feb08; diagnostic laboratory test 07Feb08 quick testing: mononucleosis negative; WBC count 07Feb08 17,270 microL; serum C-reactive protein 07Feb08

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 306035-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jan-2008	14-Jan-2008	0	28-Feb-2008	29-Feb-2008	FR	WAES0802USA05489	29-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Chills, Hepatomegaly, Immunisation reaction, Lymphocytosis, Pyrexia, Rash generalised, Splenomegaly

Symptom Text: Information has been received from a health authority, concerning a 15 year old female patient with a history of dose 1 and dose 2 being well tolerated (dates not specified), who on 14-JAN-2008 was vaccinated in the right arm, with the third dose of Gardasil (lot # not reported). On the same day, the patient experienced an immunization reaction with fever, chills, abdominal pain and generalized exanthema. On an unspecified date, she was hospitalized. An abdominal sonogram showed enlarged liver and milt. Laboratory findings showed lymphocytosis and increased C-reactive protein with 66 mg/l (normal range <10 mg/l). Sepsis and toxic shock syndrome were ruled out. On 15-JAN-2008, the patient recovered from immunization reaction, and on 17-JAN-2008, she recovered from hepatosplenomegaly. Additional information has been requested. Other business partner numbers include: E2008-01403; health authority reference # PEI2008001286.

Other Meds: Unknown

Lab Data: abdominal ultrasound ??Jan08 Comment: enlarged liver and milt; serum C-reactive protein ??Jan08 66 mg/l Normal Range: <10 -

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306198-2 (S) **Related reports:** 306198-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jan-2008	28-Jan-2008	12	21-Apr-2008	22-Apr-2008	--	200801072	22-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2864A	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	AHAUB225BC	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis aseptic

Symptom Text: Initial report received on 14 April 2008 from an other manufacturer, report number WAES0804USA00597. The other manufacturer obtained the report from a line listing the Company requested from the FDA, VAERS # 306198. The original reporting source was not identified. Verbatim from report. "This report was identified from a line listing obtained on requested by the Company from the FDA under the Act. A 15 year old female patient with no pertinent medical history, on 16-JAN-2008 was vaccinated IM in the right arm with the first dose of Gardasil (lot # 659653/1448U). Commitant suspect vaccine therapy included the first dose, IM in the right arm of HAVRIX (lot # AHAUB225BC), and the first dose, IM in the left arm, of ADACEL (lot # C2864AA). There was no illness at the time of vaccination. On 28-JAN-2008 the patient was hospitalized with aseptic meningitis. The cerebrospinal fluid (CSF) sample revealed a high CSF white blood count, and a high CSF protein. The CSF cultures, both bacterial and viral, were negative. Hospitalization lasted for 5 days. The outcome of the event was not specified." "28-JAN-2008: cerebrospinal fluid white cell count, high" "28-JAN-2008: cerebrospinal fluid total protein, high" "28-JAN-2008: cerebrospinal fluid culture, negative viral & bacterial." "The original reporting source was not identified. The VAERS identification # is 306198."

Other Meds:

Lab Data: "28-JAN-2008: cerebrospinal fluid white cell count, high"; "28-JAN-2008: cerebrospinal fluid total protein, high"; "28-JAN-2008: cerebrospinal fluid culture, negative viral & bacterial."

History: "None"

Prex Illness:

Prex Vax Illns:

Vaers Id: 306243-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Oct-2007	01-Jan-2008	82	03-Mar-2008	04-Mar-2008	FR	WAES0802USA05598	04-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Motor dysfunction, Pain, Paraesthesia, Sensory loss

Symptom Text: Information has been received from the health authority from the father of the patient concerning his 18 year old daughter with no medical history reported who on 11-OCT-2007 was vaccinated with a first dose of Gardasil (lot, route and site not reported). On 01-JAN-2008 the patient developed paraesthesia and was hospitalized. A MRI of the brain and cervical spine was investigated. No conspicuousness and in particular no reference to MS was detected. A hypomagnesia could also be excluded. The physician at the hospital excluded a correlation between the adverse event and the vaccine. The female was released from the hospital after three days with slightly amelioration, but without diagnose. Somedays after the release from the hospital, the paraesthesia abated but recurred some days ago. The female described her actual condition as follows: Pins and needles, numbness at the whole body, especially in arms and legs- handgloves and socks like paraesthesia, stitches in lower arms and legs were experienced cushioned. Numbness in fingers leads to detraction of the sense of touch. Feeling of coldness and wetness cannot be kept apart. Slight motor dysfunction: some movements are more exhausting than usual. Feeling of pain in different. The female is not yet recovered. Additional information is not expected. Other business partners included are: E2008-01496.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: brain - no conspicuousness and in particular no reference to MS was detected; magnetic resonance imaging Comment: cervical spine- no conspicuousness and in particular no reference to MS was detected

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 306556-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Jan-2008	16-Jan-2008	0	06-Mar-2008	07-Mar-2008	FR	WAES0802USA06162	07-Mar-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 Eyelid ptosis, IIIrd nerve paresis, Inflammation

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of paraesthesia in her hand, who on 07-FEB-2008 was vaccinated with a second dose of Gardasil. The route, lot, and site were not reported. On 16-JAN-2008 the patient experienced ptosis of the eyelid. The patient was admitted to the hospital on 25-JAN-2008. An oculomotor nerve paresis was diagnosed. An MRI showed inflammatory alterations of the oculomotor nerve. Further laboratory tests and examination were intended. At the time of the report, the patient was still hospitalized. It was report that the first vaccination with Gardasil was well tolerated. Other business partner numbers included; E2008-1578. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: inflammatory alteration of the oculomotor nerve

History: Paraesthesia hand

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: 306811-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Feb-2008	29-Feb-2008	21	11-Mar-2008	12-Mar-2008	FR	WAES0803USA00469	12-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Exophthalmos, Hyperthyroidism

Symptom Text: Information has been received from a pediatrician concerning a 14 year old female with a family history of goiter who on 08-FEB-2008 was vaccinated with her first dose of Gardasil (lot number, site and route of administration not reported). There was no concomitant medication. About 3 weeks post vaccination, on approximately 29-FEB-2008, the patient experienced hyperthyroidism with exophthalmus and diarrhoea. The patient was hospitalized on 22-FEB-2008. Laboratory findings showed increased triiodothyronine (T3) and barely measurable thyroid-stimulating hormone (TSH). At the time of reporting the patient's symptoms were ongoing. Other business partner numbers include E200801728. No further information is available.

Other Meds: None

Lab Data: Serum TSH barely measurable; Free serum triiodothyronine test increased.

History: None

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: 306913-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Dec-2007	11-Jan-2008	32	12-Mar-2008	02-Apr-2008	FR	WAES0803USA01142	02-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Burning sensation, Dissociative disorder, Muscular weakness, Sensory disturbance

Symptom Text: Information has been received from a gynecologist, concerning a 12 year old female patient with haemangioma (one in loge of left quadriceps muscle; one in medial of left femur condyle) and intermittent pain of the legs (one year), and a history of anti-borreliosis and knee effusion, who on 11-OCT-2007 was vaccinated with the first dose of GARDASIL, which was well tolerated (lot #0251U; batch NF56480). On 11-JAN-2008 the patient was hospitalized because of sensory disorder in both legs up to the knees, pain in the knees and weakness of legs. The patient was regularly seen in an orthopedic department for 1 year for her history of hemangioma (as above). A sonography of the knees, left thigh and abdomen were normal. The patient was treated symptomatically with ibuprofen and recovered completely within 2 days. Lab findings were inconspicuous and included: rheumatoid factor (RF), serum antinuclear antibodies test (ANA), serology (chlamydia, mycoplasma and borrelia), antistreptolysin (ASL) and "ASK." An ophthalmological exam was normal. The physicians assessed that the pre-existing hemangioma caused the symptoms. The patient was discharged on 15-JAN-2008. On 30-JAN-2008, she was again hospitalized because of pain in the lower legs, changing sides and resulting in a burning sensation that disappeared. She also complained about weakness in her legs. Clinical examination was normal. Routine lab findings were normal. Borrelia serology was negative. Cranial and spinal magnetic resonance imaging (MRI) were normal. An orthopedist stated that the patient complained about intermittent pain in her legs for 1 year and that she had a history of borreliosis and effusion of the knee. Cerebrospinal fluid (CSF) was normal except a discrete barrier disorder. A psychologist suspected a dissociative disorder, because of a strong psychological strain and a psychotherapy was planned. At discharge on 06-FEB-2008, the patient's neurological examination was normal, and she did not complain of pain anymore. In the reporting form dated 03-MAR-20

Other Meds: Unknown

Lab Data: diagnostic laboratory test 11?Jan08 Comment: inconspicuous; lower extremity X-ray 11?Jan08 Comment: normal; ophthalmological exam 11?Jan08 Comment: normal; diagnostic laboratory test 30?Jan08 Comment: normal; magnetic resonance imaging 30?J

History: Anti-borrelia antibody positive; Knee effusion; No reaction on previous exposure to vaccine

Prex Illness: Haemangioma; Pain of lower extremities

Prex Vax Illns:

Vaers Id: 307028-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Feb-2008	28-Feb-2008	1	13-Mar-2008	17-Mar-2008	WA		28-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Deep vein thrombosis, Dyspnoea, Oedema peripheral, Pain in extremity

Symptom Text: Right lower leg D.V.T. Shot given 2/27/08 approx 10:30 am. On 2/28/08 pt noticed ache in (R) lower leg. Worsened daily and to ER 3/21/08- Doppler confirmed RLE DVT Deep right posterior tibial vein. 3/27/08-records received for DOS 3/2-3/3/08- DC DX: Acute right lower extremity deep venous thrombosis. Admitted with C/O right lower extremity pain and swelling that started 4 days ago with swelling in right calf and some local pain which has increased. C/O shortness of breath.

Other Meds: NuvaRing; Fluoxetine 3/27/08-records received:current medications include Fluoxetine and NuvaRing.

Lab Data: Doppler lower extremity/VQ lung scan/CXR/ EKG 3/27/08-records received-Doppler showed acute deep venous thrombosis in right posterior tibial vein in the righ midcalf.

History: Allergic rhintis; Depression/Anxiety disorder NuvaRing.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 307161-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Jul-2007	25-Feb-2008	224	17-Mar-2008	18-Mar-2008	FR	WAES0803CAN00024	18-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0192U		Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Skin burning sensation

Symptom Text: Information has been received from a 26 year old female pharmacist who on 25-FEB-2008 was vaccinated with the third dose of Gardasil. On 16-JUL-2007 the patient was vaccinated with the first dose of Gardasil (Lot # 0192U/NG27430) and second dose on 27-SEP-2007. Concomitant therapy included ethinyl estradiol/norgestimate (TRI-CYCLEN). On 25-FEB-2008 the patient experienced burning hot pain in the area above the injection site on right arm and it gradually got worse. The pharmacist reported severe radiating burning pain, not being able to move her right arm forward or back enough. The pharmacist was unable to open prescription bottles or lift her right arm above her head. The pain was "initially on a scale from 3 to 4 and now was at 9." The pharmacist also reported if she didn't move her right arm then she didn't feel pain but as soon as she moved it she had shooting pain. The pharmacist mentioned that she did not have any problems with the first and second dose of Gardasil. The patient's burning hot pain in the area above the injection site and burning hot pain in the area above the injection site persisted. Burning hot pain in the area above the injection site and burning hot pain in the area above the injection site were considered to be disabling. Additional information has been requested.

Other Meds: Ethinyl estradiol/norgestimate (Unknown)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 307164-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Aug-2007	01-Jan-2008	132	17-Mar-2008	18-Mar-2008	FR	WAES0803USA01177	02-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, IVth nerve paralysis

Symptom Text: Information has been received from a ophthalmologist concerning a 16 year old female, who on 29-OCT-2007 was vaccinated IM in the upper arm with a second dose of Gardasil. Three months post vaccination the patient experienced diplopia. The patient was hospitalized from 07-FEB-2008 until 11-FEB-2008 for a neurological check-up. An idiopathic trochlear nerve paralysis was diagnosed. A cranial MRI and EEG were without findings. Borreliosis was ruled out. At the time of the report, the outcome of the patient was unknown. The first vaccination with Gardasil on 22-AUG-2007 was well tolerated. Other business partner numbers included: E200801928. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging without findings; electroencephalography without findings

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

Vaers Id: 307169-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jan-2008	23-Jan-2008	1	17-Mar-2008	18-Mar-2008	FR	WAES0803USA01328	18-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Musculoskeletal stiffness, Photophobia, Pyrexia

Symptom Text: Information has been received from a health professional concerning a 16 year old female patient who on 22-JAN-2008 was vaccinated IM with a first dose of Gardasil (batch # NE64100) (lot #655127/0575F). Eighteen hours after the vaccination on 23-JAN-2008 the patient presented fever (38.7 C), neck stiffness and photophobia for 24-36 hours. She was hospitalized. Date of the hospitalisation and duration unknown. A lumbar puncture (spinal tap) diagnostic test ruled out meningitis. No further information provided. The other business partner number includes: E2008-02211. Additional information is not available.

