

## Suspected Adverse Reaction Analysis

### CERVARIX Human papillomavirus (HPV) vaccine

3 December 2009

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 2 December 2009. 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](http://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 psychogenic<sup>1</sup> 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)<sup>2</sup>. 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 1.4 million doses across the UK since last September, the balance of risks and benefits of Cervarix remains positive.**

<sup>1</sup> 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.

<sup>2</sup>Using MedDRA terminology

## SUMMARY OF UK SAFETY EXPERIENCE

Total number of reports received: 2,602

Total number of suspected reactions: 5,922

Estimated number of doses administered across the UK: at least 1.4 million doses<sup>3</sup>

### 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 frequency<sup>4</sup> 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 <sup>2</sup> )	Number of cases
Pain in extremity	254
Injection site swelling	85
Injection site pain	62
Hypoaesthesia	60
Limb discomfort	59
Injection site erythema	55
Oedema peripheral	54
Erythema	30
Injection site rash	20
Skin discolouration	18
Injection site reaction	17
Musculoskeletal stiffness	16
Local reaction	15
Paraesthesia	13
Local swelling	12
Pain	12
Injection site mass	11
Injection site warmth	11
Injection site inflammation	10
Peripheral coldness	9
Rash macular	9
Contusion	7
Injection site pruritus	7
Feeling cold	6
Injection site induration	6
Myalgia	5
Asthenia	4
Injection site nodule	4
Muscular weakness	4
Sensation of heaviness	4
Sensory disturbance	4
Cyanosis	3
Feeling hot	3
Injection site anaesthesia	3

<sup>3</sup> Based on UK-wide vaccine uptake data to July 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)

<sup>4</sup> Based on clinical trial data

Injection site discharge	3
Injection site haematoma	3
Injection site infection	3
Injection site urticaria	3
Limb immobilisation	3
Pallor	3
Poor peripheral circulation	3
Rash	3
Swelling	3
Complex regional pain syndrome	2
Grip strength decreased	2
Inflammation	2
Injected limb mobility decreased	2
Injection site discolouration	2
Injection site irritation	2
Injection site vesicles	2
Musculoskeletal pain	2
Pruritus	2
Sensory loss	2
Skin reaction	2
Blister	1
Feeling abnormal	1
Hypokinesia	1
Immobile	1
Impetigo	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
Livedo reticularis	1
Lymphadenopathy	1
Muscle spasms	1
Muscle tightness	1
Neck pain	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	<b>968</b>
Total reports	<b>666</b>

**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 frequency<sup>4</sup> 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 <sup>2</sup> )	Number of cases
Rash	79
Urticaria	52
Pruritus	34
Swelling face	28
Anaphylactic reaction	26
Rash pruritic	25
Oedema peripheral	24
Erythema	23
Rash generalised	21
Lip swelling	20
Dyspnoea	19
Hypersensitivity	17
Rash macular	17
Dizziness	13
Eye swelling	13
Paraesthesia oral	12
Throat tightness	9
Chest discomfort	7
Pallor	7
Rash erythematous	7
Flushing	6
Malaise	6
Pharyngeal oedema	6
Pruritus generalised	6
Swollen tongue	6
Angioedema	5
Paraesthesia	5
Anaphylactic shock	4
Nausea	4
Syncope	4
Vomiting	4
Wheezing	4
Eye pruritus	3
Feeling hot	3
Hyperhidrosis	3
Hyperventilation	3
Nasopharyngitis	3
Ocular hyperaemia	3
Oropharyngeal pain	3
Throat irritation	3
Blister	2

Cold sweat	2
Dysphagia	2
Eyelid oedema	2
Fatigue	2
Feeling cold	2
Headache	2
Heart rate increased	2
Hypoaesthesia	2
Inflammation	2
Laryngeal oedema	2
Limb discomfort	2
Local swelling	2
Pain	2
Peripheral coldness	2
Petechiae	2
Purpura	2
Pyrexia	2
Rash maculo-papular	2
Skin discolouration	2
Skin disorder	2
Skin irritation	2
Tachycardia	2
Type I hypersensitivity	2
Abdominal pain	1
Abdominal pain upper	1
Asthenia	1
Asthenopia	1
Body temperature increased	1
Confusional state	1
Conjunctival hyperaemia	1
Convulsion	1
Cough	1
Dermatitis	1
Dermatitis allergic	1
Dermatitis contact	1
Eczema	1
Eyelid disorder	1
Eyes sunken	1
Face oedema	1
Feeling abnormal	1
Generalised erythema	1
Gingival swelling	1
Heart rate irregular	1
Hypersomnia	1
Hypertension	1
Increased bronchial secretion	1
Injection site inflammation	1
Lip ulceration	1
Migraine	1
Musculoskeletal stiffness	1
Neck pain	1
Oral discomfort	1
Oral pain	1
Pain in extremity	1

