

Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

HPRA ID	Indications	Medicinal Product(s)	Dose	Adverse Reaction(s) Event(s) (MedDRA PT)
2015-023780	Prophylaxis	GARDASIL	.5 Millilitres	Injection site swelling Rash
2015-023788	Prophylaxis	GARDASIL	Not Stated	Dizziness Asthenia Immobile Myalgia Seizure Headache Nausea Abdominal pain Visual acuity reduced Depression Chronic fatigue syndrome Mental disorder Pallor Malaise Dyspnoea Dyskinesia Pyrexia Pharyngitis streptococcal Muscular weakness Gait disturbance Psychiatric symptom Disturbance in attention Fatigue
2015-023805	Prophylaxis	GARDASIL	.5 Millilitres	Seizure Vision blurred Pain Headache Aphonia Muscle spasms Musculoskeletal stiffness Nausea Fatigue Asthenia Anxiety Chest pain Paralysis Muscle spasms Insomnia Gait disturbance Feeling cold Helicobacter infection Gastrointestinal inflammation Gastrooesophageal reflux disease Hypotension Heart rate increased Blood glucose decreased Fatigue Activities of daily living impaired Epilepsy Arthralgia Pain in extremity Headache Photosensitivity reaction Heart rate decreased Migraine Palpitations Somnolence Syncope Bedridden
2015-023819	Prophylaxis	GARDASIL	Not Stated	Dizziness Asthenia
2015-023820	Prophylaxis	GARDASIL	Not Stated	Dizziness Fatigue Asthenia Headache Nausea Abdominal pain Post viral fatigue syndrome
2015-023821	Prophylaxis	GARDASIL		Dizziness Fatigue

Please also refer to the caveat document enclosed.

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				Fibromyalgia Ovarian cyst Headache Pain Eye disorder Hyperacusis Food intolerance Transient memory impairment Disturbance in attention Post viral fatigue syndrome Chronic fatigue syndrome
2015-023833	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Seizure Transient visual impairment Eye movement disorder Abdominal pain upper Chest pain Muscular weakness Nausea Fatigue Headache Skin discolouration Aphasia Joint swelling Dizziness Dyskinesia Feeling abnormal Facial pain Eye pain Pain in extremity Musculoskeletal stiffness Hypokinesia Arthralgia Malaise
2015-023835	Prophylaxis	GARDASIL	Not Stated	Injection site swelling Cataplexy Chronic fatigue syndrome Abdominal pain Arthralgia Disturbance in attention Menstrual disorder Mood swings Dizziness Photosensitivity reaction Pyrexia
2015-023837	Prophylaxis	GARDASIL	Not Stated	Fatigue Seizure Panic attack Chest pain Ovarian cyst Depressed mood
2015-023847	Prophylaxis	MENJUGATE GARDASIL	Not Stated	Myalgia Arthralgia
2015-023920	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Musculoskeletal pain Hypoaesthesia
2015-024024	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres	Headache Alopecia
2015-024198	Prophylaxis	GARDASIL	Not Stated	Palpitations
2015-024209	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Myalgia Erythema Neuralgia Joint swelling Pain
2015-024219	Prophylaxis	GARDASIL	Not Stated	Syncope Asthenia Malaise Quality of life decreased
2015-024241	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Headache Dizziness Oropharyngeal pain Syncope Limb discomfort Abdominal pain upper Depressed mood Hypoaesthesia

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				Paraesthesia
2015-024338	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Injection site erythema Injection site swelling
2015-024347	Prophylaxis	GARDASIL	Not Stated	Malaise Pyrexia Headache Oropharyngeal pain Musculoskeletal stiffness Hallucination Vomiting
2015-024348	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope Hypotension Pallor Cold sweat
2015-024349	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Pallor Cold sweat
2015-024350	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope
2015-024351	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Nausea Pallor
2015-024352	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Feeling cold Cold sweat Syncope Generalised tonic-clonic seizure
2015-024379	Prophylaxis	GARDASIL	Not Stated	Arthralgia Somnolence Oropharyngeal pain
2015-024394	Prophylaxis	GARDASIL	Not Stated	Seizure Rash Arthralgia Migraine Oropharyngeal pain Gastrooesophageal reflux disease Irritable bowel syndrome Fatigue Dizziness Vision blurred Blood iron decreased Menorrhagia Tremor
2015-024427	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Headache Diarrhoea Constipation Fatigue Feeling cold Pain in extremity Nausea Poor quality sleep Chapped lips Dry skin Somnolence Menstruation irregular Vulvovaginal pain Vaginal discharge Urinary tract infection Weight increased Dizziness Dyspnoea Thirst Arthralgia
2015-024429	Prophylaxis	GARDASIL	Not Stated	Chronic fatigue syndrome Cognitive disorder Disturbance in attention Immune system disorder Amnesia Obsessive-compulsive disorder Insomnia Anxiety Activities of daily living impaired Menorrhagia Asthma

