

Suspected Adverse Reaction Analysis

CERVARIX Human papillomavirus (HPV) vaccine

4 February 2010

This report summarises the adverse reactions suspected to have been caused by Cervarix human papillomavirus (HPV) vaccine in the UK. This includes reports received between 14 April 2008 and 3 February 2010. These reports have been voluntarily submitted to the MHRA by healthcare professionals and members of the public via the Yellow Card Scheme (visit www.yellowcard.gov.uk) and by the manufacturers of the vaccine as part of their legal requirements.

It is essential to bear in mind that reports to the MHRA relate only to adverse medical events which the reporter considered could have been caused by the vaccine (i.e. if there was merely a **suspicion** of causality). Therefore, cases may be true side-effects or they may have been purely coincidental events due to underlying or undiagnosed illness that would have occurred anyway in the absence of vaccination. Events may also have been psychogenic¹ in origin. This report therefore cannot be considered to represent a list of known side-effects of the vaccine. These data also cannot be used to determine the frequency, or incidence, of known side-effects because they are often under-reported. The known side-effects, and their frequencies (based on clinical trial data), are available in the product information (see <http://emc.medicines.org.uk/>).

The reactions in this report have been broken down into 5 categories based on scientific assessment of individual cases by MHRA assessors: injection-site reactions; allergic reactions; 'psychogenic' events; other recognised reactions; and 'suspected adverse reactions not currently recognised' (reactions in this latter category are divided into the high-level classification of System Organ Class)². The same event term may appear in more than one category (e.g. 'rash' may be associated with injection site, allergic or unrecognised suspected reactions and 'psychogenic' events). However, an event from a single report will appear in only one category.

A single report may contain more than one reaction, more than one sign or symptom of a single reaction or different reactions in more than one of the above categories. Therefore the total number of listed reactions is greater than the total number of reports and total reports in each of the 5 tables should not be added together.

Headline summary:

To date, the vast majority of suspected adverse reactions reported to MHRA in association with Cervarix vaccine have related either to the signs and symptoms of recognised side effects listed in the product information or were due to the injection process and not the vaccine itself (i.e. 'psychogenic' in nature).

For the isolated cases of other medical conditions reported, the available evidence does not suggest that the vaccine caused the condition and these may have been coincidental events.

Following administration of more than 3.5 million doses across the UK since last September, the balance of risks and benefits of Cervarix remains positive.

¹ For this analysis, defined as non-allergic events which occurred within minutes of, or soon after, vaccination and were most likely a psychogenic response to, or anticipation of, the injection. These are not side effects to the vaccine as such and can occur with any needle injection procedure.

²Using MedDRA terminology

SUMMARY OF UK SAFETY EXPERIENCE

Total number of reports received: 3,210

Total number of suspected reactions: 7,277

Estimated number of doses administered across the UK: at least 3.5 million doses³

A. Injection-site reactions

Injection-site reactions including redness, pain and swelling are recognised side-effects of Cervarix vaccine and are listed in the product information. These may occur at a frequency⁴ of more than 1 in 10 persons vaccinated. The reported cases of 'Pain in extremity' mainly relate to a sore arm.

The cases reported to the MHRA during use of the vaccine in the UK do not indicate any change in the severity or nature of injection-site reactions.

Reported event (Preferred Term ²)	Number of cases
Pain in extremity	335
Injection site swelling	93
Oedema peripheral	75
Hypoaesthesia	74
Injection site pain	66
Limb discomfort	63
Injection site erythema	59
Erythema	36
Skin discolouration	27
Injection site rash	25
Paraesthesia	23
Injection site reaction	22
Local reaction	17
Musculoskeletal stiffness	16
Peripheral coldness	15
Local swelling	14
Pain	14
Injection site inflammation	13
Injection site mass	12
Injection site warmth	12
Rash macular	9
Contusion	7
Injection site induration	7
Injection site pruritus	7
Swelling	7
Feeling cold	6
Sensation of heaviness	6
Myalgia	5
Asthenia	4
Cyanosis	4
Injection site anaesthesia	4
Injection site nodule	4
Livedo reticularis	4
Muscular weakness	4