Other Meds: Unknown

Lab Data: spinal tap Ruled out meningitis 23?Jan08; body temp 23Jan08 38.7 C

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: 307246-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Mar-2008	06-Mar-2008	0	18-Mar-2008	26-Mar-2008	FR	WAES0803CZE00005	26-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a 19 year old female with bronchitis asthmatic and food allergy who on 06-MAR-2008 was vaccinated with Gardasil. There was no concomitant medication. On 06-MAR-2008 the patient experienced paresthesia and was hospitalized. The reporter felt that paresthesia was related to therapy with Gardasil. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Bronchitis asthmatic; Food allergy

Prex Vax Illns:

Vaers Id: 307247-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	06-Mar-2008		18-Mar-2008	19-Mar-2008	MA	WAES0803USA01616	19-Mar-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Gastrointestinal inflammation

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil. On 06-MAR-2008 after receiving Gardasil the patient was admitted to the hospital with an intestinal inflammation and (the length of the stay was unknown). Further

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 307343-1 (S) **Related reports:** 307343-2; 307343-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Mar-2008	05-Mar-2008	1	19-Mar-2008	20-Mar-2008	--	WAES0803USA01494	14-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Back pain, Chills, Fatigue, Flank pain, Hallucination, Headache, Hyperaesthesia, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning her 17 year old daughter with attention deficit disorder and an allergy to over-the-counter cold preparations, who on 04-MAR-2008 at 16:30 was vaccinated with a third dose of Gardasil. Concomitant therapy included ADDERALL TABLETS. On 05-MAR-2008, eight hours post vaccination the patient experienced a high fever, hallucinations, severe back pain, severe headache, skin sensitivity, nausea and vomiting and was hospitalized. It was reported that the patient tolerated the first and second doses of Gardasil well. At the time of the report, the patient had not recovered. No product quality complaint was involved. The high fever, hallucinations, severe back pain, severe headache, skin sensitivity, nausea and vomiting were considered to be disabling. Additional information has been requested. 4/10/2008 MR received for ER visit 3/5/2008 with DX: Primary DX: R Flank Pain. Additional DX: Fever-unknown origin. Pt presented to ER from MD's office with fever, chills, sudden onset R sided flank pain, nausea and vomiting. Pt reports fatigue and weakness as well. PE (+) for tenderness at the R CVA, fever, and pain. D/C home in improved condition

Other Meds: ADDERALL TABLETS

Lab Data: Unknown. Labs and Diagnostics: CT Abd & pelvis-no acute findings. CXR WNL. Chem WNL. LFTs WNL except Alk Phos 71. CBC WNL. UA WNL except trace ketones. Blood and UC (-).

History: No reaction on previous exposure to vaccine. PMH: Broken nose. Allergic to cough/cold meds.

Prex Illness: Attention deficit disorder; drug hypersensitivity

Prex Vax Illns:

Vaers Id: 307343-2 (S) **Related reports:** 307343-1; 307343-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Oct-2007	01-Mar-2008	123	24-Mar-2008	25-Mar-2008	DC	WAES0803USA01989	15-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal tenderness, Abnormal dreams, Back pain, Dyspnoea, Haematochezia, Hallucination, Headache, Nausea, Neurological examination abnormal, Pyrexia, Vasculitis, Visual disturbance

Symptom Text: Information has been received from a physician and a physician's assistant concerning a 17 year old female with attention deficient disorder, and a family history of Crohn's disease, and celiac disease (mother), who on 30-AUG-2007 was vaccinated with a first dose of Gardasil. On 30-OCT-2007 the patient was vaccinated with a second dose of Gardasil. The first two doses were well tolerated and without incident. On 04-MAR-2008 at approximately 16:30 the patient was vaccinated with a third dose of Gardasil. Concomitant therapy included ADDERALL TABLETS. Subsequently, the patient experienced hallucinations, visual disturbance, and nausea. On 05-MAR-2008 at approximately 01:30 the patient experienced awoke from a bizarre dream with a fever of 102F, severe low back pain, and some shortness of breath. The patient has been seen in the emergency room on four occasions in one week, mainly for intractable low back pain. The patient was treated with OXYCONTIN and PERCOCET. The shortness of breath resolved, there was no clear accounting of the fever. The patient also experienced a headache. The patient had an extensive work-up including blood tests, multiple scans, and a lumbar puncture. It was reported that the headache predated the lumbar puncture, though it was hard to distinguish from a spinal headache according to the physician. It was reported that none of the tests have been revealing. On 12-MAR-2008 the patient's physical exam was notable for some abdominal tenderness, meningeal signs, and heme positive stool. The physician believed the patient to have vasculitis and initiated a high dose of steroids, (prednisone, 60mg). At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: ADDERALL TABLETS

Lab Data: diagnostic laboratory, 03/??/08, blood test-not revealing; diagnostic radiology, 03/??/08, multiple scans-not revealing; spinal tap, 03/??/08, not revealing; physical examination, 03/12/08, some abdominal tenderness, meningeal signs, and he

History: The first two doses were well tolerated and without incident.

Prex Illness: Attention deficit disorder

Prex Vax Illns:

Vaers Id: 307627-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Feb-2008	03-Mar-2008	27	21-Mar-2008	24-Mar-2008	DE	WAES0803USA02393	24-Mar-2008

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Fatigue, Hyperhidrosis, Splenomegaly

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 05-FEB-2008 was vaccinated with Gardasil (lot number not provided). On 03-MAR-2008 the patient experienced extreme fatigue, severe stomach pains and breaking out in sweat. The patient also stated "the pain is so extreme, she can not go to school." The patient's extreme fatigue and severe stomach pains and breaking out in sweat persisted. On an unspecified date, the patient had a mononucleosis test performed-result was negative. On an unspecified date an ultrasound was also performed, results indicated that the patients spleen was slightly enlarged. Extreme fatigue, severe stomach pains and breaking out in sweat were considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound slightly enlarged spleen; serum Epstein-Barr negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 307633-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Dec-2007	01-Jan-2008	12	21-Mar-2008	24-Mar-2008	FR	WAES0803USA02581	24-Mar-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 Hypersomnia, Somnolence

Symptom Text: Information has been received from an internist concerning a 17 year old female with von willebrand's disease who on 20-DEC-2007 was vaccinated intramuscularly into the upper arm with a first dose of Gardasil (batch NG09920, lot 0482U). In January 2008, exact date not reported, the patient became somnolent and fell asleep very often. The patient was hospitalized for diagnostics. Laboratory evaluations revealed EEG, cranial MRI, and lumbar puncture, CSF were normal. A second dose of Gardasil, (batch "NG020170") was administered on 31-JAN-2008. Symptoms were ongoing at the time of reporting. Other business partner numbers include E2008-02198. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography ??Jan07 Comment: normal; magnetic resonance imaging ??Jan07 Comment: Cranial - normal; spinal tap ??Jan07 Comment: CSF normal

History:

Prex Illness: Von Willebrand's disease

Prex Vax Illns:

Vaers Id: 307668-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jan-2008	24-Feb-2008	33	21-Mar-2008	24-Mar-2008	FR	WAES0803USA02586	24-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis

Symptom Text: Information has been received from a health authority concerning a female (age unknown), who on 22-JAN-2008 was vaccinated IM with a first dose of GARDASDIL (Lot# 0467U; Batch# NG20160). Concomitant therapy included hormonal contraceptives (unspecified) for "systemic use." On 24-FEB-2008 the patient experienced purulent meningitis. The patient was hospitalized on an unspecified date. At the time of the report the patient had not recovered. The reporting physician assessed the relation to the vaccine as unlikely. Other business partner numbers included: E2008-02268. No further information was provided.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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: 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: 307892-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jan-2008	08-Feb-2008	14	24-Mar-2008	25-Mar-2008	FR	WAES0803USA03243	25-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Appendicitis, Gastrointestinal disorder, Muscle spasms, Tremor

Symptom Text: Information has been received from a health authority, concerning a 15 year old female patient who was healthy with no allergies or headache tendencies, who on 26-NOV-2007 was vaccinated with the first dose of Gardasil (lot # not reported). About 2 months after vaccination, on 22-JAN-2008 the patient developed appendicitis, intestinal disorders and muscle cramps and was hospitalized (date of hospitalization not reported). On 25-JAN-2008, the patient was vaccinated with the second dose of Gardasil (lot # 1340F; batch NF15660). About 2 weeks after the second dose, she developed muscle cramps related to a visit at a disco. The room was very smoky and there was a sharp flicker of light when the cramps started. She was shaking in both arms and the abdomen for a minute. All the time she was conscious, had no passage of urine or feces. She had not hyperventilated. The event after the second dose was reported as non-serious. The girl said that she had not drank alcohol or used any drugs. Neurological status a couple of weeks ago did not show anything abnormal. The outcome of the intestinal disorders is recovered, but the outcome of the muscle cramps was unknown, and outcome of appendicitis was not specified, at the time of reporting. This case is closed. Other business partner numbers include: E2008-02382; reference 080647.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 308074-1 (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	19-Jan-2008	3	25-Mar-2008	26-Mar-2008	FR	WAES0803USA03247	26-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1341F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Headache, Syncope, Vertigo

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with evidence of a defective position of the patient's jaw who on 16-JAN-2008, was vaccinated IM into the deltoid muscle with a first dose of Gardasil (Lot# 1341F; Batch# NF13760). On 19-JAN-2008, three days after the vaccination, the patient complained of a severe headache, vertigo, balance disorder and collapsed once. The patient was hospitalized for four days in the neurological department. All investigations including electroencephalography (EEG) and ears, nose, and throat examination (ENT) were without pathologies. Migraine was ruled out also. Further investigations are ongoing. It was reported that there was evidence of a defective position of the patient's jaw. At the time of this report, the symptoms were improving. Other business partners numbers include: E200802430. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography 19?Jan08 Comment: without pathologies, migraine ruled out; ears, nose, and throat examination 19?Jan08 Comment: without pathologies

History:

Prex Illness: Jaw malformation

Prex Vax Illns:

Vaers Id: 308201-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Feb-2008	Unknown		26-Mar-2008	27-Mar-2008	FR	WAES0803USA03250	02-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1358F	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Basedows disease, Hyperthyroidism

Symptom Text: Information has been received from a health authority via a physician concerning a 17 year old female patient who on 09-AUG-2007 was vaccinated IM with a first dose of GARDASIL (batch # NF23330) (lot #1518F). On 13-OCT-2007 she was vaccinated IM with a second dose of GARDASIL (batch # NF56480) (lot # 0233U) and on 19-FEB-2008 she received IM her third dose of GARDASIL (batch # NG01520) (lot # 1358F). In February 2008 the patient experienced Basedow's disease. An autoimmune thyreoditis was ruled out. The patient was hospitalised on an unknown date. Laboratory tests serum thyroid-stimulating hormone test (FT4), serum antithyroid antimicrosomal antibody test (MAK), serum antithyroglobulin antibody test (TRAK) and thyroid scan were carried out. No values reported. At the time of this report the outcome was unknown. It was reported that patient tolerated the first injection well. This is one of several reports from the same source. The other business partner number included: E200802490. No other information is available.

Other Meds: Unknown

Lab Data: thyroid radionuclear scan ??Feb08 Not reported: Comment: Result not reported; diagnostic laboratory test ??Feb08 Comment: Autoimmune thyreoditis ruled out; serum antithyroglobulin antibody ??Feb08 Comment: "TRAK" test (no value reported); s

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 308202-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2007	01-Feb-2008	75	26-Mar-2008	27-Mar-2008	FR	WAES0803USA03249	02-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Basedows disease, Hyperthyroidism

Symptom Text: Information has been received from a health authority (Reference no. PE12008002456) concerning a 15 year old female patient who on 28-AUG-2007 was vaccinated IM with a first dose of GARDASIL (batch # NE24240) (lot # 654884/0902F). On 18-NOV-2007 the she received IM her second dose of GARDASIL (lot # not reported). In February 2008 the patient experienced Basedow's disease. An autoimmune thyreoditis was ruled out. The patient was hospitalised on an unknown date. Laboratory tests serum thyroid-stimulating hormone test (FT4), serum thyroid-stimulating hormone test (TSH), serum antithyroid antimicrosomal antibody test (MAX), serum antithyroglobulin antibody test (TRAK) and thyroid scan carried out. No values were reported for these tests. At the time of this report the outcome was unknown by the reporter. It was reported that the patient tolerated the first injection well. This is one of several received from the same source. The other business partner number included: E200802488. No other information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test ??Feb08: Autoimmune thyreoditis ruled out; thyroid radionuclear scan ??Feb08: value not reported; TSH ??Feb08: value not reported; serum antithyroglobulin antibody ??Feb08: "TRAK" (no value reported); serum antith

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 308330-1 (S) **Related reports:** 308330-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jan-2008	02-Feb-2008	7	27-Mar-2008	28-Mar-2008	NJ	WAES0803USA03845	04-Jun-2008

VAX Detail:

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Balance disorder, Extensor plantar response, Insomnia, Muscular weakness, Neurological examination abnormal, Paraesthesia, Positive Rombergism, Urinary incontinence, Viral infection

Symptom Text: Information has been received from a physician, concerning a white female student (age not reported), with no pertinent medical history, who on 23-NOV-2007 was vaccinated with the first dose, and on 26-JAN-2008 was vaccinated, IM, with the second dose of GARDASIL (lot #659653/1448U). The physician noted that on 06-NOV-2007, the patient had been vaccinated with a dose of HAVRIX and a dose of MENACTRA. There was no illness at the time of vaccination. On 02-FEB-2008 the patient experienced paresthesias of both feet and up her legs, with some weakness, that continued through the month. On 26-FEB-2008 she experienced "pins and needles" of her arms and shoulders. The patient visited the physician, and on an unknown date, diagnostic testing included a magnetic resonance imaging (MRI) of the head and spine, a complete blood count (CBC), blood chemistries and a thyroid panel, all with normal results. At the time of this report, the outcome of the events was not recovered. The physician considered the events to be serious as disabling or incapacitating. Additional information has been requested. 6/3/08-records received-seen on 2/6/08 with C/O chronic back pain (pine and needles) both legs, hip and ankle. Trouble sleeping. Began on Monday. Feels unbalanced when standing. Urinary incontinence. PE Babinski decreased on right. Unable to stand on tiptoes. Romberg wobbly. Reflexes normal. Sensation in left toe dull. 4/30/08 symptoms continue but improving now intermittent. Neurologist: post viral syndrome. Flu vaccine administered in November along with Gardasil. Meningitis vaccine in November.