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				<ul style="list-style-type: none"> Weight decreased Oropharyngeal pain Arthralgia Myalgia Nausea Dizziness Chills Hypotension Headache Vomiting Fatigue Influenza like illness Pneumonia Muscle atrophy Home care Circulatory collapse Ear pain Vision blurred Decreased appetite Pain Lethargy Seizure Swelling
2015-024438	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Seizure Pulse abnormal Chest pain Transient visual impairment Hypotension Gastrooesophageal reflux disease Fatigue Asthenia
2015-024452	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Myalgia Fatigue Depression Panic attack Arthralgia Dizziness Palpitations Migraine Feeling abnormal Anxiety Tremor Transient visual impairment Chest pain Poor quality sleep Dyspnoea Pain Body temperature fluctuation Skin sensitisation Joint stiffness Muscle spasms Muscular weakness Mobility decreased Headache Gastrointestinal disorder Fibromyalgia Irritable bowel syndrome Developmental hip dysplasia Stress Hyperkeratosis
2015-024453	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Muscle spasms Seizure Immunodeficiency
2015-024525	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Back pain Erythema Inflammation
2015-024532	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Nausea Headache Vomiting Pain Muscular weakness Vision blurred Dyspnoea

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2015-024552	Prophylaxis	GARDASIL	Not Stated	Neck pain Headache Arthralgia Contusion Photophobia Lethargy Dizziness Pyrexia Meningitis viral Orthostatic hypotension Vomiting Sinusitis Nasal polyps Rash Muscle spasms Diarrhoea Decreased appetite Sleep terror Panic attack Palpitations Heart rate irregular Muscular weakness Anxiety Depression Irritable bowel syndrome Fatigue Myalgia Constipation Nausea Epstein-Barr virus antibody positive
2015-024559	Prophylaxis	GARDASIL	Not Stated	Pancreatitis Appendicitis Nausea Dizziness Hot flush Headache Trismus Epistaxis Fatigue Rash Eating disorder Coordination abnormal Malaise Myalgia Pain in extremity Social avoidant behaviour Pallor Pain Balance disorder Abdominal pain upper Syncope Asthenia Balance disorder Hypotension Activities of daily living impaired Arthralgia Palpitations Photophobia Hyperacusis Amnesia Disturbance in attention Inflammation Eye infection Muscle fatigue Immune system disorder Lethargy Back pain Neck pain Vitamin D deficiency Skin striae
2015-024571	Prophylaxis	GARDASIL	Not Stated	Dizziness Feeling abnormal Chest pain Tremor

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				<p>Volume blood decreased Altered visual depth perception Syncope Seizure Malaise Fatigue Arthralgia Headache Disorientation Palpitations Pain Peripheral swelling Bone pain Bedridden Joint stiffness Abdominal discomfort Skin discolouration Immune system disorder Contusion Fall Gait disturbance</p>
2015-024575	Prophylaxis	GARDASIL	Not Stated	<p>Dizziness Vision blurred Headache Pain in extremity Vomiting Panic attack Anxiety Back pain Hypotension Syncope Pain Fatigue Nightmare Diplopia Malaise Amnesia Dyspnoea Confusional state Myalgia Muscular weakness Lymphadenopathy Cyanosis Pyrexia Diarrhoea</p>
2015-024628	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Complex regional pain syndrome
2015-024638	Prophylaxis	GARDASIL	.5 Millilitres	<p>Muscular weakness Hypoaesthesia Sensory loss</p>
2015-024660	Prophylaxis	GARDASIL	Not Stated	<p>Nausea Vomiting Fatigue Anxiety Dizziness Food intolerance Amnesia Pain Abdominal pain Sleep disorder Disturbance in attention Depression Menstrual disorder</p>
2015-024667	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Transient blindness
2015-024674	Prophylaxis	GARDASIL	Not Stated	<p>Palpitations Asthenia Hypertension Hypotension Cold sweat Tremor Headache Fatigue</p>

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				Pain Syncope Dizziness
2015-024684	Prophylaxis	GARDASIL	Not Stated	Fatigue Seizure Arthralgia
2015-024689	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres	Myalgia Fatigue
2015-024698	Prophylaxis	GARDASIL DTap	Not Stated	Injection site pain Pain in extremity Myalgia Photophobia Chest pain
2015-024703	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Fatigue Insomnia Pain in extremity Diarrhoea Malaise
2015-024720	Prophylaxis	GARDASIL	Not Stated	Influenza like illness Oropharyngeal pain Vision blurred Vomiting Epistaxis Chest pain Arthralgia Myalgia Dysmenorrhoea Hormone level abnormal Dizziness Fatigue Feeling abnormal Peripheral coldness Skin striae Varicose vein Oral fungal infection Breath odour Hyperhidrosis Flushing Glassy eyes Lacrimation increased Post viral fatigue syndrome Fibromyalgia Malaise Body temperature decreased Cyanosis Seizure Autoimmune disorder Fatigue Pain Transient memory impairment Headache Aphonia
2015-024730	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres	Headache Pyrexia Nausea
2015-024743	Prophylaxis	GARDASIL	.5 Millilitres	Headache Photophobia Malaise Panic attack Irlen syndrome
2015-024760	Prophylaxis	GARDASIL	Not Stated	Back pain Amnesia SLE arthritis Connective tissue disorder Arthralgia Fatigue Joint swelling Alopecia Headache Mouth ulceration Gait disturbance Depressed mood
2015-024763	Prophylaxis	GARDASIL		Neurological symptom Palpitations