Panic reaction	1
Periorbital oedema	1
Photophobia	1
Piloerection	1
Rash follicular	1
Respiratory rate increased	1
Skin reaction	1
Sneezing	1
Somnolence	1
Speech disorder	1
Swelling	1
Thirst	1
Tremor	1
Vision blurred	1
Visual impairment	1
Total reactions	<b>631</b>
Total reports	<b>338</b>

### 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 <sup>2</sup> )	Number of cases
Syncope	232
Dizziness	216
Nausea	103
Headache	86
Pallor	85
Malaise	57
Vomiting	48
Tremor	46
Flushing	33
Vision blurred	33
Feeling hot	32
Cold sweat	29
Hyperhidrosis	20
Presyncope	18
Loss of consciousness	16
Paraesthesia	16
Convulsion	13

Dyspnoea	12
Heart rate increased	12
Muscle twitching	12
Pyrexia	12
Unresponsive to stimuli	12
Dyskinesia	11
Hyperventilation	11
Rash	11
Chest discomfort	10
Chills	10
Eye rolling	10
Somnolence	10
Asthenia	9
Hypoaesthesia	9
Panic attack	9
Tachycardia	9
Fatigue	8
Feeling cold	8
Erythema	7
Peripheral coldness	7
Rash macular	7
Tearfulness	7
Abdominal pain	6
Confusional state	6
Feeling of body temperature change	6
Lethargy	6
Muscle rigidity	6
Muscular weakness	6
Musculoskeletal stiffness	6
Visual impairment	6
Abdominal pain upper	5
Deafness	5
Dysgeusia	5
Fall	5
Feeling abnormal	5
Mydriasis	5
Nervousness	5
Throat tightness	5
Urticaria	5
Blindness transient	4
Hypotension	4
Nasopharyngitis	4
Pulse abnormal	4
Skin discolouration	4
Tinnitus	4
Blindness	3
Blood pressure decreased	3
Body temperature increased	3
Chest pain	3
Decreased appetite	3
Disorientation	3
Dizziness postural	3
Feeling drunk	3
Heart rate irregular	3

Hypoventilation	3
Muscle spasms	3
Pain	3
Photophobia	3
Sensory loss	3
Abasia	2
Abdominal discomfort	2
Agitation	2
Amnesia	2
Anxiety	2
Aphasia	2
Body temperature decreased	2
Bradycardia	2
Consciousness fluctuating	2
Cyanosis	2
Diplopia	2
Disturbance in attention	2
Dysarthria	2
Dysphagia	2
Emotional disorder	2
Hearing impaired	2
Heart rate decreased	2
Hot flush	2
Hypertension	2
Hypoacusis	2
Migraine	2
Myalgia	2
Neck pain	2
Pain in extremity	2
Panic reaction	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
Throat irritation	2
Abdominal distension	1
Altered state of consciousness	1
Balance disorder	1
Blood pressure increased	1
Blood pressure systolic decreased	1
Bruxism	1
Burning sensation	1
Cough	1
Deafness transitory	1
Dehydration	1
Depressed level of consciousness	1
Discomfort	1
Dry mouth	1
Dry throat	1

Dysstasia	1
Ear discomfort	1
Ear pain	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
Grand mal convulsion	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
Oropharyngeal pain	1
Palpitations	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
Urinary incontinence	1
Vertigo	1
Total reactions	<b>1577</b>
Total reports	<b>593</b>

