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An tÚdarás Rialála Táirgí Sláinte
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Summary listing of suspected adverse reactions/events reported to the HPRA in association with Gardasil 01/01/2010-31/12/2017

SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Blood and lymphatic system disorders	Anaemia	1
	Anaemia vitamin B12 deficiency	1
	Haemorrhagic diathesis	1
	Immune thrombocytopenic purpura	4
	Increased tendency to bruise	1
	Lymphadenitis	1
	Lymphadenopathy	19
	Lymphatic disorder	1
	Mast cell activation syndrome	1
	Thrombocytopenia	1
	No. of Reactions	**31**
	No. of Cases	**27**
Cardiac disorders	Arrhythmia	1
	Bradycardia	1
	Cardiac disorder	1
	Cyanosis	8
	Extrasystoles	1
	Palpitations	30
	Postural orthostatic tachycardia syndrome	13
	Supraventricular tachycardia	1
	Tachycardia	16
	No. of Reactions	**72**
	No. of Cases	**58**
Congenital, familial and genetic disorders	Developmental hip dysplasia	1
	Ehlers-Danlos syndrome	1
	Tourette's disorder	1
	No. of Reactions	**3**
	No. of Cases	**3**
Ear and labyrinth disorders	Deafness transitory	1
	Ear discomfort	1
	Ear pain	6
	Excessive cerumen production	1
	Hyperacusis	13
	Hypoacusis	1
	Middle ear disorder	1
	Motion sickness	1
	Tinnitus	3
	Vertigo	5
	No. of Reactions	**33**
	No. of Cases	**27**
	Addison's disease	1

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Endocrine disorders	Adrenal insufficiency	1
	Autoimmune hypothyroidism	1
	Basedow's disease	1
	Hyperthyroidism	1
	Hypothyroidism	3
	Thyroid disorder	2
	Thyroiditis	1
	No. of Reactions	**11**
	No. of Cases	**6**
Eye disorders	Altered visual depth perception	1
	Blepharitis	1
	Blepharospasm	4
	Blindness	2
	Blindness transient	4
	Diplopia	4
	Dry eye	1
	Eye discharge	1
	Eye disorder	3
	Eye irritation	2
	Eyelid oedema	3
	Eyelid ptosis	1
	Eye movement disorder	6
	Eye oedema	2
	Eye pain	6
	Eye pruritus	4
	Eye swelling	7
	Lacrimation increased	1
	Mydriasis	1
	Ocular hyperaemia	1
	Periorbital oedema	3
	Photophobia	29
	Photopsia	1
	Vision blurred	26
	Visual acuity reduced	2
	Visual impairment	20
	Vitreous floaters	1
	No. of Reactions	**137**
	No. of Cases	**103**
	Abdominal discomfort	26
	Abdominal distension	5
	Abdominal migraine	3
	Abdominal pain	53

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Gastrointestinal disorders	Abdominal pain lower	3
	Abdominal pain upper	30
	Abdominal rigidity	2
	Abdominal tenderness	1
	Appendix disorder	1
	Breath odour	1
	Chapped lips	1
	Coeliac disease	2
	Colitis	1
	Constipation	4
	Diarrhoea	20
	Dry mouth	1
	Dyschezia	1
	Dyspepsia	4
	Dysphagia	7
	Epigastric discomfort	3
	Functional gastrointestinal disorder	1
	Gastric disorder	2
	Gastritis	3
	Gastrointestinal disorder	9
	Gastrointestinal inflammation	1
	Gastrooesophageal reflux disease	4
	Haematochezia	1
	Hypoaesthesia oral	1
	Intestinal haemorrhage	1
	Irritable bowel syndrome	9
	Lip blister	1
	Lip swelling	7
	Mouth swelling	1
	Mouth ulceration	3
	Nausea	157
	Oral disorder	1
	Oral mucosal blistering	2
	Oral mucosal eruption	1
	Pancreatitis	1
	Pancreatitis acute	1
	Pancreatitis chronic	1
	Paraesthesia oral	2
	Reflux gastritis	3
	Retching	1
	Swollen tongue	5
	Tongue oedema	1
	Toothache	1