³ Based on UK-wide vaccine uptake data up to the end of 2009. As the Yellow Card data are up to the present date, the available uptake data should not be used to derive adverse reaction reporting rates (as this will result in an over-estimation)

⁴ Based on clinical trial data

Pallor	4
Rash	4
Sensory disturbance	4
Feeling hot	3
Injection site discharge	3
Injection site discolouration	3
Injection site haematoma	3
Injection site infection	3
Injection site urticaria	3
Limb immobilisation	3
Neck pain	3
Poor peripheral circulation	3
Complex regional pain syndrome	2
Dry skin	2
Feeling abnormal	2
Grip strength decreased	2
Inflammation	2
Injected limb mobility decreased	2
Injection site irritation	2
Injection site vesicles	2
Musculoskeletal pain	2
Pruritus	2
Sensory loss	2
Skin reaction	2
Blister	1
Hypokinesia	1
Immobile	1
Impetigo	1
Injection site abscess	1
Injection site cellulitis	1
Injection site discomfort	1
Injection site haemorrhage	1
Injection site joint pain	1
Injection site movement impairment	1
Injection site papule	1
Injection site paraesthesia	1
Injection site scab	1
Lymphadenopathy	1
Muscle spasms	1
Muscle tightness	1
Nodule	1
Pain of skin	1
Peripheral vascular disorder	1
Rash maculo-papular	1
Rash pruritic	1
Scab	1
Sensation of pressure	1
Tenderness	1
Tremor	1
Urticaria	1
Total reactions	1178
Total reports	811

B. Allergic reactions (including skin reactions not directly related to an injection-site reaction)

Allergic reactions are recognised side-effect of Cervarix vaccine and are listed in the product information. These may occur at a frequency⁴ between 1 in 10 persons (for non-serious types of allergic reaction such as rash and itching) to less than 1 in 10,000 persons vaccinated. Severe allergic reactions are very rare.

The cases reported to the MHRA during use of the vaccine in the UK do not indicate any change in the severity or nature of allergic reactions.

Reported event (Preferred Term ²)	Number of cases
Rash	109
Urticaria	71
Pruritus	46
Erythema	35
Swelling face	35
Anaphylactic reaction	28
Oedema peripheral	28
Rash pruritic	28
Rash generalised	27
Dyspnoea	26
Lip swelling	22
Rash macular	22
Dizziness	20
Hypersensitivity	20
Eye swelling	16
Paraesthesia oral	16
Malaise	11
Throat tightness	11
Rash erythematous	10
Pallor	9
Chest discomfort	8
Feeling hot	8
Pruritus generalised	8
Swollen tongue	8
Dermatitis allergic	7
Paraesthesia	7
Pharyngeal oedema	7
Angioedema	6
Flushing	6
Inflammation	6
Fatigue	5
Headache	5
Hyperventilation	5
Oropharyngeal pain	5
Anaphylactic shock	4
Hypoaesthesia	4
Nausea	4
Pain in extremity	4
Syncope	4
Throat irritation	4

Vomiting	4
Wheezing	4
Blister	3
Cold sweat	3
Dysphagia	3
Eye pruritus	3
Hyperhidrosis	3
Hypoaesthesia oral	3
Laryngeal oedema	3
Limb discomfort	3
Nasopharyngitis	3
Ocular hyperaemia	3
Pain	3
Peripheral coldness	3
Petechiae	3
Pyrexia	3
Abdominal pain	2
Abdominal pain upper	2
Dermatitis contact	2
Eyelid oedema	2
Face oedema	2
Feeling cold	2
Heart rate increased	2
Local swelling	2
Purpura	2
Rash maculo-papular	2
Skin discolouration	2
Skin disorder	2
Skin irritation	2
Skin reaction	2
Somnolence	2
Swelling	2
Tachycardia	2
Type I hypersensitivity	2
Vision blurred	2
Anaphylactoid reaction	1
Asthenia	1
Asthenopia	1
Back pain	1
Body temperature increased	1
Confusional state	1
Conjunctival hyperaemia	1
Convulsion	1
Cough	1
Dermatitis	1
Eczema	1
Eyelid disorder	1
Eyes sunken	1
Feeling abnormal	1
Feeling jittery	1
Generalised erythema	1
Gingival swelling	1
Heart rate irregular	1
Hypersomnia	1