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				Migraine Fatigue Dizziness Syncope Dyspnoea Hypoaesthesia Paraesthesia Pain Transient visual impairment Chest pain Disturbance in attention Depression Anxiety
2015-024790	Prophylaxis	GARDASIL	Not Stated	Epilepsy Seizure
2015-024791	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Pain Fatigue Abdominal discomfort Mental disorder Swelling face Peripheral swelling Allodynia Palpitations Amenorrhoea Headache Fatigue Feeling abnormal Dizziness Tachycardia Insomnia Hyperhidrosis Abdominal pain Dyspepsia Nausea Pneumonia chlamydial Cough Dyspnoea Blood pressure abnormal Photophobia Hyperacusis Sinus disorder Viral infection Fibromyalgia Local swelling Choking Pharyngeal oedema Oropharyngeal pain Amnesia Rash Skin striae Acne Muscular weakness Loss of consciousness Anxiety
2015-024801	Prophylaxis	GARDASIL	Not Stated	Dizziness Headache Pneumonia aspiration Fatigue Hypersomnia Seizure Dysmenorrhoea Fibromyalgia Postural orthostatic tachycardia syndrome Transient memory impairment Mental impairment Photophobia Hyperacusis
2015-024806	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Menstrual disorder Headache Syncope Seizure Oropharyngeal pain

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				Fatigue Feeling cold
2015-024826	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Dizziness Nausea Headache Vomiting Nasopharyngitis Syncope Abdominal migraine Fatigue Sleep disorder Disturbance in attention Ear pain Blepharitis Tremor Dyspnoea Chest pain Body temperature fluctuation Skin discolouration Abdominal distension Menstruation irregular Tachycardia
2015-024833	Prophylaxis	GARDASIL	Not Stated	Seizure Pain in extremity Fatigue Arthralgia Panic attack
2015-024850	Prophylaxis	GARDASIL	Not Stated	Muscle spasms Dyskinesia Blepharospasm Headache Fatigue Loss of consciousness Sleep disorder Nightmare Feeling cold Seizure Myalgia
2015-024893	Prophylaxis	GARDASIL BOOSTRIX	.5 Miliilitres	Influenza like illness Headache Lip swelling Eye swelling Pruritus Peripheral swelling Injection site swelling Malaise
2015-024908	Prophylaxis	GARDASIL	Not Stated	Gastric disorder Gastrointestinal disorder Fatigue
2015-024912	Prophylaxis	GARDASIL	.5 Miliilitres	Rash Migraine Gastrointestinal disorder
2015-024939	Prophylaxis	GARDASIL	.5 Miliilitres	Syncope Fatigue Pain in extremity Hypoaesthesia Seizure Dizziness Muscle spasms Headache Arthralgia Abdominal pain upper Rash Migraine Poor peripheral circulation Contusion
2015-024982	Prophylaxis	GARDASIL	.5 Miliilitres	Fall Seizure Bite Loss of consciousness
2015-024996	Prophylaxis	GARDASIL	.5 Miliilitres .5 Miliilitres .5 Miliilitres	Headache Transient visual impairment Chest pain

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				Palpitations Myalgia Pain in extremity Reflux gastritis Sensory disturbance Cognitive disorder Fatigue Dizziness Arthralgia Hypoaesthesia Paraesthesia Balance disorder Skin striae Menstrual disorder Amnesia
2015-025002	Prophylaxis	GARDASIL	Not Stated	Syncope
2015-025026	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Muscle spasms Asthenia Hypersomnia Gastrointestinal disorder
2015-025099	Prophylaxis	GARDASIL	Not Stated	Pain Syncope
2015-025152	Prophylaxis	GARDASIL	Not Stated	Menstrual disorder Dysmenorrhoea Fatigue Diarrhoea Depression
2015-025159	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Malaise Headache Asthenia Fatigue Thirst Myalgia Back pain Neck pain Abdominal pain upper
2015-025160	Prophylaxis	GARDASIL	Not Stated	Paraesthesia Asthenia Drop attacks Muscular weakness Fatigue Rash Dyskinesia Muscle spasms
2015-025223	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Pain Fatigue Asthenia
2015-025259	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Visual acuity reduced Vision blurred
2015-025392	Prophylaxis	GARDASIL	Not Stated	Hypoaesthesia Dizziness Rash Fatigue Pain Eye pain
2015-025396	Prophylaxis	GARDASIL	Not Stated	Migraine Dizziness Pain Fatigue Nausea Vein rupture Ovarian cyst Malaise Pharyngitis Palpitations Dyspnoea Photophobia Visual acuity reduced Nightmare Chest pain Myalgia Limb discomfort Hypersomnia
2015-025405	Prophylaxis	GARDASIL	Not Stated	Seizure