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
	Vomiting	78
	Vomiting projectile	1
	No. of Reactions	**469**
	No. of Cases	**324**

General disorders and administration site conditions	Adverse drug reaction	2
	Adverse event	1
	Asthenia	124
	Chest discomfort	18
	Chest pain	38
	Chills	19
	Chronic fatigue syndrome	18
	Condition aggravated	2
	Crying	3
	Cyst	4
	Decreased activity	1
	Developmental regression	1
	Discomfort	3
	Exercise tolerance decreased	2
	Extensive swelling of vaccinated limb	1
	Face oedema	3
	Facial pain	1
	Fatigue	213
	Feeling abnormal	38
	Feeling cold	14
	Feeling hot	17
	Feeling of body temperature change	9
	Gait disturbance	16
	Gait inability	1
	General physical health deterioration	5
	General symptom	1
	Glassy eyes	1
	Ill-defined disorder	1
	Impaired healing	1
	Inflammation	3
	Influenza like illness	26
	Injection site bruising	1
	Injection site erythema	10
	Injection site haemorrhage	1
	Injection site induration	3
	Injection site joint pain	1
	Injection site joint swelling	1
	Injection site mass	2

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	Injection site oedema	1
	Injection site pain	23
	Injection site paraesthesia	1
	Injection site pruritus	3
	Injection site rash	3
	Injection site reaction	3
	Injection site streaking	1
	Injection site swelling	10
	Injection site warmth	2
	Local reaction	4
	Malaise	105
	Mucosal haemorrhage	1
	No adverse event	25
	Oedema	1
	Oedema peripheral	1
	Pain	58
	Peripheral swelling	19
	Pyrexia	71
	Sensation of foreign body	2
	Swelling	11
	Temperature intolerance	1
	Temperature regulation disorder	5
	Tenderness	3
	Thirst	3
	No. of Reactions	**963**
	No. of Cases	**492**
Immune system disorders	Anaphylactic reaction	11
	Anaphylactoid reaction	1
	Autoimmune disorder	6
	Decreased immune responsiveness	1
	Food allergy	3
	Hypersensitivity	21
	Immune system disorder	11
	Immunodeficiency	2
	Immunosuppression	1
	Reaction to excipient	1
	Reaction to preservatives	1
	Seasonal allergy	2
	Type III immune complex mediated reaction	1
	No. of Reactions	**62**
	No. of Cases	**59**
	Abscess	1

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Infections and infestations	Adenovirus infection	1
	Appendicitis	2
	Bacterial infection	4
	Candida infection	4
	Cellulitis	2
	Coxsackie viral infection	1
	Cystitis	1
	Epstein-Barr viraemia	1
	Epstein-Barr virus infection	1
	Eye infection	1
	Fungal infection	1
	Furuncle	1
	Helicobacter infection	1
	Herpes simplex	1
	Herpes zoster	2
	Hordeolum	1
	Infection	1
	Infectious mononucleosis	3
	Kidney infection	4
	Lip infection	1
	Lower respiratory tract infection	5
	Lyme disease	6
	Meningitis viral	1
	Nasopharyngitis	3
	Oral fungal infection	1
	Otitis media	1
	Ovarian abscess	1
	Papilloma viral infection	1
	Pharyngitis	9
	Pharyngitis streptococcal	3
	Pneumonia	4
	Pneumonia chlamydial	3
	Post viral fatigue syndrome	13
	Rash pustular	1
	Respiratory tract infection	1
	Sinusitis	6
	Skin infection	1
	Tonsillitis	14
	Tonsillitis bacterial	1
	Tooth infection	1
	Tracheitis	1
	Upper respiratory tract infection	1
	Urinary tract infection	2

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
	Vestibulitis	1
	Viral infection	13
	No. of Reactions	**129**
	No. of Cases	**84**