Other Meds:

Lab Data: magnetic resonance 02?/??/08 - head and spine normal; complete blood cell 02?/??/08 - normal; blood chemistry 02?/??/08 - normal; thyroid function test 02?/??/08 - normal 6/3/08-records received-MRI thoracic spine, mild degenerative disc c

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 308333-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Feb-2008	04-Feb-2008	2	27-Mar-2008	28-Mar-2008	FR	WAES0803USA03412	28-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, No reaction on previous exposure to drug, Pharyngeal oedema, Urticaria

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with effusive psychological behavior leading to history, who on 02-FEB-2008 was vaccinated with the first dose of Gardasil. On 04-FEB-2008 (reported as 48-hours post vaccination), the patient developed severe breathing difficulties, thoracic pain, pharynx edema and urticaria reaction leading to hospitalization. The reporting physician received this information through the patient's mother. At the time of this report the patient recovered. It was reported that the patient received "past vaccinations that were well tolerated." Other business partner numbers include: E200802665. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Psychological disorder NOS

Prex Vax Illns:

Vaers Id: 308368-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Feb-2008	02-Mar-2008	3	27-Mar-2008	28-Mar-2008	MD		31-Mar-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB200BA	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Acute sinusitis, Gastritis, Headache, Insomnia, Meningism, Murphys sign positive, Musculoskeletal stiffness, Myalgia, Nasal congestion, Nausea, Neck pain, Petechiae, Pharyngolaryngeal pain, Pyrexia, Rash, Respiratory syncytial virus infection, Tenderness, Viral infection, Vomiting

Symptom Text: Pt had N/V, fever, nasal congestion, sore throat, decreased sleep, facial rash, HA, myalgia. No relieve w/ OTC Benadryl. Exam at ED found neck pain w/ flexion consistent with meningismus and RUA tenderness, (+) Murphy sign. Admitted to hospital, IV fluids and IV antibiotics. Discharged home in improving condition. 03/28/2008 MR received with VAERS report for DOS 3/2-4/2008 with D/C DX: Acute sinusitis/viral syndrome (respiratory syncytial virus) and myalgias possibly due to immunizations that she received last week. Gastritis. Pt presented to ER with fever, sore throat, vomiting and facial rash. Pt with c/o stiff neck and h/a. PE (+) for facial petechiae, neck pain c/w meningismus and RUQ tenderness. Txd with abx and IVF and d/c improved 3/4/08.

Other Meds: Imitrex; OCP

Lab Data: WBC 29.1; RSV (+), LFT's - nl, CSF nl, CSF CX (-); Monospot (-); Strep CX (-); Flu (-); HIV (-); abdominal u/s - nl; head CT - nl except pansinusitis; UA nl; UCX (-); Preg (-); EBV IgM (-); EBV IgG (+). Labs and Diagnostics: CBC with WBCs

History: asthma; migraine headaches; Irritable Bowel Syndrome. PMH: asthma, pneumonia, migraine h/a, IBS, alcohol use. NKDA.

Prex Illness: chronic diarrhea/IBS

Prex Vax Illns:

Vaers Id: 308667-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Feb-2008	Unknown		01-Apr-2008	02-Apr-2008	NY	WAES0803USA04427	02-Apr-2008

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Erythema nodosum, Pain, Rash

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with a penicillin allergy, who on 20-FEB-2008 ("five weeks ago"), was vaccinated with the first dose of GARDASIL (lot # not reported). In March 2008, 3 to 4 weeks after the vaccination, the patient developed a rash. The rash was very painful and was confirmed by biopsy as erythema nodosum. At the time of this report, the patient had not recovered. The physician felt that erythema nodosum which was very painful, was considered to be disabling. Additional information has been requested.

Other Meds:

Lab Data: biopsy, 03/??/08, erythema nodosum

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 308817-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Jan-2008	04-Jan-2008	0	03-Apr-2008	04-Apr-2008	FR	WAES0802USA06416	07-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311U	0	Left arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest pain, Ear discomfort, Fall, Fatigue, Hyperhidrosis, Hypotension, Injection site nodule, Malaise, Muscle spasms, Muscular weakness, Myalgia, Nystagmus, Pain, Tremor

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of adenoidectomy, tonsillectomy and immunization (up to date) who on 04-JAN-2008 was vaccinated SC into the left arm with a first dose of Gardasil (Lot# 0311U; Batch#NG14100). On 02-FEB-2008 the patient experienced myalgia in the arms, with a slight decrease in muscular strength. The physician also noticed the presence of a nodule at the site of injection. Work-up was performed and the results were completely normal. Follow-up information from the physician indicated that on 02-FEB-2008, the patient experienced muscle pain and decrease in muscular strength that was considered moderate and not serious. The patient first experienced the troublesome myalgia in the biceps of the left arm and pain was subsequently felt in the right arm, with a decrease in muscular strength without a clear motor deficit. Complete blood and platelet counts were normal, with no leukocytosis. No inflammation was found and sedimentation rate was 5 mm in the first hour; CRP was less than 5. The level of muscular enzymes was normal, as well as creatine kinase and transaminases. As of 29-FEB-2008, muscular discomfort of lower limbs persisted in an alternate manner and also in one of the hips. The patient received unspecified symptomatic treatment. On 25-MAR-2008, it was reported that the patient had been hospitalized from 02-MAR-2008 to 08-MAR-2008 due to muscle pain in the left upper limb, significant asthenia and an episode of malaise (previously reported that patient was not hospitalized and there were no serious criteria). The patient was reported to have fallen from her height while she was walking in her bedroom, with tremor but without loss of consciousness; described by the patient's parent as a fit of spasmophilia. The fit lasted a few seconds and subsequently the patient was very tired, thus inducing hospitalization. On arrival, her general condition was more or less maintained and hemodynamic constants were steady. Neurological examination

Other Meds: Unknown

Lab Data: physical examination ??Feb08 normal Comment: "work-up performed"; neurological examination ??Mar08 Comment: "very slight nystagmus on the left side, very intermittent and changing"; tilt test ??Mar08 positive; neurological examination ??Mar

History: Adenoidectomy; Tonsillectomy; Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 308871-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Jan-2008	18-Jan-2008	7	03-Apr-2008	04-Apr-2008	FR	WAES0804USA00530	07-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis, Malaise, No reaction on previous exposure to drug, Pyrexia

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female, who on 11-JAN-2008 was vaccinated IM in the upper arm with a third dose of GARDASIL (Lot# 0352U; Batch# NG00320). On 18-JAN-2008 the patient experienced idiopathic peripheral facial paresis. The patient was admitted to a children's hospital from 19-JAN-2008. Routine blood tests in serum including CRP and CSF values were within normal range. No information regarding infectious serology. The diagnosis was "idiopathic peripheral facial paresis right." The patient was treated with CORNEREGEL on her right eye and was discharged the next day. The outcome of the patient was reported as "recovered." The overall duration of the symptoms was not reported. The first dose of GARDASIL (Lot# 1341F; Batch# NF12410) administered on 20-APR-2007 was well tolerated. After the second dose of GARDASIL (Lot# 655101/0513F; Batch# NE35170) administered on 15-JUN-2007 the patient experienced malaise and fever. Other business partner numbers included: E2008-02603. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test 19Jan08: blood test in serum CRP and CSF within normal range

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 308886-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	22-Jan-2008	14-Feb-2008	23	04-Apr-2008	07-Apr-2008	PA	WAES0803USA03514	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autoimmune disorder, Demyelination, Eye pain, Gait disturbance, Hypoaesthesia, Inflammation, Keratitis, Neurological symptom, Paraesthesia, Visual acuity reduced

Symptom Text: Initial and follow-up information has been received from a physician concerning a 20 year old female student with allergies to amoxicillin, nickel, silver, and gold, who, on 22-JAN-2008 was vaccinated in the left deltoid with her first dose of Gardasil (lot# 659657/1487U). There were no illnesses at the time of the vaccination. Subsequently the patient experienced neurological symptoms and numbness down her arm 2 weeks after receiving the vaccine. On 14-FEB-2008 the patient experienced a sudden onset of decreased vision in her right eye that persisted. The patient was referred to a neurologist. An magnetic resonance imaging (MRI) was performed and was consistent with demyelinating disease. A lumbar puncture was performed and was consistent with inflammation. A computed axial tomography scan (CT) showed white spots on her brain, indicative of an autoimmune reaction. The patient was diagnosed with acute central nervous system demyelinating type inflammatory disease, three weeks after her first dose of Gardasil (Lot# 659657/1487U). At the time of the report, the patient had not recovered. The physician considered the acute central nervous system demyelinating type inflammatory disease, and decreased vision in the right eye to be disabling. This is one of two reports from the same source. Additional information is not expected. 4/28/2008 Neuro eval of 4/21/2008 received. Pt reports onset of decreased vision in the R eye which worsened over the following few days. Some pain reported when looking to extreme right or left. Seen for ophth consult 3/25/08 with DX: Acute viral keratoconjunctivitis. Seen in F/U by Neuro 4/2/08 with c/o tingling in the R upper and lower extremities and gait disturbance affecting the R lower extremity. Improvement noted with medrol dose pack. DX: Demyelinating disease NOS, either due to recent Gardasil vax or MS

Other Meds: MOBIC, 15 mg

Lab Data: computed axial 02/08/08 - white spots on brain; magnetic resonance 02/08/08 - brain-consistent with demyelinating disease; spinal tap 02/08/08 - consistent with inflammation; diagnostic laboratory 02/08/08. Labs and Diagnostics: Brain MRI

History: PMH: migraine headaches. MVA 9/30/07. dysmenorrhea, kidney stone 12/2007. Allergy to Amoxicillin.

Prex Illness: Penicillin allergy; Nickel sensitivity; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 308890-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jan-2008	24-Mar-2008	61	04-Apr-2008	07-Apr-2008	FR	WAES0803USA04717	07-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Haemorrhagic ovarian cyst

Symptom Text: Information has been received from a gynaecologist concerning a 17 year old female with no relevant medical history who on 23-JAN-2008 was vaccinated with a first dose of Gardasil (batch number, route and site was not reported). On 24-MAR-2008 i.e. 2 months after vaccination the patient developed haemorrhagic ovarian cyst and was hospitalized for 2 days. The patient was discharged without any specific measure. Subsequently, the patient recovered from haemorrhagic ovarian cyst a few days later and returned to school. No further information was available. Other business partners included are: E2008-02856.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 308892-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Feb-2008	20-Feb-2008	13	04-Apr-2008	07-Apr-2008	FR	WAES0804USA00349	07-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Herpes zoster, Incorrect route of drug administration, Multiple sclerosis, Optic neuritis retrobulbar

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female with a history of relapsing upper respiratory tract infection since 2 years old, who on 07-FEB-2008 was vaccinated SC in the left upper arm with a third dose of Gardasil (Lot# 0352U; Batch# NG00320). Concomitant therapy included hormonal contraceptives (unspecified) "for systemic use." On 20-FEB-2008 the patient experienced retrobulbar neuritis. On 23-FEB-2008 the patient was diagnosed with multiple sclerosis. On 28-FEB-2008 the patient developed herpes zoster from which she recovered on an unknown date. The patient was hospitalized on an unknown date and was treated with cortisone. The duration and outcome of multiple sclerosis with retrobulbar neuritis were unknown. It was reported that the previous two vaccinations with Gardasil on 04-MAY-2007 (Lot# 1340F; Batch#NF14740) and on 10-AUG-2007 (Lot# 1475F; NF37120), administered SC into the left upper arm were well tolerated. The general practitioner considered the multiple sclerosis with retrobulbar neuritis, and herpes zoster to be other important medical events. Other business partner numbers included: E2008-02646. Additional information is not expected.

Other Meds: hormonal contraceptive (unspecified), Unk - Unk

Lab Data: Unknown

History: No reaction on previous exposure to vaccine; Upper respiratory tract infection

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: 308999-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jan-2008	02-Mar-2008	34	07-Apr-2008	08-Apr-2008	FR	WAES0804USA00996	08-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female with no reported medical history who on 28-JAN-2008 was vaccinated with her first dose of Gardasil (Lot #0482U;Batch #NG09910) intramuscularly in the left deltoid. Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. On 02-MAR-2008 the patient developed a pulmonary embolism and was hospitalized on an unknown date. No cause of origin was found. Medication with MACUMAR was started. A hospital report is expected. At the time of reporting the patient's outcome was unknown. Other business partner numbers include E200802640. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **309076-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jan-2008	01-Mar-2008	60	08-Apr-2008	09-Apr-2008	FR	WAES0804USA00446	09-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 Hypoaesthesia

Symptom Text: Information has been received from Health Authority agency (reference number PEI2008002877) concerning a 24 year old female with who on an unspecified day in November 2007 was vaccinated with her first dose of Gardasil (lot number, route and site of administration not reported) and tolerated it well. On an unspecified date in January 2008 the patient received her second dose of Gardasil (lot number, route and site of administration not reported). There was no concomitant medication. On an unspecified date in March 2008 the patient experienced a left-sided hypaesthesia. The patient was hospitalized on an unspecified date. Labs were performed on an unspecified date and a magnetic resonance imaging and "liquor" were without findings, and serum antinuclear antibodies test was 1:1024. At the time of reporting symptoms were slightly improving. Other business partner numbers include E200802771. Additional information is not expected.