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				Syncope Fall Pain in extremity Peripheral coldness Musculoskeletal stiffness Muscle rigidity
2015-025416	Prophylaxis	GARDASIL	Not Stated	Fatigue Haematochezia Chest pain Anxiety Panic attack Insomnia Nausea Heart rate increased
2015-025428	Prophylaxis	GARDASIL	.5 Millilitres	Asthenia Dizziness Dysstasia Presyncope Malaise Headache Tremor Pyrexia Arthralgia Rash papular Bedridden Fatigue Feeling of body temperature change Back pain Abdominal pain upper Gait disturbance Hair colour changes
2015-025438	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres	Syncope Loss of consciousness Abdominal pain Pain in extremity Headache Nausea Photophobia
2015-025439	Prophylaxis	GARDASIL	Not Stated	Complex regional pain syndrome Peripheral swelling Pain Neck pain Headache Insomnia Fatigue
2015-025443	Prophylaxis	GARDASIL	Not Stated	Headache Nausea Migraine Asthenia
2015-025450	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres	Fatigue Headache Myalgia Depression Disturbance in attention Back pain
2015-025474	Prophylaxis	GARDASIL	Not Stated	Seizure
2015-025478	Prophylaxis	GARDASIL	Not Stated	Fatigue Headache Malaise Disturbance in attention Arthralgia Feeling abnormal
2015-025491	Prophylaxis	GARDASIL	.5 Millilitres	Endometriosis Fatigue Syncope Menorrhagia Dizziness Headache Injury
2015-025494	Prophylaxis	GARDASIL	Not Stated	Pain Raynaud's phenomenon Fibromyalgia Fatigue Arthralgia

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				Dizziness Headache Hypermobility syndrome
2015-025495	Prophylaxis	GARDASIL	.5 Millilitres	Systemic lupus erythematosus
2015-025496	Prophylaxis	GARDASIL	Not Stated	Decreased appetite Depression Abdominal pain Fatigue
2015-025497	Prophylaxis	GARDASIL	Not Stated	Syncope Seizure like phenomena Dizziness Fatigue
2015-025499	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope Migraine Irritable bowel syndrome Postural orthostatic tachycardia syndrome Loss of consciousness
2015-025523	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Hypoaesthesia Headache Dizziness Contusion Immune thrombocytopenic purpura
2015-025524	Prophylaxis	GARDASIL	.5 Millilitres	Limb discomfort Influenza like illness Nasopharyngitis Pain Headache Fatigue
2015-025547	Prophylaxis	GARDASIL	Not Stated	Fatigue Asthenia Palpitations Chest pain
2015-025559	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Lichen sclerosus Dysuria Painful defaecation Tonsillitis Candida infection
2015-025574	Prophylaxis	GARDASIL	Not Stated	Headache Nausea Chest pain Dyspnoea Back pain Rash Abdominal pain upper Arthralgia Dizziness Syncope Fatigue Lethargy Feeling abnormal Sleep disorder Gluten sensitivity Irritable bowel syndrome Menstruation irregular Dysmenorrhoea Migraine Depression Insomnia Abdominal distension Anxiety Decreased appetite Weight decreased Food allergy Depressed mood Asthenia Disturbance in social behaviour Chest discomfort Malaise Ovarian cyst ruptured Diarrhoea Vomiting Chronic fatigue syndrome

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2016-025590	Prophylaxis	GARDASIL	Not Stated	Fatigue Headache Viral infection
2016-025594	Prophylaxis	GARDASIL BOOSTRIX MEN C	Not Stated	Limb discomfort Fatigue Hypoaesthesia Nausea Menstrual disorder Gastrointestinal disorder Feeling abnormal Alopecia Tremor Oropharyngeal pain Pallor Flushing Anxiety Hyperaesthesia Post viral fatigue syndrome Lethargy Asthenia Depression
2016-025595	Prophylaxis	GARDASIL	Not Stated	Depression Flushing Syncope Malaise Migraine Fatigue Heart rate increased Depressed mood
2016-025640	Prophylaxis	GARDASIL	Not Stated	Malaise Epistaxis Decreased appetite Weight decreased Pain Temporomandibular joint syndrome
2016-025641	Prophylaxis	GARDASIL	.5 Millilitres	Seizure
2016-025642	Prophylaxis	GARDASIL	.5 Millilitres	Syncope
2016-025643	Prophylaxis	GARDASIL	.5 Millilitres	Pallor
2016-025645	Prophylaxis	GARDASIL	Not Stated	Chest pain Pain Monoplegia Musculoskeletal stiffness Heart rate increased Hypertension Syncope Aphasia Palpitations Supraventricular tachycardia
2016-025648	Prophylaxis	GARDASIL	Not Stated	Weight decreased Pain Malaise Syncope Dizziness Pain in extremity Back pain
2016-025651	Prophylaxis	GARDASIL	.5 Millilitres	Swelling Nausea Eating disorder Sleep disorder Arthralgia Heart rate irregular Blood pressure fluctuation Postural orthostatic tachycardia syndrome
2016-025695	Prophylaxis	GARDASIL	.5 Millilitres	Tremor Fatigue Headache Vomiting Asthenia Pyrexia Malaise Bedridden Body temperature fluctuation