Injury, poisoning and procedural complications	Bite	1
	Contusion	11
	Exposure during pregnancy	21
	Extra dose administered	6
	Fall	6
	Head injury	2
	Inappropriate schedule of drug administration	2
	Injury	3
	Joint dislocation	1
	Medication error	7
	Peroneal nerve injury	1
	Wound haemorrhage	1
	No. of Reactions	**62**
	No. of Cases	**58**

Investigations	Blood alkaline phosphatase increased	1
	Blood glucose decreased	2
	Blood glucose increased	1
	Blood iron decreased	3
	Blood iron increased	1
	Blood pressure abnormal	1
	Blood pressure decreased	1
	Blood urine present	1
	Body temperature decreased	2
	Body temperature fluctuation	5
	Body temperature increased	8
	Epstein-Barr virus antibody positive	1
	Grip strength decreased	1
	Heart rate abnormal	2
	Heart rate decreased	1
	Heart rate increased	9
	Heart rate irregular	5
	Hormone level abnormal	1
	Liver function test abnormal	1
	Liver function test increased	1
	Platelet count decreased	1
	Platelet count increased	1
	Pulse abnormal	4
	Pulse absent	1

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
	Quality of life decreased	2
	Respiratory rate increased	1
	Thyroid function test abnormal	1
	Vitamin D decreased	2
	Volume blood decreased	1
	Weight decreased	14
	Weight increased	4
	White blood cell count increased	1
	No. of Reactions	**81**
	No. of Cases	**70**

Metabolism and nutrition disorders	Abnormal loss of weight	2
	Decreased appetite	28
	Food intolerance	7
	Gluten sensitivity	1
	Hypophagia	1
	Hypovitaminosis	1
	Polydipsia	1
	Tetany	4
	Type 1 diabetes mellitus	1
	Vitamin B12 deficiency	1
	Vitamin D deficiency	1
	Weight fluctuation	2
	No. of Reactions	**50**
	No. of Cases	**48**

	Arthralgia	74
	Arthritis	2
	Arthropathy	3
	Axillary mass	1
	Back disorder	1
	Back pain	29
	Bone pain	5
	Connective tissue disorder	1
	Costochondritis	1
	Fibromyalgia	16
	Flank pain	1
	Groin pain	2
	Hypermobility syndrome	4
	Intervertebral disc degeneration	2
	Joint crepitation	1
	Joint hyperextension	1
	Joint stiffness	3
	Joint swelling	7

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Musculoskeletal and connective tissue disorders	Limb deformity	1
	Limb discomfort	16
	Mobility decreased	2
	Muscle atrophy	1
	Muscle fatigue	1
	Muscle rigidity	2
	Muscle spasms	20
	Muscle tightness	1
	Muscle twitching	9
	Muscular weakness	36
	Musculoskeletal pain	8
	Musculoskeletal stiffness	13
	Myalgia	50
	Myositis	1
	Neck pain	14
	Osteitis	1
	Osteoarthritis	1
	Pain in extremity	86
	Pain in jaw	1
	Polyarthritis	1
	Posture abnormal	1
	Rheumatoid arthritis	1
	SLE arthritis	1
	Spinal pain	3
	Synovial cyst	1
	Systemic lupus erythematosus	1
	Temporomandibular joint syndrome	2
	Trismus	1
	No. of Reactions	**430**
	No. of Cases	**225**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	1
	Skin papilloma	1
	No. of Reactions	**2**
	No. of Cases	**2**
	Allodynia	1
	Amnesia	26
	Aphasia	7
	Aphonia	2
	Balance disorder	5
	Basilar migraine	1
	Burning sensation	2
	Carpal tunnel syndrome	1