Other Meds: None

Lab Data: magnetic resonance imaging Comment: without findings; diagnostic laboratory test Comment: "liquor" - without findings; serum ANA 1:1024

History: None

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: 309170-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Mar-2008	12-Mar-2008	1	09-Apr-2008	10-Apr-2008	FR	WAES0804USA00987	10-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 Abdominal pain, Abdominal pain upper, Eye pain, Insomnia, Palpitations, Torticollis

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female patient with a family history of hypertension and renal insufficiency for older sister who on 11-MAR-2008 was vaccinated with a second dose of GARDASIL (route and site not reported). On 12-MAR-2008 the patient complained of sleeplessness, abdominal and stomach pain. She experienced "palpitations" (heart rate 90/minute, blood pressure of 140/80 mm/Hg). An inpatient cardiological examination, magnetic resonance imaging (MRI) and laboratory parameters showed no pathologies. On 18-MAR-2008, the patient experienced torticollis and complained of eye pain. The patient was in a critical family situation (parents divorcing). She was treated with TAVOR, ZOPICLOEN and tetrazepam. Psychotherapy was started. At the time of this report symptoms were still ongoing. The other business partner number included: E2008-02902. Additional information is not available.

Other Meds: Unknown

Lab Data: blood pressure measurement 12Mar08 140/80 mm/Hg; magnetic resonance imaging 12Mar08 Comment: No pathologies; diagnostic laboratory test 12Mar08 Comment: Cardiological examination showed no pathologies; total heartbeat count 12Mar08 90/minut

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 309171-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jan-2008	24-Jan-2008	0	09-Apr-2008	10-Apr-2008	FR	WAES0804USA00990	10-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0277U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Chills, Cystitis haemorrhagic, Headache, Nausea, Pyrexia

Symptom Text: Information has been received from a consumer and was confirmed by a gynaecologist concerning an 18 year old female patient with a family history of headache who on 24-JAN-2008 was vaccinated into left upper arm with a first dose of Gardasil (batch # NG00020) (lot # 0277U). The same day the patient complained of headache and nausea. On an unspecified date in March 2008 blood sample was taken and showed increased serum C-reactive protein (up to 240 mg/l) and increased blood sedimentation (value not reported). The patient was hospitalized from 20-MAR-2008 till 25-MAR-2008. Haemorrhagic cystitis with fever and chills was diagnosed. She was treated with penicillin (unspecified). At the time of reporting the patient had recovered except for back pain in kidney area, which started on an unknown date. The other business partner number included: E2008-02928. Additional information is not available.

Other Meds: Unknown

Lab Data: serum C-reactive protein ??Mar08 240 mg/l; erythrocyte sedimentation rate ??Mar08 Increased

History: Unknown

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: 309312-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	09-Feb-2008	09-Feb-2008	0	11-Apr-2008	14-Apr-2008	FR	WAES0803PHL00007	14-Apr-2008

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Drug exposure during pregnancy, Haemorrhage, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 30 year old female with no history of previous pregnancy, stillbirths or miscarriage, who on 09-FEB-2008 was vaccinated with her first dose of GARDASIL. Subsequently, she became pregnant. Date of last menstrual period is 20-JAN-2008 and estimated date of delivery is on 26-OCT-2008. There were no concomitant medications or diseases at the time of vaccination. Vaccination schedule will be interrupted until infant is delivered. On approximately 14-MAR-2008, the patient experienced bleeding. She was not able to report for work on that day because she was required complete bed rest. Causality of bleeding is unknown. Additional information regarding the event has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 20Jan08)

Prex Vax Illns:

Vaers Id: 309320-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Feb-2008	Unknown		11-Apr-2008	14-Apr-2008	FR	WAES0804USA01500	14-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eye disorder, Hemiplegia

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no medical history reported who on 21-FEB-2008 was vaccinated intramuscularly into the left upper arm with a third dose of Gardasil. Subsequently, on an unknown date the patient experienced hemiplegia and complained about eye disorder. The patient was admitted to the hospital. It was reported that symptoms were ongoing at the time of reporting. Other business partner numbers include: E200802994. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 309410-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Jan-2008	06-Feb-2008	16	14-Apr-2008	15-Apr-2008	FR	WAES0804USA01917	15-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eye haemorrhage, Eye pain, Optic neuritis retrobulbar, Papilloedema, Visual acuity reduced

Symptom Text: Information has been received from a health authority concerning a 16 year old female patient with diabetes mellitus insulin-dependent (for eight years) and asthma who on 21-DEC-2007 and 21-JAN-2008 was vaccinated intramuscularly with the first and second doses of Gardasil, respectively. Concomitant therapy included LANTUS, NOVORAPID and SYMBICORT. On approximately 06-FEB-2008, reported as "In early February, 15 days before 21-FEB-2008," the patient experienced a reduction of her visual acuity with peri-orbital pain in the right eye, which subsequently resolved. On 21-FEB-2008 the patient was hospitalized due to decreased visual acuity of the right eye. Retrobulbar optic neuropathy was diagnosed. Examination of the fundus oculi found significant papilloedema of the right eye. On 22-FEB-2008, lung x-ray was unremarkable; the patient had glycosylated hemoglobin level of 11.7%, serum C reactive protein was less than 5 and normal electrolyteogram. Visual acuity was measured by movements of the hand on the right side. Anterior segment was normal; intraocular pressure was normal; fundus oculi revealed papilloedema, 2 slight "flame-like" peripapillary haemorrhages but no macular oedema and no hyalitis. Contralateral examination found visual acuity of 6/10 P2, a normal anterior segment and normal intraocular pressure. Fundus oculi was normal. No sign of diabetic retinopathy nor papilloedema. Fluorescein angiography found slight delay in peripapillary choroidal filling of the right eye. Visual evoked potentials were completely destructured on the right and normal on the left. The suggested diagnosis was retrobulbar optic neuropathy of the right eye. Differential diagnosis was suggested given the patient's history of ill-balanced diabetes, assessment of cardiovascular risk factors, of acute anterior ischemic optic neuropathy and search for infectious or inflammatory papillitis. Brain MRI of 22-FEB-2008 found asymmetric signal between both optic nerves with T2 hypersignal on the right of the optic nerve that

Other Meds: LANTUS, Unk - Unk; NOVORAPID, Unk - Unk; SYMBICORT, Unk - Unk

Lab Data: angiography, ??Feb08, slight delay in peripapillary choroidal filling of the right eye; visual evoked potential, ??Feb08, destructured on right; normal on left; chest computer axial tomography, ??Feb08, normal; ultrasound, ??Feb08, heart -

History:

Prex Illness: Diabetes mellitus insulin-dependent; Asthma

Prex Vax Illns:

Vaers Id: 309414-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jan-2008	21-Jan-2008	14	14-Apr-2008	15-Apr-2008	FR	WAES0804USA01217	15-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 Asthenia, Headache, Meningism, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 07-JAN-2008 was vaccinated with the second dose of GARDASIL. On approximately 21-JAN-2008, "about two-three weeks post vaccination," the patient complained of severe headache, nausea, vomiting and asthenia. Tentative diagnosis of meningeal irritation was established. Because of ongoing symptoms the patient was hospitalized on 02-APR-2008 for check up. The patient received treatment with ibuprofen and dipyrone (METAMIZOLE). It was also reported that the previous vaccination with GARDASIL was well tolerated. Other business partner numbers include: E200802991. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 309417-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2008	02-Apr-2008	1	14-Apr-2008	15-Apr-2008	FR	WAES0804USA02122	15-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG34780	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a paediatrician concerning a 14 year old female, who on 01-APR-2008 was vaccinated IM into the left upper arm with a first dose of GARDASIL (Batch# NG34780). On 02-APR-2008 the patient experienced paraesthesia in the palm of her left hand, left fingers without thumb, left dorsal lower arm, and left foot. The patient was hospitalized on 04-APR-2008. At the time of the report, the patient's symptoms were improving. other business partner numbers included: E200803231. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

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: 309502-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Jan-2008	13-Mar-2008	51	15-Apr-2008	16-Apr-2008	FR	WAES0804USA02158	16-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Leukoencephalomyelitis

Symptom Text: Information has been received from a health authority (PEI2002008003461) concerning a 15 year old female, who on 22-JAN-2008 was vaccinated IM in the right upper arm with a first dose of Gardasil (Batch# NS58150). Since the beginning of February the patient complained about a headache, which was ongoing at the time of the report. On 13-MAR-2008 suspicion of disseminated encephalomyelitis was diagnosed. The patient was hospitalized and several tests were made (results not reported). It was reported that viral meningitis, borreliosis, and multiple sclerosis were ruled out. At the time of the report, the patient's symptoms were ongoing. It was reported that previous unspecified vaccinations were well tolerated. Other business partner numbers included: E2008-03156. Additional information is not available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, viral meningitis, borreliosis, and MS were ruled out

History: Unknown

Prex Illness:

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: 309586-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Nov-2007	01-Feb-2008	71	16-Apr-2008	17-Apr-2008	NE	WAES0804USA02231	30-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1265U	0	Unknown	Intramuscular	
FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Bronchospasm, Diarrhoea, Dizziness, Fatigue, Flank pain, Flushing, Inflammation of wound, Nausea, Pallor, Pyrexia, Renal disorder, Syncope, Vomiting

Symptom Text: Information has been received from a physician, concerning a 14 year old female with no pertinent medical history, who on 22-NOV-2007 was vaccinated IM with the first dose, 0.5 ml, of GARDASIL (lot # 659435/1265U). Concomitant therapy included a dose of influenza virus vaccine (manufacturer unspecified). On 11-JAN-2008, the patient had a physical, and had no symptoms. On 15-FEB-2008, she was seen in the office by another physician, with complaints of 2 weeks (onset 01-FEB-2008) of vomiting, diarrhea, low grade fevers and abdominal pain; the reporting physician also noted the patient had tiredness, and fainting spells. On 19-FEB-2008, an ultrasound of the abdomen and upper right quadrant to rule out gallstones, was negative. A computed axial tomography (CAT) scan to rule out a cyst. A complete blood count (CBC), and a urinalysis were normal. A laparoscopy of the pelvis was also normal. On 01-MAR-2008, the patient was hospitalized for severe abdominal pain and vomiting, and also complained of nausea and diarrhea. At discharge, on 07-MAR-2008, she was diagnosed with increased blood pressure, and was started on therapy with propanolol (not specified). An ultrasound indicated that both kidneys were enlarged. Although the CBC was normal, IV ROCEPHIN was started as a precautionary measure, and the patient was discharged on SUPRAX. On 10-MAR-2008 the patient was seen by the reporting physician and normal blood pressure, tender right and left flanks, and "on and off" flushing of the face. On 12-MAR-2008, she was seen again and flushing of the face was present, with blood pressure of 140/90 mmHg; a urine culture was negative. The patient was also seen by a nephrologist (date not specified), and "everything was normal, including blood pressure of 125/82." On 28-MAR-2008 the patient was lightheaded with a fever, and the wound from the laparoscopy was found to be infected; AUGMENTIN was initiated. On 02-APR-2008, the patient was pale and was admitted to the hospital with severe abdominal pain of the left flank with persisten

Other Meds:

Lab Data: abdominal ultrasound 02/19/08 - negative; computed axial 02/19/08 - negative; diagnostic urinalysis 02/19/08 - normal; renal ultrasound 03/07?/08 - both kidneys enlarged; blood pressure 03/12/08 140/90 mmHg; pelvic ultrasound 04/02?/08 - no

History: Unknown 4/28/08-records received- Previously admitted in early February, CAT scan, endoscopy, colonoscopy and biopsies were negative. PMH:sinus infections.

Prex Illness:

Prex Vax Illns:

Vaers Id: 309588-1 (S) **Related reports:** 309588-2; 309588-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Mar-2008	01-Apr-2008	1	16-Apr-2008	17-Apr-2008	--	WAES0804USA02557	02-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
DTAP	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site erythema, Injection site irritation, Injection site pain, Injection site streaking, Injection site warmth, Pain in extremity, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with allergic reaction to most antibiotics (products not reported) and a history of "deflux surgery for her kidneys" who in November 2007, was vaccinated with the first dose of GARDASIL, injection, single dose and concomitantly with meningococcal vaccine (unspecified). In January 2008, the patient was vaccinated with the second dose of GARDASIL, injection, single dose, left arm and concomitantly with varicella virus vaccine live (MSD). On 31-MAR-2008, the patient was vaccinated with the third dose of GARDASIL, injection, single dose, right arm and concomitantly with diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid, injection, left arm. In November 2007 following the first dose GARDASIL, the patient experienced a burning sensation while GARDASIL was being administered and had a little tenderness around the injection site. In January 2008 following the second dose GARDASIL, the patient experienced burning sensation while GARDASIL was administered and had a little tenderness around the injection site. Approximatley two weeks after receiving the second dose of GARDASIL, the same arm where she was given GARDASIL (left arm), the patient began shaking uncontrollably and she had severe pain in this arm. The patient was taken to the hospital where she was admitted and stayed for 24 hours. X-rays, EEG, and blood tests were performed which determined that she had not had any seizures. On 31-MAR-2008 following the third dose of GARDASIL, the patient's right arm turned bright red and was also hot to the touch. On 01-APR-2008 one day later, the patient developed a huge welt on her right arm which persisted for 72 hours. Subsequently on unspecified dates, the patient recovered from the events. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: electroencephalograpy; diagnostic laboratory; X-ray

History: Surgery

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 309795-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Feb-2008	23-Feb-2008	15	17-Apr-2008	18-Apr-2008	KY	WAES0804USA01880	18-Apr-2008

VAX Detail:

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Cough, Hypoaesthesia, Paraesthesia, Pharyngolaryngeal pain, Rhinorrhoea

Symptom Text: Information has been received from a registered nurse (RN) concerning her 19 year old daughter who on 30-JUL-2007 was vaccinated with her first dose of GARDASIL (lot, route and site not reported). On 05-OCT-2007 she was vaccinated with her second dose of GARDASIL (lot, route and site not reported) and on 08-FEB-2008 was vaccinated with her third dose of GARDASIL (lot, route and site not reported). Concomitant therapy included hepatitis A virus vaccine (unspecified) (manufacturer unknown) on 30-JUL-2007 and a booster of hepatitis A virus vaccine (unspecified) (manufacturer unknown) on 08-FEB-2008, meningococcal vaccine (unspecified) on 30-JUL-2007, influenza virus vaccine (unspecified) on 05-OCT-2007, and fexofenadine hydrochloride (ALLEGRA), pseudoephedrine HC1 (SUDAFED) and hormonal contraceptives (unspecified). The nurse stated that after completing the series, on 23-FEB-2008 her daughter developed a sore throat, arthralgia, coughing, runny nose, hand numbness and tingling. The patient contacted the physician on an unspecified date. A test for strep throat (date not reported) was negative. The patient's liver and spleen were within normal limits. Also, the patient's complete blood count, thyroid stimulating hormone, glucose, and erythrocyte sedimentation rate were within normal limits. At the time of reporting the patient had not recovered. No other information was available. Sore throat, arthralgia, coughing, runny nose, hand numbness and tingling were considered to be disabling by the reporter. Additional information has been requested.