Hypertension	1
Increased bronchial secretion	1
Infusion site swelling	1
Injection site inflammation	1
Lip ulceration	1
Local reaction	1
Migraine	1
Muscle tightness	1
Musculoskeletal stiffness	1
Neck pain	1
Oedema mouth	1
Oral discomfort	1
Oral pain	1
Panic reaction	1
Periorbital oedema	1
Photophobia	1
Piloerection	1
Rash follicular	1
Rash papular	1
Respiratory rate increased	1
Sneezing	1
Speech disorder	1
Tenderness	1
Thirst	1
Tremor	1
Visual impairment	1
Total reactions	838
Total reports	431

C. 'Psychogenic' events

Psychogenic events including vasovagal syncope, faints and panic attacks can occur with any injection procedure, not just vaccination, and can be common in adolescents. These are due to fear and/or anticipation of the needle injection and are **not side-effects of Cervarix vaccine** as such. Such events can be associated with a wide range of temporary signs and symptoms including loss of consciousness, vision disturbance, injury, limb jerking (often misinterpreted as a seizure/convulsion), limb numbness or tingling, difficulty in breathing, hyperventilation etc.

The events in the list below were considered 'psychogenic' in nature based on MHRA assessment of the individual case details reported. The reported cases which do not refer specifically to vasovagal syncope, faint or panic attack (e.g. convulsion, transient blindness which refers to temporary loss of vision at the start of a faint) were concurrently reported as signs or symptom of the psychogenic event; **i.e. these also were not side-effects of the vaccine itself.**

Reported event (Preferred Term ²)	Number of cases
Dizziness	276
Syncope	254
Nausea	136
Headache	103
Pallor	96

Vomiting	70
Malaise	67
Tremor	52
Vision blurred	42
Feeling hot	38
Flushing	37
Cold sweat	31
Hyperhidrosis	23
Presyncope	21
Chills	17
Hyperventilation	17
Paraesthesia	17
Loss of consciousness	16
Somnolence	16
Dyspnoea	14
Convulsion	13
Heart rate increased	13
Muscle twitching	13
Pyrexia	13
Rash	13
Fatigue	12
Feeling cold	12
Unresponsive to stimuli	12
Chest discomfort	11
Dyskinesia	11
Eye rolling	11
Hypoaesthesia	11
Asthenia	10
Panic attack	10
Tachycardia	10
Erythema	9
Rash macular	9
Nervousness	8
Tearfulness	8
Abdominal pain upper	7
Chest pain	7
Peripheral coldness	7
Visual impairment	7
Abdominal pain	6
Confusional state	6
Fall	6
Feeling of body temperature change	6
Lethargy	6
Muscle rigidity	6
Muscular weakness	6
Musculoskeletal stiffness	6
Mydriasis	6
Nasopharyngitis	6
Photophobia	6
Anxiety	5
Deafness	5
Dysgeusia	5
Feeling abnormal	5
Skin discolouration	5

Throat tightness	5
Urticaria	5
Blindness transient	4
Body temperature increased	4
Decreased appetite	4
Dizziness postural	4
Hypotension	4
Migraine	4
Muscle spasms	4
Pulse abnormal	4
Tinnitus	4
Abasia	3
Blindness	3
Blood pressure decreased	3
Disorientation	3
Disturbance in attention	3
Feeling drunk	3
Hearing impaired	3
Heart rate irregular	3
Hot flush	3
Hypoventilation	3
Pain	3
Panic reaction	3
Sensory loss	3
Throat irritation	3
Vertigo	3
Abdominal discomfort	2
Agitation	2
Amnesia	2
Balance disorder	2
Body temperature decreased	2
Bradycardia	2
Colour blindness acquired	2
Consciousness fluctuating	2
Cyanosis	2
Diplopia	2
Dry mouth	2
Dysarthria	2
Dysphagia	2
Dysstasia	2
Emotional disorder	2
Heart rate decreased	2
Hypertension	2
Hypoacusis	2
Myalgia	2
Neck pain	2
Oropharyngeal pain	2
Pain in extremity	2
Procedural dizziness	2
Pruritus	2
Pulse pressure decreased	2
Pupil fixed	2
Rash generalised	2
Respiratory rate increased	2