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Nervous system disorders	Cataplexy	2
	Central nervous system lesion	1
	Cerebral cyst	2
	Clonus	1
	Clumsiness	1
	Cluster headache	1
	Cognitive disorder	7
	Complex regional pain syndrome	4
	Coordination abnormal	1
	Demyelination	1
	Depressed level of consciousness	1
	Diplegia	1
	Disturbance in attention	42
	Dizziness	320
	Dizziness postural	1
	Drooling	1
	Drop attacks	2
	Dysarthria	5
	Dysgeusia	2
	Dyskinesia	7
	Dysstasia	5
	Epilepsy	10
	Facial paralysis	4
	Focal dyscognitive seizures	1
	Formication	1
	Generalised tonic-clonic seizure	2
	Headache	325
	Head discomfort	1
	Hemiplegia	1
	Hyperaesthesia	3
	Hypersomnia	7
	Hypoaesthesia	34
	Hypokinesia	3
	Hypotonia	1
	Irlen syndrome	1
	Lethargy	37
	Loss of consciousness	13
	Memory impairment	14
	Mental impairment	2
	Migraine	28
	Migraine with aura	1
	Monoparesis	1
	Monoplegia	4

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
	Movement disorder	1
	Multiple sclerosis	3
	Myoclonic epilepsy	1
	Myoclonus	2
	Narcolepsy	3
	Neuralgia	4
	Neurological symptom	2
	Neuromyelitis optica spectrum disorder	1
	Neuropathy peripheral	1
	Nystagmus	1
	Optic neuritis	1
	Paraesthesia	36
	Paralysis	4
	Paraparesis	1
	Paresis	2
	Parosmia	1
	Petit mal epilepsy	3
	Poor quality sleep	5
	Presyncope	15
	Psychomotor hyperactivity	1
	Restless legs syndrome	1
	Seizure	46
	Seizure like phenomena	1
	Sensory disturbance	3
	Sensory loss	3
	Sleep paralysis	2
	Slow response to stimuli	1
	Somnolence	27
	Speech disorder	2
	Syncope	143
	Tonic clonic movements	2
	Tremor	23
	Unresponsive to stimuli	1
	Visual field defect	1
	No. of Reactions	**1291**
	No. of Cases	**691**
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3
	No. of Reactions	**3**
	No. of Cases	**3**
	Abnormal behaviour	4
	Agitation	2
	Anger	1

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Psychiatric disorders	Anxiety	42
	Anxiety disorder	1
	Apathy	2
	Attention deficit/hyperactivity disorder	3
	Bruxism	1
	Confusional state	10
	Conversion disorder	2
	Depressed mood	11
	Depression	30
	Disorientation	9
	Disturbance in social behaviour	1
	Dysphemia	1
	Eating disorder	1
	Emotional distress	5
	Hallucination	3
	Helplessness	1
	Hypomania	1
	Inappropriate affect	3
	Insomnia	32
	Intentional self-injury	5
	Irritability	3
	Listless	1
	Mental disorder	3
	Mental fatigue	1
	Mood altered	1
	Mood swings	8
	Nightmare	5
	Obsessive-compulsive disorder	1
	Panic attack	24
	Personality change	2
	Phonophobia	1
	Psychiatric symptom	2
	Psychogenic seizure	2
	Restlessness	1
	Self esteem decreased	1
	Sleep disorder	15
	Sleep terror	2
	Social anxiety disorder	1
	Social fear	1
	Stress	6
	Suicidal behaviour	2
	Suicide attempt	1
	Trance	2

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SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
	No. of Reactions	**257**
	No. of Cases	**130**
Renal and urinary disorders	Bladder disorder	1
	Dysuria	1
	Hypertonic bladder	1
	Ketonuria	1
	Pollakiuria	4
	Renal pain	1
	Urinary incontinence	2
	Urinary retention	2
	No. of Reactions	**13**
	No. of Cases	**11**
Reproductive system and breast disorders	Amenorrhoea	3
	Breast mass	2
	Breast pain	1
	Dysmenorrhoea	8
	Endometriosis	2
	Menorrhagia	11
	Menstrual disorder	23
	Menstruation delayed	1
	Menstruation irregular	8
	Ovarian cyst	10
	Ovarian cyst ruptured	6
	Ovarian failure	1
	Ovulation pain	1
	Pelvic pain	2
	Polycystic ovaries	2
	Polymenorrhoea	1
	Premature menopause	3
	Vaginal discharge	1
	Vulvovaginal pain	1
	No. of Reactions	**87**
	No. of Cases	**60**
	Asthma	6
	Bronchospasm	3
	Choking	1
	Cough	20
	Cyanosis central	1
	Dyspnoea	39
	Epistaxis	8
	Hiccups	1

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Respiratory, thoracic and mediastinal disorders	Hyperventilation	8
	Hypopnoea	6
	Nasal congestion	3
	Nasal polyps	1
	Oropharyngeal pain	43
	Pharyngeal oedema	3
	Pharyngeal ulceration	1
	Pneumonia aspiration	1
	Pulmonary embolism	2
	Respiratory disorder	1
	Respiratory distress	1
	Rhinorrhoea	1
	Sinus disorder	1
	Sleep apnoea syndrome	1
	Sneezing	2
	Stridor	2
	Tachypnoea	1
	Throat irritation	1
	Throat tightness	10
	Tonsillar disorder	1
	Wheezing	6
	No. of Reactions	**175**
	No. of Cases	**126**

	Acne	5
	Alopecia	19
	Angioedema	3
	Blister	3
	Butterfly rash	1
	Chronic spontaneous urticaria	1
	Cold sweat	13
	Dermal cyst	1
	Dermatitis	1
	Dermatitis allergic	3
	Dermatitis bullous	1
	Dry skin	3
	Eczema	5
	Erythema	26
	Erythema multiforme	1
	Erythema nodosum	3
	Guttate psoriasis	1
	Hair colour changes	1
	Henoch-Schonlein purpura	2

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Skin and subcutaneous tissue disorders	Hyperhidrosis	15
	Hyperkeratosis	1
	Lichen sclerosus	1
	Livedo reticularis	1
	Pain of skin	1
	Photosensitivity reaction	5
	Pityriasis rosea	3
	Pruritus	31
	Psoriasis	2
	Purpura	2
	Rash	53
	Rash erythematous	16
	Rash generalised	2
	Rash macular	8
	Rash maculo-papular	2
	Rash papular	3
	Rash pruritic	18
	Rash vesicular	1
	Scar pain	1
	Skin discolouration	6
	Skin discomfort	1
	Skin disorder	2
	Skin hypopigmentation	1
	Skin odour abnormal	1
	Skin reaction	1
	Skin sensitisation	1
	Skin striae	14
	Skin warm	1
	Swelling face	7
	Urticaria	66
	No. of Reactions	**360**
	No. of Cases	**253**
Social circumstances	Bedridden	20
	Immobile	1
	Impaired quality of life	1
	Loss of personal independence in daily activities	14
	Social problem	1
	Wheelchair user	2
	No. of Reactions	**39**
	No. of Cases	**29**
	Appendicectomy	2
	Bladder catheterisation	1

Please also refer to the caveat document enclosed.
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Summary listing of suspected adverse reactions/events reported to the HPRA in association with Gardasil 01/01/2010-31/12/2017

SOC	Adverse Reaction (MedDRA PT)	No. of Cases (Count)
Surgical and medical procedures	Home care	1
	Ovariocentesis	1
	Tonsillectomy	1
	No. of Reactions	**6**
	No. of Cases	**4**
Vascular disorders	Blood pressure fluctuation	1
	Circulatory collapse	3
	Deep vein thrombosis	1
	Flushing	20
	Haematoma	1
	Haemorrhage	3
	Hot flush	2
	Hypertension	3
	Hypotension	20
	Orthostatic hypotension	2
	Pallor	54
	Peripheral coldness	15
	Poor peripheral circulation	1
	Raynaud's phenomenon	5
	Thrombosis	1
	Varicose vein	1
	Vein rupture	1
	No. of Reactions	**134**
	No. of Cases	**115**
	Total Number of Reactions	**4900**
	Total Number of Cases	**1112**

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STATEMENT TO ACCOMPANY ADVERSE REACTION DATA RELEASED BY THE HPRA

Introduction

This document provides background information on the HPRA adverse reaction reporting system and provides advice on interpretation of information collected through this system.