Other Meds: Allegra; Hormonal contraceptives; Sudafed

Lab Data: Diagnostic laboratory strep throat test negative; Diagnostic laboratory spleen tests within normal limits; Hepatic function tests within normal limits; Complete blood cell within normal limits; Serum TSH within normal limits; Blood glucose

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 310280-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Mar-2008	26-Mar-2008	0	21-Apr-2008	22-Apr-2008	NJ	WAES0804USA01944	22-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Lethargy, Myalgia, Pain, Skin warm

Symptom Text: Information has been received from a physician concerning an approximately 25 year old female patient with no known drug allergies or medical history reported, who on 26-MAR-2008 was vaccinated intramuscularly into the left deltoid with the first 0.5 mL dose of GARDASIL (Lot #0152X). There was no concomitant medication. On approximately 02-APR-2008, the patient developed pain, warmth and diffuse muscle tenderness in her left upper arm. She was examined by the physician on 02-APR-2008 and prescribed corticosteroids (unspecified). She was also examined on 08-APR-2008 and reported that her upper body was hot and sore and she was lethargic. It was reported that there were no abnormal findings on physical exam other than mild injection site tenderness and no fever. Diagnostic laboratory testing performed included blood tests with unknown results. No product quality complaint was involved. The reporting physician considered these events to be disabling/incapacitating. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory 04/??/08 - results unknown; physical examination 04/??/08 - afebrile; mild injection site tenderness

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 310282-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2008	02-Jan-2008	0	21-Apr-2008	22-Apr-2008	FR	WAES0804USA02313	22-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0277U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bradycardia, Immediate post-injection reaction, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 02-JAN-2008 was vaccinated intramuscularly into the deltoid muscle with the second dose of Gardasil (Lot # 0277U; batch # NG00020). "Immediately, about thirty minutes post vaccination," she experienced syncope (twice). She recovered completely but was referred to the hospital by the doctor on emergency. An electrocardiogram showed bradycardia. The patient recovered completely within an unspecified time. It was also reported that the previous vaccination on 23-OCT-2007 with Gardasil, was well tolerated. The third dose, will be administered under hospital monitoring. Other business partner numbers include: E200803207. No further information is available.

Other Meds:

Lab Data: electrocardiogram, 02Jan08, bradycardia

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 310492-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Mar-2008	13-Mar-2008	0	22-Apr-2008	23-Apr-2008	FR	WAES0804USA02312	23-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bronchospasm, Discomfort, Flushing, Tension, Tetany, Tremor

Symptom Text: Information has been received from a Health Authorities agency concerning a 14 year old female who on 13-MAR-2008 at 19:30 am was vaccinated with her first dose of GARDASIL (Lot #1475F; Batch #NF27910) intramuscularly in the deltoid (injection site). At about 19:45, on the same day, the patient presented with discomfort, and at 20:00 she developed tremors, tenseness, flushing, bronchospasm and tetany. The patient was admitted to the emergency room where she was with adrenalin at 20:05 and at 20:35 with adrenaline and betamethasone sodium phosphate (BENTELAN) intravenously. At 23:00 there was a resolution of symptoms. The patient was kept in the emergency room under clinical observation for an unspecified duration. It is also reported that the objective exam performed prior to the vaccination was negative. The patient completely recovered on 13-MAR-2008 at 23:00. This case is closed. Other business partner numbers include E200803222 and IT137/08. The reporter considered discomfort, tremors, tenseness, flushing, bronchospasm and tetany to be other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 310749-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Feb-2008	28-Mar-2008	51	23-Apr-2008	24-Apr-2008	NJ		24-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cerebrovascular accident, Hypoaesthesia, Hypoaesthesia facial, Oral contraception

Symptom Text: Pt had CVA on 3/28/08. Started with L hand & facial numbness which progressed on that 1/2 of body, went to ER. Oral contraception.

Other Meds: Seasonique

Lab Data: MRI of brain, small area of restricted diffusion, scattered foci of altered signal in deep white matter. 4/24/08-MRI report received for DOS 3/28/08-Impression:small area of restricted diffusion, scattered foci of altered signal within dee

History: seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: 310887-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Dec-2007	04-Jan-2008	24	25-Apr-2008	28-Apr-2008	FR	WAES0804CZE00004	28-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Condition aggravated, Grand mal convulsion, Incontinence

Symptom Text: Information has been received from an agency concerning a 17 year old female with contraception and a history of epilepsy who on 11-DEC-2007 was vaccinated with Gardasil. Concomitant therapy included LOGEST. On 04-JAN-2008 the patient experienced grand mal with incontinence and amnesia and was hospitalized from 4-Jan-2008 to 11-Jan-2008. Therapy Agapurin i.v., administration of specific epileptic therapy. From that time the patient was followed again in outpatient office for epilepsy. The reporter felt that grand mal was related to therapy with Gardasil. Additional information has been requested.

Other Meds: ethinyl estradiol (+) gestodene, Unk - Unk

Lab Data: Unknown

History: Epilepsy

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: 310893-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jan-2008	09-Jan-2008	1	25-Apr-2008	28-Apr-2008	PA	WAES0804USA03527	28-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Injection site swelling, Muscular weakness, Oedema peripheral, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with no known drug allergies and no past medical history, who on 08-JAN-2008 was vaccinated intramuscularly into the left deltoid with the second dose of Gardasil (Lot # 659439/1267U). There was no concomitant medication, and no other shots were received that day. No trauma to the arm was reported. On 09-JAN-2008 the patient developed pain at the injection site pain radiating down to the fingertips, swelling of the left upper arm, numbness, tingling and weakness in the hand. The patient was seen on 26-FEB-2008 and treated with over the counter medication ADVIL which decreased the pain. Diagnostic testing included an MRI indicating a 5x11x9 millimeter and a small focus edema 1 to 2 centimeters deep in the subcutaneous fat of the lateral upper left arm. No abnormal bone marrow or muscle. Re-evaluation on 02-APR-2008 revealed tenderness over biceps, no erythema, no warmth, and no palpable cord. Neurovascular exam was intact. It was also reported that she had no problems on 05-NOV-2007 with the first dose of Gardasil. The reporting physician considered the injection site pain radiating down to the fingertips, swelling of the left upper arm, numbness and tingling and weakness in the hand to be disabling and another important medical event. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance, 5x11x9 mm; small focus edema; 1-2 cm deep in subcutaneous fat

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 310894-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jan-2008	26-Feb-2008	32	25-Apr-2008	28-Apr-2008	FR	WAES0804USA04078	28-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain neoplasm, Surgery, Visual disturbance

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no medical history, who on 25-JAN-2008 was vaccinated intramuscularly into the deltoid with a first dose of GARDASIL. On 26-FEB-2008, one month after vaccination, the patient experienced anomalies of her visual field and consulted her physician. On an unspecified date, primary brain tumour was diagnosed. The patient was hospitalised and the tumour was operated on. At the time of reporting, the patient had not recovered. She was discharged home and chemotherapy was scheduled. Other business partner numbers included: E200803623. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 310895-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Apr-2008	09-Apr-2008	0	25-Apr-2008	28-Apr-2008	FR	WAES0804USA04098	28-Apr-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH10080	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema, Hypoaesthesia facial, Induration, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 17 year old female with a history of trichorhinophalangeal syndrome, who on 09-APR-2008 was vaccinated IM in the left deltoid with a first dose of GARDASIL (Batch# NH10080). In the evening post vaccination the patient experienced redness and induration of the upper arm. The patient developed paresthesia of the face and arm, tingling in the arm, and numbness of the left side of the face. The tingling and paraesthesia in the arm was resolved. The patient was treated with floxacillin sodium (STAPHYLEX) for three days and then the treatment was stopped. The patient was admitted to the hospital on 11-APR-2008. The paresthesia and numbness of the face was ongoing at the time of the report. Other business partner numbers included: E200803449. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Trichorhinophalangeal syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: 310917-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Apr-2008	09-Apr-2008	0	25-Apr-2008	28-Apr-2008	--	WAES0804USA02772	28-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Convulsion, Head injury, Headache, Hypertension, Injection site pain, Nausea, Suture insertion, Syncope, Vomiting

Symptom Text: Information has been received from an office manager at a physician's office concerning a 20 year old female who was vaccinated with a first dose of GARDASIL (lot number, route and site not reported) on an unspecified date. The patient received a second dose of GARDASIL (lot number not reported) intramuscularly on an unspecified date. The office manager reported that the patient fainted and hit her head on a railing while making an appointment for her third dose at the receptionist desk. The patient also became hypertensive, began seizing, and throwing up. The patient was admitted to the hospital where she received 7 stitches. A computed axial tomography was performed (results not reported). The patient was admitted on 09-APR-2008 and released on 10-APR-2008. After being released the patient is still experiencing pain at the injection site, headaches, nausea and back pain. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial - no results reported

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 311000-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Feb-2008	21-Feb-2008	2	28-Apr-2008	29-Apr-2008	MN	WAES0804USA04062	29-Apr-2008

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with depression and no known drug allergies, who on 19-FEB-2008 was vaccinated with the first dose of Gardasil. Concomitant therapy included EFFEXOR and TOPAMAX. On 21-FEB-2008 the patient developed urticaria after administration of her first dose of Gardasil. The patient was examined in the Emergency Room and was treated with epinephrine and prednisone. She was not admitted and was released the same day (date unknown). No diagnostic laboratory testing was performed. It was reported that she was currently taking prednisone and an antihistamine. At the time of this report, the outcome had not recovered. No product quality complaint was involved. The reporting physician considered the urticaria to be disabling, due to the patient's mental stress. Additional information has been requested.

Other Meds: TOPAMAX; EFFEXOR

Lab Data: None

History:

Prex Illness: Depression

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 Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 311178-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Apr-2008	15-Apr-2008	0	29-Apr-2008	30-Apr-2008	FR	WAES0804USA04636	30-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Information has been received from a pharmacist at the local Health Authorities concerning a 19 year old female with no relevant medical history who on 14-APR-2008 was vaccinated with a dose of GARDASIL (lot # not reported) IM. Concomitant therapy included hormonal contraceptives (unspecified). On 15-APR-2008, one day after vaccination, the patient experienced pulmonary embolism. At the time of reporting, the outcome was unknown. Other business partner numbers included: E2008-03719. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

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: 311263-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Feb-2008	07-Mar-2008	9	30-Apr-2008	01-May-2008	FR	WAES0804USA05403	01-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood blister, Blood product transfusion, Immunoglobulins, Intra-abdominal haemorrhage, Oropharyngeal blistering, Petechiae, Thrombocytopenia

Symptom Text: Information has been received from a health authority concerning a 17 year old female patient with asthma who on 27-FEB-2008 was vaccinated with a dose of GARDASIL. Concomitant suspect therapy included montelukast sodium, 10 mg daily for the treatment of asthma. Other concomitant therapy included SYMBICORT and Neovletta 28 for several years. Three days later, on 01-MAR-2008 she was started with montelukast sodium as a complement for her asthma treatment. On 07-MAR-2008 the patient experienced blood-filled blisters in the mouth, petechiae and bleedings from the lower abdomen. The patient was hospitalized on an unspecified date. A control of the thrombocytes indicated a low value - only 5 (no unit reported). After treatment with globulin, immune (OCTAGAM), steroids and tranexamic acid (CYKLOKAPRON) the thrombocytes increased. On 14-MAR-2008, the thrombocytes had been normalized. At the time of this report the patient had not yet recovered. Other business partner numbers include: E200803620 and 081262. No further information is available. This case is closed.

Other Meds: SYMBICORT, Unk - Unk; hormonal contraceptives (unspecified), Unk - Unk; TAB SINGULAIR, 10 mg/DAILY, 01Mar08-Unk

Lab Data: platelet count ??Mar08 Comment: low value - only 5 (no unit reported)

History:

Prex Illness: Asthma; Oral contraception

Prex Vax Illns:

Vaers Id: 311391-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Apr-2008	22-Apr-2008	0	01-May-2008	02-May-2008	FR	WAES0804USA05686	02-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Dizziness, Feeling hot, Pallor

Symptom Text: Information has been received from a gynecologist, concerning a 16 year old female patient, who on 22-OCT-2007 was vaccinated with the first dose (well tolerated), on 19-DEC-2007, with the second dose (well tolerated), and on 22-APR-2008 with the third dose, IM, of Gardasil (lot 1113U; batch NH10080, dose 3). On the night after vaccination, the patient experienced a "hot feeling" (no fever) and chills. On 23-APR-2008, she developed dizziness and was extremely pale ("white as chalk"). She was hospitalized (details not specified). At the time of this report, the outcome of the events was not specified. Additional information has been requested. Other business partner numbers include: E2008-03822; E2008-03823 (non-serious report, same reporter, same product).

Other Meds: Unknown

Lab Data: Unknown

History: No reaction on previous exposure to vaccine.