Retching	2
Salivary hypersecretion	2
Shock	2
Urinary incontinence	2
Abdominal distension	1
Abnormal behaviour	1
Altered state of consciousness	1
Aphasia	1
Blood pressure increased	1
Blood pressure systolic decreased	1
Bruxism	1
Burning sensation	1
Circulatory collapse	1
Cough	1
Deafness transitory	1
Depressed level of consciousness	1
Discomfort	1
Dissociation	1
Dry throat	1
Ear discomfort	1
Ear pain	1
Eating disorder	1
Emotional distress	1
Epistaxis	1
Eyelid oedema	1
Face injury	1
Facial spasm	1
Fear	1
Feeling of despair	1
Foaming at mouth	1
Gait disturbance	1
Grand mal convulsion	1
Head banging	1
Head discomfort	1
Hemiparesis	1
Hypersomnia	1
Hypokinesia	1
Hypotonia	1
Incontinence	1
Lip swelling	1
Livedo reticularis	1
Myoclonus	1
Nervous system disorder	1
Oral discomfort	1
Palpitations	1
Paraesthesia oral	1
Peripheral circulatory failure	1
Pharyngeal oedema	1
Poor peripheral circulation	1
Psychomotor hyperactivity	1
Respiratory arrest	1
Respiratory rate decreased	1
Seizure anoxic	1
Sensation of heaviness	1

Sinus tachycardia	1
Sleep attacks	1
Sudden onset of sleep	1
Tachypnoea	1
Total reactions	1880
Total reports	725

D. 'Other recognised' reactions

This section includes other events recognised to be side-effects of Cervarix vaccine and not already included in sections A and B above. This also includes signs and symptoms of recognised side effects. The frequencies, where known, are listed in the product information.

The cases reported to the MHRA during use of the vaccine in the UK so far do not indicate any change in the severity or nature of these reactions.

Reported event (Preferred Term ²)	Number of cases
Headache	439
Nausea	434
Dizziness	414
Vomiting	197
Malaise	159
Pyrexia	130
Fatigue	118
Abdominal pain	59
Abdominal pain upper	43
Diarrhoea	41
Myalgia	38
Feeling hot	32
Body temperature increased	30
Lethargy	29
Pain	22
Arthralgia	21
Oropharyngeal pain	19
Pallor	18
Chills	15
Asthenia	14
Influenza like illness	14
Somnolence	13
Paraesthesia	12
Abdominal discomfort	11
Flushing	10
Pain in extremity	10
Tremor	8
Pruritus	7
Musculoskeletal stiffness	6
Decreased appetite	5
Neck pain	5
Feeling cold	4
Migraine	4

Rash	4
Back pain	3
Cough	3
Hyperhidrosis	3
Hypoaesthesia	3
Nervousness	3
Feeling abnormal	2
Feeling of body temperature change	2
Gait disturbance	2
Head discomfort	2
Joint swelling	2
Listless	2
Muscle fatigue	2
Photophobia	2
Skin warm	2
Abdominal pain lower	1
Axillary mass	1
Body temperature	1
Body temperature fluctuation	1
Disturbance in attention	1
Erythema	1
Generalised erythema	1
Hot flush	1
Ill-defined disorder	1
Induration	1
Insomnia	1
Local swelling	1
Loss of consciousness	1
Lower respiratory tract infection	1
Lymphadenopathy	1
Mobility decreased	1
Muscle spasms	1
Muscle twitching	1
Muscular weakness	1
Musculoskeletal chest pain	1
Musculoskeletal discomfort	1
Musculoskeletal pain	1
Nasal congestion	1
Night sweats	1
Oedema peripheral	1
Peripheral coldness	1
Pharyngitis	1
Pruritus generalised	1
Psoriasis	1
Respiratory disorder	1
Restlessness	1
Rhinorrhoea	1
Sensation of heaviness	1
Swelling	1
Thirst	1
Throat irritation	1
Throat tightness	1
Upper respiratory tract infection	1
Urticaria	1