Spontaneous adverse reaction reports

The spontaneous monitoring system was established in 1968. Reports of suspected adverse reactions are received from patients and consumers, healthcare professionals and pharmaceutical companies through the online reporting options accessible from the HPRA website, in hardcopy format via freepost or by telephone. Anonymised report details are included on a computerised database to facilitate processing and evaluation of reports.

Information collected through this system is an important method of monitoring drug safety in normal clinical practice, by increasing knowledge about known adverse reactions and also by acting as an early warning system for the identification of previously unrecognised adverse reactions. Such information is one of the tools used by the HPRA in its ongoing safety evaluation of marketed drugs and is vital in identifying drugs where a change in their authorisation (licence) status is required such as the addition of warnings and precautions for use, restriction in usage, or rarely, withdrawal from the marketplace.

The HPRA issues a Drug Safety Newsletter (DSN) which is distributed through professional organisations to healthcare professionals approximately six times a year, providing updated information on adverse reactions and providing advice on safe use of specific medicines. Copies of these newsletters are available from the HPRA website (www.hpra.ie) or from the Pharmacovigilance Department, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Phone 01-6764971, Fax 01-6767836.

Adverse reaction listings

- Lists all the reactions reported to have occurred in association with a suspected drug substance/product.

- Lists all reactions included on the original report (please note that many reports contain more than one reaction, therefore the total number of reactions may exceed the number of reports received for the drug). Each report relates to an individual patient.

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- Lists reactions for a specific drug substance irrespective of whether the reporter provided the approved drug substance name or a brand name of that substance. Brand names are included in the listing if they have been provided.

- Includes data for reports when the drug substance is given either as a single constituent or combination (multi-constituent product). In the case of the latter it may not be always possible to identify which (if any) of the drug substances in the combination product was responsible for a particular reaction.

- Uses adverse reaction terms known as 'preferred terms'. This system is used in order to ensure consistency of terminology and facilitate exchange of information with pharmaceutical companies and international bodies.

Guidance on interpretation of adverse reaction listings

Interpretation of the data in an adverse reaction listing should take into account the following:

- Reports submitted to the HPRA in many instances arise from suspicions occurring during observation of an unexpected and/or unwanted event.

- In many cases only limited details about each suspected adverse reaction report are received.

- Numerical comparisons should not be made between reactions associated with different drugs on the basis of the data included in listings alone. Comparisons may be misleading because of the limitations of the data.

- The inclusion of a particular reaction on the listing does not necessarily mean it has been caused by the suspect drug. Many factors have to be taken into account in assessing a causal relationship including temporal association, the possible contribution of concomitant medication, and the underlying disease.

- Interpretation of reactions to medicines in cases where multiple other therapies have been used requires special care. This is particularly relevant for vaccines as many are administered in combination. In these circumstances it may be difficult to ascribe a causal reaction to an individual vaccine or drug.

- Certain reported reactions are conditions which often occur spontaneously. In these cases there may be a temporal relationship between the medicine and the reaction which is not necessarily causal. This applies particularly to vaccines.

- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known. Adverse reaction reporting rates are influenced by the seriousness

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of the reactions, their ease of recognition and the extent of use of a particular drug. Report rates may also be stimulated by promotion and publicity about a drug.

- Reporting tends to be highest for newly authorised medicines during the first one or two years on the market and then falls off over time.

Publication

If you wish to copy either this listing or circulate this listing or information contained within it to others please ensure a copy of this note is also provided. The HPRA encourages use of data from the reporting system in publications but wishes to facilitate interpretation of the data. For this reason, we request that a copy of any proposed publications should be sent to the HPRA in advance for review/comment. Copies of proposed manuscripts and requests to quote data should be addressed to the Director of Human Products Monitoring, at the above address. We shall endeavour to respond to all requests quickly.

ADVERSE REACTION REPORTING IS VITAL FOR DRUG SAFETY; PLEASE SUPPORT THE REPORTING SCHEME BY NOTIFYING SUSPECTED ADVERSE REACTIONS.

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