#### 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 <sup>2</sup> )	Number of cases

Headache	361
Nausea	345
Dizziness	315
Vomiting	145
Malaise	119
Pyrexia	109
Fatigue	106
Abdominal pain	49
Myalgia	36
Abdominal pain upper	35
Diarrhoea	33
Body temperature increased	25
Feeling hot	25
Lethargy	25
Arthralgia	22
Pain	18
Oropharyngeal pain	16
Chills	15
Pallor	14
Paraesthesia	13
Somnolence	13
Asthenia	10
Abdominal discomfort	9
Influenza like illness	9
Pain in extremity	8
Pruritus	7
Musculoskeletal stiffness	6
Feeling cold	4
Flushing	4
Neck pain	4
Tremor	4
Back pain	3
Cough	3
Decreased appetite	3
Hypoaesthesia	3
Rash	3
Head discomfort	2
Joint swelling	2
Listless	2
Photophobia	2
Skin warm	2
Abdominal pain lower	1
Body temperature fluctuation	1
Erythema	1
Feeling abnormal	1
Feeling of body temperature change	1
Gait disturbance	1
Hot flush	1
Hyperhidrosis	1
Ill-defined disorder	1
Induration	1
Insomnia	1
Local swelling	1
Loss of consciousness	1

Lower respiratory tract infection	1
Migraine	1
Muscle fatigue	1
Muscle spasms	1
Muscle twitching	1
Muscular weakness	1
Musculoskeletal chest pain	1
Musculoskeletal discomfort	1
Musculoskeletal pain	1
Nasal congestion	1
Nervousness	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 tightness	1
Upper respiratory tract infection	1
Urticaria	1
Total reactions	<b>1966</b>
Total reports	<b>1037</b>

#### **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 1.4 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 two 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 1.4 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 <sup>2</sup> )	Number of cases
Blood and lymphatic system disorders	Anaemia	1
	Eosinophilia	1
	Lymphadenopathy	14
Cardiac disorders	Cyanosis	1
	Palpitations	3
	Sinus tachycardia	1
	Tachycardia	1
Congenital, familial and genetic disorders	Arteriovenous malformation	1
Ear and labyrinth disorders	Deafness	1
	Deafness bilateral	1
	Ear pain	6
	Tinnitus	1
Eye disorders	Diplopia	1
	Dry eye	1
	Excessive eye blinking	1
	Eye pain	1
	Eye swelling	1
	Mydriasis	1
	Myodesopsia	1
	Photophobia	2
	Vision blurred	6
	Visual impairment	4
Gastrointestinal disorders	Abdominal discomfort	1
	Abdominal pain	6
	Abdominal pain lower	1
	Abdominal pain upper	1
	Abnormal faeces	1
	Colitis	1
	Colitis ulcerative	1
	Constipation	1
	Diarrhoea	5
	Diarrhoea haemorrhagic	1
	Flatulence	1
	Frequent bowel movements	1
	Gastrointestinal disorder	1
	Hypoaesthesia oral	1
	Lip blister	1
	Lip swelling	1
	Mouth ulceration	2

	Nausea	16
	Paraesthesia oral	1
	Vomiting	11
General disorders and administration site conditions	Abasia	3
	Asthenia	5
	Axillary pain	1
	Chest discomfort	5
	Chest pain	11
	Chills	3
	Chronic fatigue syndrome	3
	Condition aggravated	1
	Fatigue	10
	Feeling abnormal	2
	Feeling cold	4
	Feeling hot	1
	Gait disturbance	2
	Hyperpyrexia	1
	Inflammation	1
	Influenza like illness	26
	Local swelling	1
	Malaise	12
	Oedema peripheral	3
	Pain	10
	Pyrexia	7
	Sensation of foreign body	1
	Sensation of pressure	1
	Swelling	1
	Thirst	1
	Infections and infestations	Abscess
Acarodermatitis		1
Anogenital warts		1
Application site pustules		1
Bronchitis		1
Folliculitis		1
Furuncle		1
Herpes zoster		2
Infectious mononucleosis		1
Influenza		2
Kidney infection		1
Lower respiratory tract infection		5
Nasopharyngitis		4
Pharyngitis		1
Pneumonia viral		1
Post viral fatigue syndrome		4
Severe acute respiratory syndrome		1
Staphylococcal infection		1
Streptococcal sepsis		1
Tonsillitis		1
Urinary tract infection		2
Varicella	1	
Viral infection	6	