Weight decreased	1
Total reactions	2458
Total reports	1286

E. Suspected adverse reactions not currently recognised

This section includes reports which, based on MHRA assessment of the case details provided, do not fit into one of the above 4 categories.

These suspected ADRs are not currently recognised as side effects of Cervarix vaccine and the available evidence does not suggest a causal link with the vaccine. These are isolated medical events which may have been coincidental with vaccination. These reports are continually assessed by the MHRA.

Guillain Barre Syndrome (GBS) naturally occurs in the population and is usually thought to be caused by a preceding infectious illness. More than 3.5 million doses of Cervarix have been given to girls and there is no evidence that the vaccine has increased the frequency of GBS above that expected to occur naturally in the population.

Encephalitis naturally occurs in the population and it is most often caused by a preceding viral infection. The four cases of encephalitis reported so far, amongst the several hundred thousand girls vaccinated, do not exceed the numbers normally expected in the absence of vaccination. There is therefore no suggestion at present that the vaccine can cause encephalitis.

Chronic fatigue syndrome (CFS) is not an uncommon condition amongst adolescents and rates are greater in females than in males. Given that more than 3.5 million doses of Cervarix have now been given in the UK, it is inevitable that conditions such as CFS will occur not long after vaccination regardless of any causal association with the vaccine.

MHRA has conducted an analysis of reported cases of CFS compared to the normal background frequency. This analysis shows that amongst the population of 12-13 yr old girls immunised so far in the UK, we would have expected to observe more than 70 new cases of CFS already, regardless of vaccination. We would also expect to have seen many more cases of chronic fatigue-like syndrome that have not necessarily met the diagnostic criteria for CFS amongst this population.

The Government's independent expert advisory Committee on vaccines and medicines safety, the Commission on Human Medicines (CHM), recently reviewed the cases of CFS, post-viral fatigue syndrome and cases that could possibly represent a chronic fatigue-like syndrome. They advised that the available evidence does not support a causal association between Cervarix vaccine and CFS, and the balance of risks and benefits of Cervarix remains positive. Cases of possible CFS will remain under close and continual review by the MHRA.

System Organ Class	Reported event (Preferred Term ²)	Number of cases
Blood and lymphatic system disorders	Anaemia	1
	Aplastic anaemia	1
	Eosinophilia	1
	Lymphadenopathy	14
	Neutropenia	1
Cardiac disorders	Cyanosis	1
	Palpitations	5
	Sinus tachycardia	1

	Tachycardia	1
Congenital, familial and genetic disorders	Arteriovenous malformation	1
	Hypospadias	1
	Pilonidal cyst congenital	1
Ear and labyrinth disorders	Deafness	1
	Deafness bilateral	1
	Ear pain	6
	Tinnitus	1
	Vertigo	2
Endocrine disorders	Adrenocortical insufficiency acute	1
Eye disorders	Conjunctival hyperaemia	1
	Diplopia	2
	Dry eye	1
	Excessive eye blinking	1
	Eye disorder	1
	Eye pain	1
	Eye swelling	1
	Gaze palsy	1
	Mydriasis	2
	Myodesopsia	1
	Photophobia	2
	Vision blurred	6
	Visual impairment	4
	Gastrointestinal disorders	Abdominal discomfort
Abdominal pain		9
Abdominal pain lower		1
Abdominal pain upper		1
Abnormal faeces		1
Colitis		1
Colitis ulcerative		1
Constipation		1
Diarrhoea		7
Diarrhoea haemorrhagic		1
Flatulence		1
Frequent bowel movements		1
Gastrointestinal disorder		1
Hypoesthesia oral		1
Intestinal functional disorder		1
Lip blister		1
Lip swelling		1
Mouth ulceration		2
Nausea		21
Paraesthesia oral		1
Vomiting		13
General disorders and administration site conditions	Abasia	3
	Asthenia	6
	Axillary pain	1
	Chest discomfort	5
	Chest pain	12
	Chills	3