Prex Illness:

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 Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 311534-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-Jun-2007	01-Jan-2008	202	02-May-2008	05-May-2008	TX	WAES0802USA06239	05-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0389U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Cervicitis

Symptom Text: This is in follow-up to report(s) previously submitted on 3/14/2008. Information has been received from a physician and a registered nurse concerning a 24 year old white female (height 61") who in December 2006 was vaccinated with her first dose of GARDASIL (lot # not reported), IM. On 19-FEB-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #655503/0012U), IM in the deltoid. On 13-JUN-2007, the patient was vaccinated with the third dose of GARDASIL (Lot #657736/0389U), IM in the deltoid. Concomitant medication was not reported. The patient was not sexually active during the time frame when she received all three GARDASIL doses. The patient became sexually active in August 2007. On 10-AUG-2007, the following laboratory tests were performed HIV screen, Chlamydia trachomatis, Neisseria gonorrhoeae, HCV Ab (0.2 s/co ratio - normal) and HBsAg screen and all results were negative. On 22-JAN-2008, the patient had a PAP test performed and results were abnormal and showed epithelial cell abnormality, low grade squamous intraepithelial lesion mild dysplasia at least was present cells suspicious for a high grade lesion are also present. In February 2008, the patient underwent a colposcopy and 2 sites were found with moderate dysplasia. On 20-FEB-2008, uterine cervix biopsy was performed which showed chronic cervicitis, negative for dysplasia and malignancy, high grade squamous intraepithelial lesion (moderate dysplasia, CIN 2) at the transition zone extending into the endocervical glands. A endocervical currettage performed this same day showed tissue insufficient for evaluation. On 27-FEB-2008, endocervical currettage was performed which showed benign endocervical fragments negative for dysplasia and malignancy. On 25-MAR-2008, a loop electrosurgical excision procedure was performed which showed squamous and endocervical mucosa with low grade squamous intraepithelial lesion encompassing up to mild dysplasia (CIN1), dysplasia identified at margins of resection. It was reported that on 25-

Other Meds: Unknown

Lab Data: Colposcopy 02/??/08 - 2 sites w/moderate dysplasia; Biopsy 02/20/08 - uterine cervix: chronic cervicitis, negative for dysplasia and malignancy; Biopsy 02/20/08 - uterine cervix: high grade SIL mod dysplasia, CIN II at trans zone extending

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 311567-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	20-Apr-2008		05-May-2008	06-May-2008	FR	WAES0804USA05667	06-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Drug exposure during pregnancy, Peripheral vascular disorder, Vomiting

Symptom Text: Information has been received from a physician concerning her 17 year old daughter who in March 2008, was vaccinated with a third dose of Gardasil. On 20-APR-2008 the patient was admitted to the hospital with severe vomiting, diarrhea and circulatory disorder. The physician of the hospital was contacted by phone on 22-APR-2008 and reported that the symptoms resolved after 1 and a half days. It was reported that the patient was in her fourth month of pregnancy. It was also reported that the first and second vaccination were well tolerated. Other business partner numbers include: E200803769. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Jan08)

Prex Vax Illns:

Vaers Id: 311568-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Mar-2008	06-Mar-2008	0	05-May-2008	06-May-2008	FR	WAES0804USA05671	06-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Muscular weakness

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 06-MAR-2008 was vaccinated IM in the deltoid muscle with the third dose of GARDASIL (Lot# not reported). Dates and lot #s of previous two vaccinations of GARDASIL were not reported. There were no concomitant medications reported. On 06-MAR-2008 about 10 minutes post vaccination the patient experienced injection site pain and numbness "starting from below the injection site and spreading down to the hand". In the course she additionally developed weakness of the hand. It was reported that the injection site pain resolved after one day and the numbness and weakness were ongoing. It was reported that on 22-APR-2008 the patient was admitted to the hospital for diagnostics. The physician reported that the first two doses of the vaccine were well tolerated. Other business partner numbers include E2008-03768. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **311580-4 (S)** **Related reports:** 311580-1; 311580-2; 311580-3; 311580-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Mar-2008	14-Mar-2008	0	13-May-2008	14-May-2008	GA	WAES0805USA00532	30-May-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune disorder, Lymphadenopathy, Pyrexia

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 19 year old female patient with sulfonamide allergy who on 14-MAR-2008 was vaccinated with a dose of Gardasil. The nurse stated that the patient did not receive the Gardasil at her office and it was unknown which dose in the series of the vaccine was given. The nurse reported that the patient developed a fever of 102 to 103 degrees F after she received the Gardasil vaccine which has started for the past month (start date was not specified). The fever came and went almost every day, but did not last the whole day. The patient was hospitalized on 24-APR-2008 in relation to the fever and was discharged on 01-MAY-2008. During her hospitalization it was determined that she had a low white blood cell count and might have a possible auto immune disease. Serum antinuclear antibodies test (ANA) screen was done. Results not provided. A computerized Axial Tomographic (CAT) scan indicated that the patient had enlarged lymph nodes in abdominal cavity, small bowel, and in upper pelvis. She had unspecified blood and laboratory tests done. It was reported that patient was improving and was on steroid therapy. No other information available at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial 04/24/08 enlarged lymph nodes; diagnostic laboratory 04/24/08; serum ANA 04/24/08 Possible auto immune disease; body temp 03/??/08 102 F for the past one month; body temp 03/??/08 103 F for the past one month; WBC count 04/24

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 311689-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Oct-2007	04-Feb-2008	119	06-May-2008	07-May-2008	IA	WAES0804USA02241	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Acute sinusitis, Balance disorder, Dizziness, Fatigue, Headache, Hypotension, Lethargy, Nasal congestion, Oral intake reduced, Pharyngitis, Pharyngolaryngeal pain, Sinus headache, Somnolence, Vertigo, Viral infection, Weight decreased

Symptom Text: Initial and follow-up information has been received from a physician concerning a 12 year old female, who on 23-JUL-2007 was vaccinated with her first dose of Gardasil (lot# 658094/0524U). Concomitant vaccination included Tdap (Lot# AC5213018A13). On 08-OCT-2007 the patient was vaccinated with her second dose of Gardasil (lot# 658558/1061U). On 04-FEB-2008 the patient was seen in the office and complained of a sore throat, headache, and stomach ache. The patient was diagnosed with acute pharyngitis. The physician believed the pharyngitis to probably be viral, but would follow culture to 48hours. The strep ID was negative. The patient was given information on how to treat and what to watch for. On 18-FEB-2008 the patient was seen at the office with complaints of dizziness/vertigo, severe headache, and felt "off balance." The patient was diagnosed with fatigue, lethargy, and a headache. The patient also experienced weight loss. The patient's head, ears, eyes, nose, and throat (HEENT) was within normal limits, complete blood count (CBC) was normal, serum Epstein-Barr virus antibody test was negative, and blood pressure was 106/60. The patient appeared to be recovering from viral illness. The physician discussed low blood pressure with the patient. The patient was reminded to stand up slow, eat a healthy diet and to call if signs and symptoms worsened or did not improve. On 25-FEB-2008 the patient was seen in the office with complaints of headache, dizziness, and a decrease in oral intake with a 6-10 pound weight loss over the week. The patient's mother reported that the patient has been sleepy during the week. The patient experienced nasal congestion, and mild pain over frontal sinuses. The patient was diagnosed with headache and acute sinusitis. The patient was prescribed ZITHROMAX TRI-PAK. It was reported that the headache was gone. The patient was advised to take antibiotic with chocolate milk or a meal to help with the upset stomach and to continue the ZITHROMAX TRI-PAK and call with any oth

Other Meds: albuterol

Lab Data: diagnostic laboratory, results unknown; diagnostic laboratory, 02/18/08, head, ears, eyes, nose, throat (HEENT)-within normal limits; blood pressure, 02/18/08, 106/6; serum Epstein-Barr, 02/18/08, negative; body weight measurement, lost 6-1

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311690-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2008	10-Mar-2008	21	06-May-2008	07-May-2008	FR	WAES0804USA05694	07-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermatitis

Symptom Text: Information has been received from a health authority concerning a 15 year old female who on 18-FEB-2008 was vaccinated with a third dose of Gardasil. On 10-MAR-2008 the patient experienced dermatitis on both thighs. Based on a biopsy done on an unspecified date, the diagnosis of interface dermatitis was established. It was reported that livedo racemosa was ruled out. The patient was admitted to the hospital. At the time of this report, the symptoms were ongoing. It was also reported that the first and second vaccination were well tolerated. Other business partner numbers include: E200803917 and PEI2008005289. No further information is available.

Other Meds: Unknown

Lab Data: biopsy interface dermatitis

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 311784-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jan-2008	07-Apr-2008	70	07-May-2008	08-May-2008	FR	WAES0804USA06200	08-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Gait disturbance, Mycoplasma infection, Ophthalmoplegia

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient who on 28-JAN-2008 was vaccinated with a first dose of Gardasil and on 27-MAR-2008 was vaccinated IM into the upper arm with a second dose of Gardasil (batch # NG20180, lot # 0510U). On 07-APR-2008 she developed ophthalmoplegia and diplopia followed by gait disturbance on same day. The patient was hospitalised on 13-APR-2008. Internuclear ophthalmoplegia and suspicion of multiple sclerosis was diagnosed. Cerebral spinal fluid (CSF) shoed: three oligoclonal bands (a control was sent to a reference laboratory, result not yet available), normal cell count, albumin ratio pathologically increased, slight barrier disorder and no borreliosis. Cranial magnetic resonance imaging (MRI) revealed multiple inflammatory lesions (mesencephal) and periventricular), spinal MRI was normal. Auditory evoked potential (AEP), somatosensory evoked potential (SEP), Visual evoked potential (VEP) and nerve conduction were normal as well as electroconvulsive therapy (ECT) test. Ophthalmological examination, visus of right eye was 0.8 and left eye was 0.7. Serology test revealed a seroactive infection with Mycoplasma pneumoniae. The patient was treated with URBASON one gram per day for three days. The patient improved during the stay in the hospital. The patient was discharged on 21-APR-2008. Further therapy with physiotherapy and adaptation of glasses was planned. The reporter assessed the relation to the vaccine as possible. The other business partner number included: E200803914. The file is closed. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 13Mar08, Cranial MRI revealed multiple inflammatory lesions (mesencephal); auditory evoked potential, 13Mar08, Normal; ophthalmological exam, 13Mar08, 0.8, Visus of right eye; ophthalmological exam, 13Mar08, 0.7,

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311788-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Feb-2008	Unknown		07-May-2008	08-May-2008	FR	WAES0804USA06506	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema, Local reaction, Malaise, Pain, Swelling

Symptom Text: Information has been received from a general practitioner concerning a 21 year old female who on 23-FEB-2008 was vaccinated with a first dose of Gardasil (Lot# 1201U); Batch# NG41880). After the vaccination but on an unspecified date the patient experienced a sensation of malaise and a local reaction with erythema, pain and swelling. The patient was hospitalized on an unspecified date. The reporter was not the physician who vaccinated the patient. At the time of this report, the patient's outcome was not specified. Other company numbers included: E200804034. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 311931-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jan-2008	01-Feb-2008	23	09-May-2008	12-May-2008	--	WAES0805USA00064	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Cerebrovascular accident

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with allergy to azithromycin (ZITHROMAX) who on 09-NOV-2007 was vaccinated with the first dose of GARDASIL, 0.5 mL, (injection form) (Lot # not reported). On 09-JAN-2008, the patient was vaccinated with the second dose of GARDASIL, 0.5 mL, (injection form) (Lot # not reported). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). On 01-FEB-2008, after getting the second dose of GARDASIL, the patient experienced a stroke and was hospitalized. The patient stayed in the hospital for one week. At the time of this report, the patient was recovering from the event. The causality of the event was not reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: YAZ

Lab Data:

History:

Prex Illness: Contraception; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 311933-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Oct-2007	14-Apr-2008	189	09-May-2008	12-May-2008	FR	WAES0805USA00840	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Nausea, Pain, Peripheral vascular disorder, Pruritus generalised, Pyrexia

Symptom Text: Information has been received from a gynecologist, concerning a 16 year old female patient who on 08-OCT-2007 was vaccinated IM with the first dose (lot #0251U; batch NF56480; well tolerated), and on 10-DEC-2007, vaccinated IM with the second dose (lot #0276U; batch NF58550; well tolerated), and on 14-APR-2008 vaccinated IM with the third dose (lot # 1068U; batch NH06410) of GARDASIL. On 14-APR-2008 after vaccination, the patient complained about chills, nausea, and pain concerning the whole body. After treatment with paracetamol, twice, the patient developed a fever of up to 39 degrees C. The patient was admitted to the hospital on 15-APR-2008 because of generalized pain and a peripheral circulatory disorder. On 15-APR-2008 and 16-APR-2008, the patient's C-reactive protein (CRP) was increased (values 7.5 and 9.4, respectively - units not specified). On 16-APR-2008, leukocytes were decreased at 3,200, and thrombocytes were decreased at 105,000 (units not specified). Under medication with unspecified infusion and ibuprofen, she recovered on 17-APR-2008, and was discharged from the hospital. On 21-APR-2008, there were no abnormal lab findings. Other business partner numbers include: E2008-03964. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test 21Apr08 no abnormal findings; body temp 14Apr08 39 degrees C; serum C-reactive protein 15Apr08 7.5 increased; WBC count 16Apr08 3,200 decreased; platelet count 16Apr08 105,000 decreased; serum C-reactive protein 1

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: 312159-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		13-May-2008	14-May-2008	FR	WAES0805AUS00051	14-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	28101		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Genital ulceration

Symptom Text: Information was obtained on requested by the Company from the agency via a Public Case Detail Form and Case Line Listing concerning a 17 year old single female with one sexual partner, with no history of HSV infection who was vaccinated with GARDASIL. Subsequently after vaccination with GARDASIL, the patient developed genital ulceration which was described as severe deep genital ulcers on labia and perineum 2 weeks after vaccination with GARDASIL. In June 2007, 2 HSV PCR swabs done were negative. Serology was negative at 6 weeks. At the time of reporting on 17-OCT-2007 the patient had recovered from the genital ulceration. The agency considered that genital ulceration was possibly related to therapy with GARDASIL. Genital ulceration was considered to be disabling by the agency. The original reporting source was not provided. Subsequently the patient's experience was reported to an article, 25-JAN-2008, page 6. Additional information is not expected.