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				Arthralgia Asthenia Nausea Abdominal pain upper Viral infection Limb discomfort
2016-025696	Prophylaxis	GARDASIL	Not Stated	Myalgia Arthralgia Asthenia Fatigue Headache Dysstasia Disturbance in attention Photophobia Phonophobia Dizziness Insomnia
2016-025731	Prophylaxis	GARDASIL	Not Stated	Syncope Palpitations Myalgia Headache
2016-025742	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres	Headache Limb discomfort Injection site erythema Fatigue Myalgia Muscular weakness Abdominal pain Ovarian cyst Dizziness postural Alopecia Body temperature decreased Peripheral coldness Muscle spasms Lymphadenopathy Paraesthesia Tremor Transient memory impairment Chest pain Tachycardia Temporomandibular joint syndrome Fibromyalgia Oropharyngeal pain Rhinorrhoea Dysphagia Asthenia Back pain Pharyngitis Disturbance in attention Aphasia Skin lesion Joint crepitation Pneumonia Lyme disease Diplegia Syncope Malaise Immune system disorder Infection Bedridden Insomnia Feeling abnormal
2016-025747	Prophylaxis	GARDASIL	Not Stated	Syncope Fatigue Dizziness Abdominal pain Epistaxis Insomnia Palpitations Feeling abnormal Menorrhagia Dry skin Gastrointestinal disorder Asthenia

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2016-025748	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Headache Headache Malaise Fatigue Neck pain Back pain Influenza like illness Arthralgia Muscle spasms Pain in extremity
2016-025802	Prophylaxis	GARDASIL	Not Stated	Arthralgia Myalgia Headache Fatigue Dizziness Confusional state Menstrual disorder Palpitations Abdominal pain upper Chest pain Back pain Urticaria Nausea Chills Fibromyalgia Raynaud's phenomenon Hypersomnia Wheelchair user Influenza like illness Amnesia Pain in extremity Spinal pain Skin striae Paraesthesia Pain in extremity Photophobia Ear pain Insomnia Pain Pruritus Feeling abnormal Irritability Disturbance in attention Erythema Pain of skin Asthenia Seasonal allergy Eczema Pruritus Balance disorder Dysphemia Muscular weakness Food intolerance Hyperhidrosis Paralysis Skin discolouration Hyperacusis Hyperaesthesia Body temperature fluctuation Tinnitus Excessive cerumen production Tremor Pain General physical health deterioration
2016-025803	Prophylaxis	GARDASIL	.5 Millilitres	Dyskinesia Paralysis Amnesia Disturbance in attention Disorientation Neck pain Body temperature fluctuation Intentional self-injury Dysarthria Drooling

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				Paraesthesia Insomnia Heart rate increased Tachycardia Spinal pain
2016-025829	Prophylaxis	GARDASIL	Not Stated	Malaise Dizziness Migraine Myalgia Abdominal pain Fatigue Nasopharyngitis Pharyngitis Abdominal discomfort Dyspepsia Raynaud's phenomenon Psoriasis Alopecia Back pain
2016-025843	Prophylaxis	GARDASIL	Not Stated	Pain in extremity Restless legs syndrome Fatigue Decreased appetite Ovarian cyst Abdominal pain Pyrexia
2016-025846	Prophylaxis	GARDASIL	Not Stated	Headache Myalgia Muscle spasms Pain Abnormal loss of weight Blood pressure decreased Transient visual impairment
2016-025854	Prophylaxis	GARDASIL	Not Stated	Depression Panic attack Insomnia Anxiety disorder Transient memory impairment Mood swings Headache Abdominal pain upper Rash erythematous Decreased appetite Eye disorder Gait disturbance Discomfort Activities of daily living impaired Swelling
2016-025873	Prophylaxis	GARDASIL	Not Stated	Headache Fatigue Decreased appetite Cold sweat Abdominal pain Chest pain Cough Oropharyngeal pain Nasal congestion Kidney infection Pyrexia Arthralgia Amnesia Disturbance in attention
2016-025874	Prophylaxis	GARDASIL	Not Stated	Malaise Arthralgia Pyrexia Headache Decreased appetite Asthenia
2016-025878	Prophylaxis	GARDASIL	Not Stated	Fatigue Arthralgia Skin striae Abdominal pain Pyrexia Headache

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

2016-025892	Prophylaxis	GARDASIL	Not Stated	Cognitive disorder Fibromyalgia Synovial cyst Intervertebral disc degeneration Arthralgia General physical health deterioration Hypersomnia Depression Panic attack Skin striae Hypothyroidism Fatigue Malaise
2016-025914	Prophylaxis	GARDASIL	Not Stated	Asthenia Dizziness Dyspnoea Palpitations Fatigue Pallor
2016-025942	Prophylaxis	GARDASIL	Not Stated	Peroneal nerve injury Fatigue Weight decreased Amenorrhoea
2016-025943	Prophylaxis	GARDASIL	Not Stated	Dizziness Nausea Fatigue Menstrual disorder
2016-025951	Prophylaxis	GARDASIL	.5 Millilitres	Urinary incontinence Blood urine present Myalgia Arthralgia Muscular weakness
2016-025988	Prophylaxis	GARDASIL	Not Stated	Fatigue Syncope Seizure Paraesthesia Hypoaesthesia Skin disorder Headache Muscle twitching Amnesia Muscle spasms Dizziness Disturbance in attention
2016-025996	Prophylaxis	GARDASIL	.5 Millilitres .5 Millilitres .5 Millilitres	Headache Nausea Lethargy Malaise Abdominal pain Fatigue
2016-026014	Prophylaxis	GARDASIL	Not Stated	Fatigue Alopecia Syncope Polycystic ovaries
2016-026027	Prophylaxis	GARDASIL	Not Stated	Fatigue Feeling abnormal Headache Arthralgia Insomnia Abdominal discomfort Feeling of body temperature change Dizziness Nausea Gait disturbance Migraine Abdominal pain upper Back pain Transient blindness Myalgia Anaemia Carpal tunnel syndrome
2016-026042	Prophylaxis	GARDASIL	Not Stated	Abdominal pain Abdominal distension Swelling