	Chronic fatigue syndrome	3
	Condition aggravated	2
	Fatigue	13
	Feeling abnormal	2
	Feeling cold	5
	Feeling hot	1
	Gait disturbance	2
	Hyperpyrexia	1
	Inflammation	1
	Influenza like illness	27
	Local swelling	1
	Malaise	15
	Oedema peripheral	3
	Pain	10
	Pyrexia	9
	Sensation of foreign body	1
	Sensation of pressure	1
	Swelling	1
Hepatobiliary disorders	Jaundice	1
Infections and infestations	Abscess	1
	Acarodermatitis	1
	Anogenital warts	1
	Application site pustules	1
	Beta haemolytic streptococcal infection	1
	Bronchitis	1
	Folliculitis	1
	Furuncle	1
	Herpes zoster	2
	Infectious mononucleosis	1
	Influenza	2
	Kidney infection	1
	Laryngitis	1
	Lower respiratory tract infection	5
	Nasopharyngitis	5
	Pharyngitis	1
	Pneumonia viral	1
	Post viral fatigue syndrome	4
	Severe acute respiratory syndrome	1
	Staphylococcal infection	1
	Streptococcal sepsis	1
	Urinary tract infection	2
	Varicella	1
	Viraemia	1
	Viral infection	6
Injury, poisoning and procedural complications	Accidental overdose	1
	Contusion	4
	Drug exposure before pregnancy	2
	Drug exposure during pregnancy	8
	Fall	1

	Inappropriate schedule of drug administration	1	
	Wrong technique in drug usage process	1	
Investigations	Alanine aminotransferase increased	1	
	Blood cortisol decreased	1	
	Blood glucose increased	4	
	Blood pressure increased	1	
	Body temperature increased	1	
	Cell marker increased	1	
	Grip strength decreased	1	
	Heart rate decreased	1	
	Neutrophil count decreased	1	
	Respiratory rate increased	1	
	Weight decreased	3	
	Weight increased	2	
	Metabolism and nutrition disorders	Decreased appetite	7
		Dehydration	2
Diabetes mellitus inadequate control		1	
Diabetic ketoacidosis		1	
Hypoglycaemia		1	
Increased appetite		1	
Type 1 diabetes mellitus		1	
Musculoskeletal and connective tissue disorders		Arthralgia	15
	Arthritis	1	
	Arthritis reactive	1	
	Arthropathy	1	
	Back pain	10	
	Bone pain	1	
	Flank pain	1	
	Groin pain	1	
	Joint stiffness	1	
	Joint swelling	1	
	Mobility decreased	1	
	Muscle spasms	2	
	Muscle twitching	3	
	Muscular weakness	10	
	Musculoskeletal chest pain	1	
	Musculoskeletal pain	1	
	Musculoskeletal stiffness	5	
	Myalgia	8	
	Neck pain	5	
	Pain in extremity	19	
	Palindromic rheumatism	1	
	Rheumatoid arthritis	1	
	Sensation of heaviness	3	