Injury, poisoning and procedural complications	Contusion	4
	Drug exposure during pregnancy	5
	Wrong technique in drug usage process	1
Investigations	Alanine aminotransferase increased	1
	Blood glucose increased	3
	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	2
	Weight increased	2
	Metabolism and nutrition disorders	Decreased appetite
Dehydration		1
Diabetes mellitus inadequate control		1
Diabetic ketoacidosis		1
Hypoglycaemia		1
Increased appetite		1
Type 1 diabetes mellitus		1
Musculoskeletal and connective tissue disorders	Arthralgia	13
	Arthritis	1
	Arthritis reactive	1
	Back pain	4
	Bone pain	1
	Flank pain	1
	Groin pain	1
	Joint swelling	1
	Mobility decreased	1
	Muscle spasms	2
	Muscle twitching	3
	Muscular weakness	9
	Musculoskeletal chest pain	1
	Musculoskeletal pain	1
	Musculoskeletal stiffness	5
	Myalgia	7
	Neck pain	5
	Pain in extremity	18
	Palindromic rheumatism	1
	Rheumatoid arthritis	1
	Sensation of heaviness	2
	Weight bearing difficulty	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia
Benign hydatidiform mole		1
Neoplasm malignant		1

Nervous system disorders	Ataxia	1
	Burning sensation	1
	Convulsion	19
	Coordination abnormal	1
	Crying	2
	Diplegia	2
	Disturbance in attention	2
	Dizziness	20
	Dizziness postural	1
	Dysarthria	3
	Dysgeusia	1
	Dyskinesia	3
	Dysstasia	4
	Encephalitis	2
	Epilepsy	5
	Facial palsy	1
	Grand mal convulsion	5
	Guillain-Barre syndrome	2
	Headache	27
	Hemiparesis	2
	Hypoaesthesia	11
	Lethargy	10
	Loss of consciousness	7
	Meningism	1
	Migraine	11
	Migraine with aura	1
	Monoplegia	1
	Myoclonic epilepsy	1
	Optic neuritis	1
	Paraesthesia	8
	Paralysis	1
	Petit mal epilepsy	1
	Psychomotor hyperactivity	1
	Radiculitis brachial	1
	Sensory disturbance	4
	Sensory loss	1
	Somnolence	11
	Status epilepticus	1
	Syncope	21
	Tremor	5
Unresponsive to stimuli	2	
Visual field defect	3	
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	7
	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, visual	1
	Hypomania	1
	Insomnia	5
	Paranoia	1
	Screaming	1
	Sleep disorder	2
	Somatisation disorder	1
	Tearfulness	1
Renal and urinary disorders	Pollakiuria	1
	Urinary incontinence	2
	Urinary retention	1
Reproductive system and breast disorders	Amenorrhoea	3
	Breast pain	1
	Breast swelling	1
	Breast tenderness	1
	Cervix inflammation	1
	Dysmenorrhoea	1
	Menorrhagia	3
	Menstrual disorder	1
	Menstruation irregular	1
	Metrorrhagia	1
	Vaginal discharge	1
	Vaginal haemorrhage	6
	Vaginal lesion	1
	Vulval ulceration	1
Respiratory, thoracic and mediastinal disorders	Asthma	5
	Cough	5
	Dyspnoea	16
	Epistaxis	6
	Haemoptysis	2
	Hypoventilation	1
	Increased upper airway secretion	1
	Oropharyngeal blistering	1
	Oropharyngeal pain	9
	Productive cough	1
	Rhinorrhoea	2
	Upper airway obstruction	1
	Wheezing	4
Skin and subcutaneous tissue disorders	Acne	1
	Alopecia	4
	Alopecia areata	2
	Blister	4
	Cold sweat	1
	Dermatitis allergic	1
	Eczema	4
	Erythema	2
	Erythema multiforme	4
	Guttate psoriasis	1
	Hyperhidrosis	3
	Hypoesthesia facial	4

	Rash	3
	Rash generalised	1
	Rash maculo-papular	1
	Rash vesicular	1
	Skin discolouration	3
	Skin exfoliation	2
	Skin hypertrophy	1
	Skin lesion	1
	Stevens-Johnson syndrome	1
	Trichorrhexis	1
	Urticaria	2
Surgical and medical procedures	Abortion induced	1
Vascular disorders	Circulatory collapse	1
	Deep vein thrombosis	1
	Flushing	1
	Haemorrhage	1
	Hot flush	1
	Hypotension	3
	Pallor	2
	Peripheral coldness	8
Total reactions		<b>780</b>
Total reports		<b>428</b>

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.