Other Meds: Unknown

Lab Data: HSV type 1 and/or 2 identification PCR ??Jun07 Comment: negative; HSV type 1 and/or 2 identification PCR ??Jun07 Comment: negative; clinical serology test Comment: negative at 6 weeks

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312161-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Apr-2008	Unknown		13-May-2008	14-May-2008	FR	WAES0805USA01090	14-May-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 Abdominal pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female, who in April 2008, was vaccinated with a second dose of GARDASIL. Subsequently, exact onset not reported, the patient experienced severe abdominal cramps and was admitted to the hospital. All examinations (not specified) showed normal results. The patient was treated with infusions and omeprazole. The patient recovered within an unspecified time. It was reported that after the patient was vaccinated with the first dose of GARDASIL she experienced slight abdominal cramps. Other business partner numbers included: E200804082. Additional information is not available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test Comment: not specified-normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312436-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2008	06-May-2008	0	16-May-2008	21-May-2008	OH		30-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	1267U	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	U2359AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction, Anxiety, Dizziness, Dyspnoea, Hyperhidrosis, Hyperventilation, Loss of consciousness, Nausea, Oxygen saturation decreased, Palpitations, Pharyngeal oedema, Pruritus, Reaction to previous exposure to any vaccine, Tremor, Urticaria, Vaccination complication, Vision blurred

Symptom Text: Patient complained of itching approximately 15-20 minutes after receiving MENACTRA and GARDASIL. Patient given 50 mg Benadryl p.o. Cool compresses to neck and back. Patient anxious, hyperventilating. Patient placed in supine position. P.O. 97, pulse 83. Doctor at bedside. Reduce of pulse OX 87, P 72. Patient placed on O2. SATS 99-100. Code team called - SQ epinephrine given and patient transferred to ER. 5/29/08 Reviewed hospital medical records of 5/7-5/8/2008. FINAL DX: anaphylaxis to Gardasil or Menactra Records reveal patient experienced blurred vision, itch, hives, diaphoreses, dizziness, lightheadedness, SOB, nausea, palpitations, throat swelling, shaking & passed out. Patient reported similar reaction to prior flu vaccination. Tx in ER & admitted for observation. Ortho & psych consults done for old fx & anxiety related to anaphylaxis. No further difficulties & d/c to home next day w/allergy med & epi-pen.

Other Meds: Allegra D

Lab Data: Mom stated patient had similar reaction to Influenza vaccine approximately 1 year ago - (office not notified of RXN).

History: Penicillin; Morphine PMH: fracture left tibia plateau; migraines. Allergies: PCN, morphine & shellfish

Prex Illness: S/P MVA 9/24/07

Prex Vax Illns: ~Influenza (no brand name)~UN~19~In Patient

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

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	31-Mar-2008	05-May-2008	35	27-May-2008	28-May-2008	--	WAES0805USA03671	28-May-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Acute myeloid leukaemia

Symptom Text: Information has been received from a consumer's mother concerning her 19 year old daughter with no pertinent medical history or drug reactions/allergies who at the end of March 2008, was vaccinated with a third dose of GARDASIL 0.5 mL injection. There was no concomitant medication. On 05-MAY-2008 the patient was diagnosed with acute myelogenous leukemia and was hospitalized on 07-MAY-2008, and remained in the hospital at the time of the report. On an unspecified date the patient had a diagnostic laboratory test and a bone marrow biopsy performed. Results of the tests were unknown. The patient's acute myelogenous leukemia persisted. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory; bone marrow biopsy

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 312525-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2008	06-May-2008	0	19-May-2008	20-May-2008	OH	WAES0805USA01675	20-May-2008

VAX Detail:

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on 06-MAY-2008 "two days ago" was vaccinated a dose of Gardasil (lot # not available). Concomitant therapy included MENACTRA. The physician in the hospital reported that one half hour after the patient received a dose of Gardasil, she started to have trouble breathing and was admitted to the hospital. At the time of this report the patient was in the hospital and had been there for "two day so far." No further information was available. The patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312529-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	03-May-2008	2	19-May-2008	20-May-2008	NJ	WAES0805USA01353	20-May-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Encephalopathy

Symptom Text: Information has been received from a physician concerning a 11 year old female patient with hypothyroidism who on 01-MAY-2008 was vaccinated with a first dose of Gardasil. Concomitant therapy included SYNTHROID. On 03-MAY-2008 the patient experienced encephalopathy after receiving the first injection, was seen at the emergency room (ER). Subsequently she was hospitalized. Laboratory diagnostic test spinal tap was done. No further information was provided. The patient had not recovered. Additional information has been requested.

Other Meds: SYNTHROID

Lab Data: spinal tap 05/03/08 - Partially abnormal

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vaers Id: 312530-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Mar-2008	09-May-2008	42	19-May-2008	20-May-2008	FR	WAES0805USA02846	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539F	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain stem syndrome, Dizziness, Headache, Infection, Somnolence

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 28-MAR-2008 was vaccinated intramuscularly into the deltoid with the third dose of GARDASIL. Six weeks post vaccination, on approximately 09-MAY-2008, the patient experienced brain stem infection with headache, somnolence, and dizziness. She was admitted to the hospital on an unspecified date. At the time of this report, the patient's outcome was unknown. It was reported that the first (14-SEP-2007, Lot # 1539F, batch # NF42170) and second (30-OCT-2007, Lot # 0354U, batch NF58150) vaccinations with GARDASIL were well tolerated. Other business partner numbers include: E200804162. Further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 312645-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Mar-2008	02-Apr-2008	21	20-May-2008	21-May-2008	FR	WAES0805USA02847	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Headache, Nausea, Spinal cord oedema, Vomiting

Symptom Text: Information has been received from a physician concerning a 20 year old female with concomitant medications and pertinent medical history unspecified, who on 14-JAN-2008 was vaccinated with the first dose of GARDASIL IM, (dose not reported), (Lot# 0277U, Batch#NG00020), this was tolerated well. On 12-MAR-2008 the patient was vaccinated with the second dose of GARDASIL IM to the Deltoid, (dose not reported) (Lot#10684, Batch#42070). After the vaccination, (approximately 02-APR-2008, 3 weeks post vaccination) the patient complained about headaches, nausea, vomiting and double vision. On 29-APR-2008 she was admitted to the hospital, cranial MRI on an unspecified date showed spinal cord oedema. The patient was treated with cortisone, IV, and GLYCEROL over a period of 4 -5 days. Symptoms of headache, double vision, vomiting and nausea were resolved on approximately 03-MAY-2008. Other business partner numbers include E2008-04237. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: spinal cord oedema

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312646-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Mar-2008	06-Mar-2008	0	20-May-2008	21-May-2008	FR	WAES0805USA02845	21-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Injection site pain, Muscular weakness

Symptom Text: Information has been received from a neurologist concerning a 16 year old female with a history of gastroenteritis (2 weeks prior to 06-MAR-2008), and no reported concomitant medications, who on 06-MAR-2008 was vaccinated with the third dose of GARDASIL IM into the deltoid muscle, (Lot # not reported). On unspecified dates the patient had previously received the first and second doses of GARDASIL injection, (Lot #'s not reported), it was noted that these were well tolerated. On 06-MAR-2008 about 10 minutes post vaccination with GARDASIL, the patient complained about injection site pain and experienced numbness, starting from "below injection site" and spreading down to the hand. In the course she additionally developed weakness of the hand. Injection site pain resolved after 1 day (07-MAR-2008), other symptoms were ongoing. On 22-APR-2008 she was admitted to the hospital for diagnostics. The physician reported that ENG, EMG, SEP, CSF, and cranial MRI showed normal results, (test dates not specified). The symptoms could not be allocated to a concrete nerve. Tentative diagnosis was "plexopathy." Under physiotherapy symptoms improved remarkably. At discharge (date unspecified) only discreet complaints were seen. Other business partner numbers include E2008-03768. Additional information is not available.

Other Meds: Unknown

Lab Data: Electronystagmography, 22?Apr08, normal; Electromyography, 22?Apr08, normal; Somatosensory evoked potential, 22?Apr08, normal; Diagnostic laboratory test, 22?Apr08, csf normal; Magnetic resonance imaging, 22?Apr08, cranial normal.

History: Gastroenteritis

Prex Illness:

Prex Vax Illns:

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: 312962-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		22-May-2008	23-May-2008	FR	WAES0805CZE00002	23-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Joint swelling

Symptom Text: Information has been received from a physician a concerning a 16 year old female with a history of allergy on aluminous carrier in a vaccine who was vaccinated with GARDASIL. Subsequently the patient experienced joint swelling (similar to rheumatic symptoms) and was admitted to a hospital on May 9, 2008. The reporter felt that joint swelling was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Allergy to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: 312964-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Apr-2008	Unknown		22-May-2008	23-May-2008	NC	WAES0805USA03398	23-May-2008

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

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Hepatic enzyme increased, Joint swelling, Myalgia, Nausea, Pain, Pyrexia, Rash, Vomiting, Weight increased

Symptom Text: Information has been received from a certified medical assistant concerning a 22 year old female with a history of removal of condylomas/genital warts, and a family history of breast cancer, who on 02-APR-2008 was vaccinated IM in the left upper quadrant of the thigh with a dose of GARDASIL (Lot# 659437/1266U). Concomitant therapy included PROVERA. On 04-APR-2008 the patient felt ill, feverish and achy. On 05-APR-2008 the patient developed a rash and swollen joints which were painful. The patient went to the emergency room and it was suspected that the patient had chicken pox, which was later ruled out. At this time the patient was not admitted to the hospital. On 09-APR-2008 the patient was admitted to the hospital for possible inflammatory arthritis, possible lupus, or possible rheumatoid arthritis. The patient experienced nausea, vomiting, and a rash with myalgia and arthralgias. Other symptoms included swelling and aches in her joints, elevated liver enzymes, fever, malaise, body aches, a rash over her trunk, arms, and legs, and an immediate weight gain of 20 pounds. It was unknown when the weight gain actually started. Rheumatoid studies were conducted. The patient's phosphatase level was 283 and her Creatinine reactive protein test was high. The patient's electrolytes, glucose, and abdominal ultrasound were normal and the blood culture was negative for infection. The patient was treated with intravenous fluid, intravenous pain medications, SOLU-MEDROL and MOTRIN. The patient was admitted to the hospital for three days and discharged with a diagnosis of a possible reaction to the vaccination. It was reported that there was a 75% resolution of acute symptoms with the use of SOLU-MEDROL and MOTRIN. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: PROVERA

Lab Data: abdominal ultrasound, 04/??/08, normal; serum alkaline, 04/??/08, 283; serum C-reactive, 04/??/08, high; blood culture, 04/??/08, negative for infection; serum electrolytes test, 04/??/08, normal; serum glucose, 04/??/08, normal

History: Genital wart; Wart excision; Condyloma

Prex Illness:

Prex Vax Illns:

Vaers Id: 312967-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jan-2008	12-Feb-2008	32	22-May-2008	23-May-2008	FR	WAES0805USA02815	23-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Joint swelling, Leukocytosis, Myalgia, Oedema peripheral

Symptom Text: Information has been received from an agency concerning a 16 year old female occasional tobacco user with a history of acne and hypersensitivity who on 11-JAN-2008 was vaccinated with GARDASIL. Concomitant suspect therapies included minocycline and JASMINE. On 12-FEB-2008 the patient developed muscle soreness with myalgia, oedema of the fingers, swelling knees and joint pain and was hospitalized. Laboratory results revealed a transient hyper leucocytosis (11000 leucocyte and then 7500 leukocyte) and an increase of the inhibitor of component C1-INH test at 0.43 and of component C4 test at 0.4. Laboratory results for cryoglobulinemia, antinuclear factors and hematology laboratory test were all negative. No etiology was found. On an unspecified date the patient was considered to have recovered from the events. Additional information has been requested. Other business partner numbers included: E2008-04334.

Other Meds: minocycline; JASMINE, 05?Feb08 - Unk

Lab Data: WBC count, 12?Feb08, 11000; WBC count, ??Feb08, 7500; hematology, ??Feb08, Comment: negative; serum ANA, ??Feb08, Comment: negative; component C1-INH test, ??Feb08, 0.43; component C4 test, ??Feb08, 0.4; serum cryoglobulins test, ??Feb08, C

History: Acne; Hypersensitivity

Prex Illness: Tobacco user; Contraception

Prex Vax Illns:

Vaers Id: 312968-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	13-Feb-2008	8	22-May-2008	23-May-2008	FR	WAES0805USA02813	23-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Thrombocytopenia

Symptom Text: Information has been received from a health care authority (reference number PO20080132) concerning a 17 year old female with a history of appendicitis, adenoidal disorder and myringotomy and a history of a 29-SEP-1999 laboratory results with a blood platelet count at 261000/mm3 who on 05-FEB-2008 was vaccinated IM with GARDASIL (Lot # not reported). There were no concomitant medications reported. Eight days post vaccination on 13-FEB-2008 the patient's laboratory results included a blood platelet count at 46000/mm3, the patient was diagnosed with thrombocytopenia and was hospitalized. On 20-FEB-2008 laboratory results revealed a blood platelet count at 40000/mm3, the patient was treated with CORTANCYL, 50mg. On 03-MAR-2008 her blood platelet count was 222000/mm3 and she was treated with prednisone, 40 mg. On 10-MAR-2008 her blood platelet count was 215000/mm3 and she was treated with prednisone, 20mg. On 17-MAR-2008 her blood platelet count was 235000/mm3 and she was treated with prednisone, 10mg. On an unspecified date a myelogram showed normal marrow and antibodies anti platelets were negative. It was reported that on an unspecified date the patient was considered to have recovered from thrombocytopenia. Additional information has been requested. Other business partner numbers included: E200804338.