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Hyperhidrosis Fatigue Insomnia Headache Tremor Vomiting Disturbance in attention
2016-026069	Prophylaxis	GARDASIL	Not Stated	Syncope Rash
2016-026118	Prophylaxis	GARDASIL	Not Stated	Fatigue Dizziness Viral infection Asthenia Arthralgia Headache Photophobia Oropharyngeal pain Ear pain Feeling abnormal Developmental regression Pityriasis rosea
2016-026120	Prophylaxis	GARDASIL	Not Stated	Pancreatitis acute Pancreatitis chronic
2016-026155	Prophylaxis	GARDASIL	Not Stated	Fatigue Dizziness Transient visual impairment Hyperhidrosis Palpitations Asthenia Dyspnoea Rash Candida infection
2016-026170	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Fatigue Dizziness
2016-026211	Prophylaxis	GARDASIL	Not Stated	Autoimmune disorder Fatigue Cognitive disorder Amnesia Disturbance in attention Depression Anxiety Feeling abnormal Aphasia Panic attack Headache Myalgia Neck pain Back pain Poor quality sleep Nightmare Asthenia Attention deficit/hyperactivity disorder Intentional self-injury Suicide attempt
2016-026214	Prophylaxis	GARDASIL	Not Stated	Fatigue Somnolence Abdominal pain Asthenia Syncope
2016-026331	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Mental disorder Dizziness Tachycardia Fatigue Insomnia Hyperhidrosis Abdominal pain Nausea Petit mal epilepsy Epilepsy Pneumonia Reaction to drug excipients Cough Costochondritis

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Dyspnoea Visual acuity reduced Photosensitivity reaction Vitreous floaters Hyperacusis Sinusitis Headache Fibromyalgia Vision blurred Menstruation irregular Ovulation pain Local swelling Oropharyngeal pain Peripheral swelling Pain in extremity Peripheral swelling Feeling abnormal Transient memory impairment Disturbance in attention Rash Eczema Fungal infection Skin striae Acne Temperature regulation disorder Hypoaesthesia Asthenia
2016-026437	Prophylaxis	GARDASIL	Not Stated	Malaise Premature menopause Thyroiditis Hypothyroidism Autoimmune disorder Pain Lethargy
2016-026466	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Dizziness Swelling face Erythema Urticaria Asthenia
2016-026477	Prophylaxis	GARDASIL	Not Stated	Headache Injection site swelling Dyspnoea Chest pain Postural orthostatic tachycardia syndrome Palpitations Seizure Syncope Fatigue
2016-026479	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Dizziness Conversion disorder Blepharospasm
2016-026481	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Malaise Pain in extremity Arthralgia Nausea Pyrexia Dysarthria Confusional state Photophobia Neck pain Back pain Paraesthesia Headache Asthenia
2016-026490	Prophylaxis	GARDASIL	Not Stated	Wheelchair user Influenza like illness Amnesia Nausea
2016-026495	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Diarrhoea
2016-026512	Prophylaxis	GARDASIL	Not Stated	Asthenia Dizziness Headache Abdominal pain

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Pallor Discomfort Pharyngitis Tonsillitis Lethargy Fatigue Muscular weakness Feeling abnormal Abdominal migraine
2016-026518	Prophylaxis	GARDASIL	Not Stated	Headache Asthenia Disturbance in attention Nausea Pyrexia
2016-026520	Prophylaxis	GARDASIL	Not Stated	Seizure Abasia Insomnia
2016-026521	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Syncope Headache Nausea Fatigue Disturbance in attention
2016-026526	Prophylaxis	GARDASIL	Not Stated	Bedridden Fatigue Pallor Hypopnoea Dyspnoea Pain in extremity Peripheral swelling Chest discomfort Anxiety Ovarian cyst Headache Breast mass Oropharyngeal pain Chronic fatigue syndrome Myalgia Hypoaesthesia Paraesthesia Arthralgia Chest pain Palpitations Influenza like illness Photosensitivity reaction Peripheral coldness Abdominal pain Rash Transient memory impairment Disturbance in attention Syncope Vomiting Suicidal behaviour Menstrual disorder Pollakiuria Insomnia Temperature regulation disorder Cyst Cerebral cyst Sweat gland disorder
2016-026527	Prophylaxis	GARDASIL	Not Stated	Bedridden Fatigue Pallor Hypopnoea Dyspnoea Pain in extremity Peripheral swelling Chest discomfort Anxiety Immune system disorder Ovarian cyst Headache Breast mass

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Oropharyngeal pain Chronic fatigue syndrome Myalgia Hypoaesthesia Paraesthesia Arthralgia Chest pain Palpitations Cerebral cyst Photosensitivity reaction Peripheral coldness Abdominal pain Rash Transient memory impairment Disturbance in attention Syncope Vomiting Suicidal behaviour Menstrual disorder Sweat gland disorder Pollakiuria Insomnia Temperature regulation disorder Cyst
2016-026529	Prophylaxis	GARDASIL	Not Stated	Dizziness Nausea Headache Groin pain Syncope Muscle twitching Pain in extremity Disturbance in attention Psychogenic seizure
2016-026543	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Malaise Menstruation irregular Headache Dizziness Dyspnoea Pain Abdominal pain upper Oropharyngeal pain Hypotension Syncope Asthenia
2016-026592	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Malaise Nausea Dizziness Vertigo
2016-026622	Prophylaxis	GARDASIL	Not Stated	Dizziness Feeling abnormal Unresponsive to stimuli Asthenia Disturbance in attention
2016-026652	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Somnolence Eye movement disorder Diplopia Slow response to stimuli Peripheral coldness Heart rate irregular
2016-026653	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Rash erythematous Rash pruritic
2016-026661	Prophylaxis	GARDASIL	Not Stated	Nausea Headache Fatigue Muscular weakness Syncope Dyspnoea Confusional state Dizziness Arthralgia Myalgia Malaise Amnesia

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Depression Anxiety Nightmare Agitation Sleep paralysis Disturbance in attention
2016-026691	Prophylaxis	GARDASIL	Not Stated	Wheelchair user Seizure Mental impairment Autoimmune disorder Influenza like illness Amnesia Nausea Headache Pain in extremity Spinal pain Arthralgia Hypersomnia General physical health deterioration Inappropriate schedule of drug administration Medication error Feeling abnormal Muscular weakness Palpitations Fatigue Injury General physical health deterioration Chest pain Helplessness Scar pain
2016-026698	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Malaise Vomiting Peripheral swelling Pyrexia Pain in extremity
2016-026709	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Eye swelling
2016-026715	Prophylaxis	GARDASIL	Not Stated	Malaise Influenza like illness Hypoaesthesia Monoplegia Fatigue Headache Dizziness Polymenorrhoea Syncope Poor quality sleep Pyrexia Vomiting
2016-026738	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Asthenia Syncope Pyrexia Palpitations Bedridden Food intolerance Disturbance in attention Viral infection
2016-026742	Prophylaxis	GARDASIL	Not Stated	Cataplexy Narcolepsy Arrhythmia Arthralgia Insomnia Activities of daily living impaired Abnormal loss of weight Syncope
2016-026770		GARDASIL	Not Stated	Migraine Malaise Headache Vision blurred Abdominal pain Nausea Dyspepsia Asthenia

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Blood iron increased Liver function test abnormal Food intolerance Gastroesophageal reflux disease Anxiety Panic attack Skin striae Myalgia Abdominal distension Photophobia
2016-026817	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Headache Fatigue Weight increased
2016-026877	Prophylaxis	GARDASIL MENINGITIS C VACCINE	Not Stated	Syncope Dizziness
2016-026907	Prophylaxis	GARDASIL	Not Stated	Panic attack Anxiety Psychiatric symptom Multiple sclerosis Menstrual disorder Hypomania Disorientation Weight decreased
2016-026921	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres .5 Millilitres	Alopecia
2016-026932	Prophylaxis	GARDASIL MENJUGATE	.5 Millilitres	Headache Malaise Dizziness Fatigue
2016-026940	Prophylaxis	GARDASIL	Not Stated	Fatigue
2016-027006	Prophylaxis	GARDASIL	Not Stated	Bone pain Influenza like illness Dizziness Vision blurred Headache Fatigue Lower respiratory tract infection Asthma Vomiting Syncope Asthenia
2016-027069	Prophylaxis	GARDASIL	Not Stated	Pyrexia Muscle twitching Tremor Vomiting Headache Photophobia Arthralgia Fatigue Pain
2016-027070	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Malaise Headache Arthralgia Fatigue Somnolence Hypermobility syndrome Condition aggravated
2016-027090	Prophylaxis	GARDASIL	Not Stated	Headache Dizziness Muscular weakness Epistaxis Vision blurred Fatigue Hyperacusis Feeling abnormal Vomiting Nausea
2016-027099	Prophylaxis	GARDASIL	Not Stated	Headache Arthralgia Malaise Myalgia Asthenia Confusional state Rash

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Chills Abdominal pain upper Menstrual disorder Urinary tract infection Haemorrhage Anaemia vitamin B12 deficiency Oropharyngeal pain Blood iron decreased Fatigue Sleep disorder Irritable bowel syndrome
2016-027114	Prophylaxis	GARDASIL	Not Stated	Fatigue Arthralgia Headache Nausea Viral infection Menstrual disorder Malaise
2016-027167	Prophylaxis	GARDASIL	Not Stated	Influenza like illness Fatigue Balance disorder Somnolence Headache Gait disturbance Malaise Limb discomfort Arthralgia Sinusitis Viral infection Temperature regulation disorder Peripheral coldness Amnesia Loss of consciousness Hyperacusis Photophobia Syncope Multiple sclerosis Weight decreased Spinal pain
2016-027174	Prophylaxis	GARDASIL	.5 Millilitres	Fatigue Pain Depression Anxiety Injection site swelling Headache Fatigue Influenza like illness Cough Oropharyngeal pain Epigastric discomfort Eye discharge Ear pain Chest pain Abdominal pain Arthralgia Gastritis Diarrhoea Abdominal tenderness Menorrhagia Mood swings Disturbance in attention Urticaria Eye pain Syncope Back pain Dizziness Nausea Feeling abnormal Alopecia Polycystic ovaries Menstruation irregular Muscle spasms Hypoaesthesia Pruritus

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				<ul style="list-style-type: none"> Rash Increased tendency to bruise Wound haemorrhage Impaired healing Lip swelling Lip injury Oral mucosal blistering Insomnia Muscle twitching Aphasia Hyperacusis Photophobia Temperature intolerance Irritability Pain in jaw Toothache Weight fluctuation Candida infection Pain in extremity Seizure Breast pain Heart rate increased Heart rate irregular Formication Lip infection Dyskinesia Arthralgia Pharyngeal oedema Injection site erythema Dermatitis Discomfort Gait disturbance
2016-027206	Prophylaxis	GARDASIL	.5 Millilitres	<ul style="list-style-type: none"> Malaise Fatigue Alopecia
2016-027321	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Lyme disease Coxsackie viral infection Herpes simplex
2016-027364	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Nausea Dizziness Headache Heart rate increased Weight decreased
2016-027394	Prophylaxis	GARDASIL	.5 Millilitres	<ul style="list-style-type: none"> Asthenia Decreased appetite Self esteem decreased Insomnia Pharyngitis
2016-027683	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	<ul style="list-style-type: none"> Syncope Fatigue Headache Nausea
2016-027687	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Immunodeficiency Viral infection Pyrexia Headache Nausea Fatigue Pain Arthralgia
2016-027689	Prophylaxis	GARDASIL	Not Stated	<ul style="list-style-type: none"> Intentional self-injury Disturbance in attention Eye movement disorder Neck pain Fatigue Headache Photophobia Oropharyngeal pain Pyrexia Anger Depression Anxiety Attention deficit/hyperactivity disorder
2016-027690	Prophylaxis	GARDASIL	.5 Millilitres	<ul style="list-style-type: none"> Eczema

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

2016-027691	Prophylaxis	GARDASIL	.5 Millilitres	Alopecia Nausea Fatigue Pallor Dyspnoea Depressed mood Menstrual disorder
2016-027692	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Type 1 diabetes mellitus Malaise Fatigue Weight decreased Lethargy Pollakiuria
2016-027735	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Vomiting Muscle spasms Weight decreased Anxiety
2016-027736	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Rash Headache Syncope Fatigue Nausea Vomiting Chronic fatigue syndrome Insomnia Myalgia Asthenia
2016-027826	Prophylaxis	GARDASIL	Not Stated	Ovarian cyst ruptured Malaise Diarrhoea Vomiting Migraine Chronic fatigue syndrome Gastrointestinal disorder
2016-027844	Prophylaxis	GARDASIL	Not Stated	Injection site swelling Headache Pyrexia Nausea Lymphadenopathy Muscular weakness Paraesthesia Vomiting Arthralgia Myalgia Fatigue Chills Haemorrhagic diathesis Contusion Menstrual disorder Skin striae Rash Hypermobility syndrome Syncope Injection site pain Injection site bruising Fibromyalgia
2016-027877	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres	Fatigue Feeling abnormal Back pain Arthralgia Inflammation Bacterial infection Viral infection Lymphadenitis Gastrointestinal disorder Hypersensitivity Bronchospasm
2016-027884	Prophylaxis	GARDASIL	.5 Millilitres	Asthenia Fatigue Pain
2016-027889	Prophylaxis	GARDASIL	Not Stated	Feeling abnormal Arthralgia Lyme disease Pharyngeal ulceration

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Summary details of suspected adverse reactions/events associated with the use of Gardasil 01/06/2015-30/09/2016

				Headache Migraine Sinusitis
2016-027910	Prophylaxis	GARDASIL	Not Stated	Seizure Fatigue Vision blurred Swelling Headache Migraine Abdominal pain upper Abdominal distension Reflux gastritis Somnolence Feeling abnormal Activities of daily living impaired
2016-027923	Prophylaxis	GARDASIL	Not Stated	Fatigue Muscular weakness Gastric disorder Syncope Dizziness Feeling abnormal Headache Oropharyngeal pain Tonsillitis Anxiety Depression Insomnia Cystitis Rash Skin striae Ovarian cyst ruptured Menstrual disorder Nausea Motion sickness
2016-027933	Prophylaxis	GARDASIL BOOSTRIX	.5 Millilitres .5 Millilitres	Rash Fatigue
2016-027976	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Urticaria
2016-027978	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Urticaria Headache Nausea
2016-027985	Prophylaxis	GARDASIL	Not Stated	Seizure Syncope Fall Malaise
2016-028017	Prophylaxis	GARDASIL	Not Stated	Seizure Crying Headache Speech disorder Movement disorder
2016-028044	Prophylaxis	GARDASIL	Not Stated	Malaise Tonsillitis Headache Dizziness Fatigue Pain Nausea Feeling hot Epistaxis Sleep paralysis Feeling cold Bruxism Hypotension Depressed mood Stress

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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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