	Weight bearing difficulty	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	1
	Benign hydatidiform mole	1
	Neoplasm malignant	1
Nervous system disorders	Aphasia	1
	Aphonia	1
	Ataxia	1
	Balance disorder	1
	Burning sensation	1
	Convulsion	20
	Coordination abnormal	1
	Crying	2
	Diplegia	2
	Disturbance in attention	2
	Dizziness	26
	Dizziness postural	1
	Dysarthria	3
	Dysgeusia	1
	Dyskinesia	3
	Dysstasia	4
	Encephalitis	4
	Epilepsy	5
	Facial palsy	2
	Grand mal convulsion	5
	Guillain-Barre syndrome	3
	Headache	34
	Head discomfort	1
	Hemiparesis	2
	Hypoaesthesia	17
	IVth nerve paralysis	1
	Lethargy	13
	Loss of consciousness	8
	Meningism	1
	Migraine	11
	Migraine with aura	1
	Monoplegia	1
	Movement disorder	1
	Myoclonic epilepsy	1
	Optic neuritis	1
	Paraesthesia	17
	Paralysis	1
	Petit mal epilepsy	1
	Presyncope	1
	Psychomotor hyperactivity	1
	Radiculitis brachial	1
	Sensory disturbance	5
	Sensory loss	2
Somnolence	12	
Status epilepticus	1	
Syncope	22	
Tremor	6	
Unresponsive to stimuli	2	
Visual field defect	3	

Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	9
	Pregnancy with injectable contraceptive	1
	Premature baby	1
Psychiatric disorders	Abnormal behaviour	1
	Acute psychosis	1
	Aggression	1
	Anxiety	3
	Confusional state	2
	Depression	1
	Disorientation	1
	Dysphemia	1
	Eating disorder	1
	Emotional disorder	2
	Fear	1
	Hallucination	5
	Hallucination, auditory	1
	Hallucination, visual	1
	Hypomania	1
	Insomnia	5
	Paranoia	1
	Psychotic disorder	1
	Screaming	1
	Sleep disorder	2
Somatisation disorder	1	
Tearfulness	1	
Renal and urinary disorders	Neurogenic bladder	1
	Pollakiuria	1
	Urinary incontinence	2
	Urinary retention	2
Reproductive system and breast disorders	Amenorrhoea	4
	Breast pain	1
	Breast swelling	1
	Breast tenderness	1
	Cervix inflammation	1
	Dysmenorrhoea	2
	Menorrhagia	4
	Menstrual disorder	1
	Menstruation delayed	1
	Menstruation irregular	2
	Metrorrhagia	1
	Vaginal discharge	1
	Vaginal haemorrhage	7
	Vaginal lesion	1
Vulval ulceration	1	
Respiratory, thoracic and mediastinal disorders	Asthma	5
	Cough	5
	Dyspnoea	16
	Epistaxis	7
	Haemoptysis	2
	Hypoventilation	1
	Increased upper airway secretion	1
	Oropharyngeal blistering	1

	Oropharyngeal pain	10
	Productive cough	1
	Rhinorrhoea	2
	Upper airway obstruction	1
	Wheezing	4
Skin and subcutaneous tissue disorders	Acne	1
	Alopecia	6
	Alopecia areata	2
	Blister	4
	Cold sweat	1
	Dermatitis allergic	1
	Eczema	4
	Eczema vesicular	1
	Erythema	2
	Erythema multiforme	4
	Guttate psoriasis	1
	Hyperhidrosis	3
	Hypoaesthesia facial	5
	Livedo reticularis	1
	Rash	4
	Rash generalised	1
	Rash maculo-papular	1
	Rash vesicular	1
	Skin discolouration	3
	Skin exfoliation	2
	Skin hypertrophy	1
	Skin irritation	1
	Skin lesion	1
	Stevens-Johnson syndrome	1
	Trichorrhexis	1
	Urticaria	2
Surgical and medical procedures	Abortion induced	1
Vascular disorders	Circulatory collapse	2
	Deep vein thrombosis	1
	Flushing	1
	Haemorrhage	1
	Hot flush	1
	Hypotension	3
	Pallor	2
	Peripheral coldness	9
Total reactions		923
Total reports		494

In relation to safety in pregnancy, during pre-licensing studies of Cervarix it was found that almost 870 women became pregnant before or after receiving the vaccine. The overall rates of spontaneous abortion in these clinical trials were no greater than the background rates in the general population (i.e. regardless of vaccination). There is currently no evidence to suggest that Cervarix vaccine carries any risks during pregnancy. Nonetheless, Cervarix is not recommended for use in pregnancy.