Other Meds: None

Lab Data: bone marrow myelogram, normal; platelet count, 29Sep99, 261000 mm3; platelet count, 13Feb08, 46000 mm3; platelet count, 20Feb08, 40000 mm3; platelet count, 03Mar08, 222000 mm3; platelet count, 10Mar08, 215000 mm3; platelet count, 17Mar08, 2

History: Appendicitis; Adenoidal disorder; Myringotomy

Prex Illness:

Prex Vax Illns:

Vaers Id: 312969-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-May-2008	09-May-2008	0	22-May-2008	23-May-2008	FR	WAES0805KOR00005	23-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebral haemorrhage, Dizziness, Fall, Head injury, Loss of consciousness, Vomiting

Symptom Text: Information has been received from a physician concerning a 25 year old Asian female who on 09-MAY-2008 was vaccinated with GARDASIL. Right after vaccination with GARDASIL at approximately 14:30 on 09-MAY-2008, the patient experienced loss of consciousness and fell down. When falling down, the patient hit the back of her head on the floor. The patient was treated with 5% glucose 500 ml and SOLU-CORTEF injection. After 1 minute after loss of consciousness, the patient regained consciousness. However she complained dizziness and vomiting. The patient went home at 18:00 after 3 hour and 30 minute-bed rest. The physician made a call to the patient's parent at night on the same day and found dizziness and vomiting persisted. The physician recommended the patient to visit the hospital. The patient visited to a general hospital for the further evaluation on 10-MAY-2008 and received the CT. The CT result showed the brain hemorrhage due to hitting her head on the floor and the patient was hospitalized on 10-MAY-2008. The dizziness and vomiting still persisted on 13-MAY-2008. The patient was treated for the brain hemorrhage and follow up CT will be performed soon. The causality with GARDASIL was not reported so far. Additional information has been requested.

Other Meds: Unknown

Lab Data: Computed axial tomography, 10May08, brain hemorrhage.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313042-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2008	21-Apr-2008	0	22-May-2008	23-May-2008	FR	D0057331A	23-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TD	GLAXOSMITHKLINE BIOLOGICALS	AC12B016GA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	NG34780		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Burning sensation, Paraesthesia, Pruritus

Symptom Text: This case was reported by a regulatory authority (vaccines, biologicals) # DE-PEI-PEI2008006370) and described the occurrence of burning sensation in a 17-year-old female subject who was vaccinated with TD-RIX (GlaxoSmithKline). Co-suspect vaccination included GARDASIL (Sanofi Pasteur MSD). Previous vaccination included a booster dose of TD-RIX (GlaxoSmithKline) given in 1996 and GARDASIL (Sanofi Pasteur MSD) given on 25 February 2008. On 21 April 2008 the subject received a dose TD-RIX (unknown route, right upper arm) and a dose of GARDASIL (unknown route, left upper arm). Few hours after co-administered vaccination with GARDASIL and TD-RIX, the subject experienced burning sensation, tingling and itching of both feet, lower legs, both hands and arms over a period of 10 days. The subject was hospitalised. No further information will be available.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: 313144-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Apr-2008	04-Apr-2008	1	23-May-2008	27-May-2008	NC	WAES0805USA02288	27-May-2008

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

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthritis reactive, Asthenia, Familial risk factor, Fatigue, Gait disturbance, Pallor, Presyncope, Rash generalised, Serum sickness, Urticaria, Varicella

Symptom Text: Initial and follow up information has been received from a physician and by telephone call from the healthcare professional concerning a 22 year old female patient with family history of rheumatoid arthritis and autoimmune disease who on 03-APR-2008 was vaccinated IM with a dose of GARDASIL (lot # not available). The physician reported that the patient experienced serum sickness, full body rash, and severe arthritis and joint pain. She was taken to the emergency room and was admitted to the hospital. In follow up telephone call the health care professional reported that on 04-APR-2008 patient developed fatigue, temperature of 102, weakness, near syncope episode at work, blanchable rash all over body, very achy joints hands, knees and ankles, and had trouble walking. She went to the emergency room (E.R.) on 04-APR-2008 and was sent home. On 05-APR-2008, she went to the ER and was told she had chicken pox and was sent home. On 08-APR-2008 the patient went to the ER and was sent home. On 09-APR-2008 the patient was admitted to the hospital. The patient's final diagnosis was reactive arthritis, possible reaction to GARDASIL, urticaria associated with reactive arthritis, abnormal liver function test (LFT's) possibly related to fatty liver or polycystic ovary syndrome or possibly related to reactive arthritis. Her hepatitis A, hepatitis B and hepatitis C, Lyme, Rocky Mountain fever, serum antinuclear antibodies (ANA), serum antineutrophil cytoplasmic antibody (ANCA) test was normal. Her Rheumatoid factor tests were all normal and her sed rate was slightly elevated. Serum C Reactive protein test was 29.9. The patient was treated with intravenous (IV) steroids and improved. She was in the hospital for four days. On 21-APR-2008, the patient was seen in the office and it was noted that she was "remarkably better". Skin rash was resolved, ache in joints/stiffness still there especially after sleeping. Fever was gone. The patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 04/09?/08, Rocky Mountain Fever titer (normal); erythrocyte, 04/09?/08, slightly elevated; serum C-reactive, 04/09?/08, 29.9; serum ANCA, 04/09?/08, Normal; serum hepatitis A, 04/09?/08, normal; serum rheumatoid facto

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 313381-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Nov-2007	05-Feb-2008	92	27-May-2008	28-May-2008	FR	WAES0805USA04647	28-May-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paralysis, Vocal cord paralysis

Symptom Text: Information has been received from a gynaecologist concerning a 21 year old female who on 05-NOV-2007 was vaccinated with a second dose of GARDASIL. Concomitant medication was not reported. The first dose of GARDASIL was received on 05-NOV-2007 and was well tolerated. On 06-FEB-2008, the patient was diagnosed with paralysis of the recurrent nerve and was admitted to the hospital. The reporting gynaecologist felt that paralysis of the recurrent nerve was not related to therapy with GARDASIL. The symptoms, further course and outcome have not been reported. Other business partner numbers included E2008-04503. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313385-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-May-2008	12-May-2008	0	27-May-2008	28-May-2008	KS	WAES0805USA02363	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Cold sweat, Dizziness, Nausea, Pallor

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient with no medical history or allergies reported, who on 12-MAY-2008 was vaccinated intramuscularly with the first dose 0.5 ml dose of GARDASIL (Lot #655604/0052X). Concomitant therapy included oral contraceptives (unspecified). On 12-MAY-2008, "within a few minutes of receiving her first dose," the patient became lightheaded, pale, developed a cold sweat and nausea. No diagnostic laboratory testing was performed. On 12-MAY-2008 the patient recovered while in the office. No product quality complaint was involved. The reporter considered lightheadedness, pale, cold sweat and nausea to be disabling for a short time while the patient was in the office. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313736-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Apr-2008	01-May-2008	3	28-May-2008	29-May-2008	WA	WAES0805USA02970	29-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2604AA		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	
DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B06BAA		Unknown	Unknown	
IPV	UNKNOWN MANUFACTURER	AC52B06BAA		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Nausea, Pain

Symptom Text: Initial and follow up information has been received from a physician and by telephone from a registered nurse (R.N.) concerning a 17 year old female patient who on 28-APR-2008 was vaccinated with a first dose of GARDASIL lot # 659180/1758U. Concomitant therapy included DTAP-IPV, MENACTRA and ACCUTANE. On 01-MAY-2008 the patient experienced severe headache and nausea and after getting the first injection and went to the emergency room (ER). The next day, on 02-MAY-2008 she went to her physician's office and her physician sent her to the hospital. While at the hospital she was given Intravenous (IV) Fluids and narcotics for the pain. Unspecified laboratory blood work was done. In follow up telephone call to the office the nurse reported that there was no documentation regarding patient's hospitalization. No additional information was provided. The patient was reported as recovered at the time of this report. Additional information has been requested.

Other Meds: ACCUTANE

Lab Data: diagnostic laboratory, 05/01?/08

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314318-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jan-2008	03-Jan-2008	0	30-May-2008	02-Jun-2008	FR	WAES0802USA02824	02-Jun-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy, Premature labour, Uterine contractions during pregnancy

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 03-JAN-2008 was vaccinated IM into the upper arm with a third dose of GARDASIL. On 21-JAN-2008, the physician diagnosed the pregnancy at 10 weeks. Last menstrual period was on 17-NOV-2007. It was reported that the pregnancy was timely and normal. On 03-MAY-2008, the patient was admitted to the hospital by ambulance due to regular increased uterine contractions and breech presentation. An emergency cesarean section was performed due to a completely opened cervix and a prolapsed amniotic sac. A premature female was born in week 24 with a weight of 784 grams. The APGAR score was 5/6/7. The child was transferred to a pediatric hospital on 03-MAY-2008. On 07-MAY-2008 the patient was discharged in good condition. It was reported that the first and second vaccination with GARDASIL were well tolerated. Other business partner numbers include: E2008-00657. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 314319-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Dec-2007	01-Jan-2008	31	30-May-2008	02-Jun-2008	FR	WAES0805USA04649	02-Jun-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Aspartate aminotransferase increased, Asthenia, Blood cholesterol increased, Constipation, Helicobacter infection, Hepatic haemorrhage, Red blood cell sedimentation rate increased, Splenomegaly

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history reported who in December 2007 was vaccinated with the first dose of GARDASIL. Concomitant medication was not reported. In approximately January 2008, 4 week post vaccination, the patient developed weakness, constipation and wasn't able to eat. The patient was hospitalized for 4 days. The findings showed increased liver parameters especially serum aspartate aminotransferase test (SGOT); increased cholesterol; and blood sedimentation (35/70). Further to this an abdominal sonography was performed and it showed a splenomegaly and the liver showed haemorrhagic bleeding. A gastroscopy showed an infection with helicobacter, so treatment with PANTOLOC was started. Subsequently on an unspecified date, the patient recovered from weakness, constipation and wasn't able to eat. Other business partner numbers included E2008-04606. It was also reported that the patient was vaccinated with a second dose of GARDASIL and experienced adverse events (E2008-04621). Additional information has been requested.

Other Meds: Unknown

Lab Data: abdominal ultrasound, ??Jan?08, splenomegaly and liver showed haemorrhagic bleeding; gastroscopy, ??Jan?08, infection with helicobacter

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314321-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-May-2008	17-May-2008	8	30-May-2008	02-Jun-2008	FR	WAES0805USA04983	02-Jun-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Dyspnoea, Malaise, Paraesthesia, Sensation of heaviness, Skin warm

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 09-MAY-2008 was vaccinated in the shoulder (route not reported) with the third dose of GARDASIL. On 17-MAY-2008 (eight days after the vaccination), the patient experienced severe malaise with loss of speech and paresthesia in the left lower limb. She was brought to the hospital. A doppler ultrasound was performed for suspected phlebitis. The result was negative and the patient was discharged the same day. on 18-MAY-2008, the patient experienced a second episode of malaise and paresthesia and was brought to the hospital again. The patient also experienced dyspnea. A chest CT scan was performed as pulmonary embolism was suspected. The result was normal. A head CT scan was performed and had normal results. The patient was seen by a cardiologist and a neurologist who both found nothing. All reflexes were present, however the patient had sequelae of paresthesia in the left lower limb: she felt heaviness and warmth in the leg. Complete blood work-up was performed. No diagnosis was reported further to hospitalization. No local reaction was observed. Noted was that the patient was coming back from a trip to a foreign country. The patient also experienced (vasovagal reaction 10 to 15 days after first and second injection of GARDASIL (dates not reported) (cf. linked case E2008-4653). Other business partner numbers include E2008-04583 and E2008-04653.

Other Meds: Unknown

Lab Data: Ultrasound, 17May08, negative; Chest computed axial tomography, 18May08, Normal; Head computed axial tomography, 18May2008, Normal.

History: Unknown

Prex Illness:

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:

Vaers Id: 314527-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-May-2008	19-May-2008	0	02-Jun-2008	03-Jun-2008	FR	WAES0805USA05505	03-Jun-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, General physical condition abnormal, Nausea, Pallor, Vomiting

Symptom Text: Information has been received from a pediatrician concerning a 14 year old female who on 19-MAY-2008 was vaccinated with a third dose of GARDASIL (lot # not reported) IM into the upper arm. On 19-MAY-2008 in the evening post vaccination the patient experienced chills, pallor, nausea and vomiting. The general condition was reduced. The patient was hospitalised for diagnostics. At the time of reporting the symptoms were still ongoing. Previous two vaccinations with GARDASIL were given on unknown dates and were well tolerated. Other business partner numbers included are: E2008-04584. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Previous two vaccinations with GARDASIL were given on unknown dates and were well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: 314559-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-May-2008	31-May-2008	9	02-Jun-2008	05-Jun-2008	NC		05-Jun-2008

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Pericardial effusion, Pericarditis

Symptom Text: 05/31/08- SOB and chest pain 06/01/08- Chest pain, pericardial effusion, Pericarditis

Other Meds: Ventolin, Prednisone, Zithromax, Ibuprofen

Lab Data:

History: Asthma

Prex Illness: NONE

Prex Vax Illns: