

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP): All spontaneous, UK, suspected Adverse Drug Reaction (ADR) reports associated with Infanrix Hexa. Data Lock Point (DLP) up to 15th March 2021.

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Leukocytoses NEC</b></i>		
Lymphocytic infiltration	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymphadenopathy	2	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Myelosuppression	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	2	0
<b>Blood disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	7	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac arrest neonatal	1	1
Cardio-respiratory arrest	2	1
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>14</b>	<b>3</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear swelling	4	0
<b>Ear disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
Gaze palsy	3	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	1	0
<b>Eye disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	39	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	4	0
Faecaloma	1	0
Faeces discoloured	11	0
Faeces hard	1	0
Faeces pale	1	0
Mucous stools	6	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	5	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain upper	10	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	8	0
Gastrooesophageal reflux disease	6	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Infant dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discolouration	1	0
<i>Nausea and vomiting symptoms</i>		
Retching	1	0
Vomiting	33	0
Vomiting projectile	12	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	6	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>170</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
 Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	6	0
Decreased activity	1	0
Fatigue	4	0
Malaise	11	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	1	0
<i><b>Death and sudden death</b></i>		
Death	4	4
Sudden death	3	3
Sudden infant death syndrome	4	4
<i><b>Febrile disorders</b></i>		
Pyrexia	109	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	6	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	4	0
Thirst decreased	2	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	3	0
Gait inability	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	2	0
Crying	64	0
Developmental delay	1	0
Developmental regression	1	0
General physical health deterioration	1	0
Glassy eyes	3	0
High-pitched crying	6	0
Induration	1	0
Influenza like illness	1	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	14	0
Screaming	22	0
Secretion discharge	1	0
Swelling	4	0
Swelling face	4	0
<i><b>Inflammations</b></i>		
Inflammation	3	0
Systemic inflammatory response syndrome	1	0
<i><b>Injection site reactions</b></i>		
Injection site induration	1	0
Injection site mass	2	0
Injection site vesicles	1	0
<i><b>Oedema NEC</b></i>		
Oedema	1	0
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Discomfort	5	0
Pain	25	0
Tenderness	1	0

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Vaccination site erythema	10	0
Vaccination site haemorrhage	1	0
Vaccination site induration	2	0
Vaccination site inflammation	3	0
Vaccination site mass	9	0
Vaccination site pain	6	0
Vaccination site rash	1	0
Vaccination site swelling	7	0
Vaccination site vesicles	1	0
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>372</b>	<b>11</b>



## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
 Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	9	0
Multiple allergies	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Food allergy	3	0
Milk allergy	3	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	8	0
Anaphylactic shock	1	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>30</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	2	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i><b>Bordetella infections</b></i>		
Pertussis	2	0
<i><b>Central nervous system and spinal infections</b></i>		
Meningitis	2	0
Meningitis aseptic	2	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
<i><b>Enteroviral infections NEC</b></i>		
Meningitis enteroviral	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus infection	4	0
Meningitis haemophilus	1	0
<i><b>Infections NEC</b></i>		
Abscess	3	0
Abscess limb	1	0
Infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	1	0
Pneumonia	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Eczema infected	1	0
Skin infection	1	0
<i><b>Staphylococcal infections</b></i>		
Staphylococcal infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Croup infectious	1	0
Nasopharyngitis	1	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Bronchiolitis	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>38</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Wound secretion	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	5	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
<i>Product preparation errors and issues</i>		
Product preparation issue	5	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Skin injuries NEC</i>		
Contusion	5	0
Scratch	1	0
Skin injury	1	0
<i>Vaccination related complications</i>		
Vaccination failure	5	0
<b>Injuries SOC TOTAL</b>	<b>31</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	2	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	1	0
Heart rate increased	1	0
Pulse abnormal	1	0
<i><b>Immunoglobulin analyses</b></i>		
Blood immunoglobulin G increased	2	0
<i><b>Liver function analyses</b></i>		
Alanine aminotransferase increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood magnesium decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	8	0
Breath sounds abnormal	1	0
Respiratory rate increased	3	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	3	0
<i><b>White blood cell analyses</b></i>		
Lymphocyte count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>31</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	21	0
Food refusal	2	0
Hypophagia	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	4	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
Food aversion	1	0
Poor feeding infant	20	0
Weight gain poor	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Lactic acidosis	1	0
Metabolic acidosis	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>58</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
 Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	2	0
Muscle twitching	3	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	14	0
Muscle rigidity	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	2	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Infantile back arching	4	0
Limb mass	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Musculoskeletal pain	1	0
Pain in extremity	5	0
<i><b>Soft tissue disorders NEC</b></i>		
Groin pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>42</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	4	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	2	0
Nystagmus	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	1	0
Lethargy	7	0
Loss of consciousness	1	0
Postictal state	1	0
Somnolence	23	0
Syncope	2	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	8	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<b><i>Eye movement disorders</i></b>		
VIth nerve paralysis	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	5	0
<b><i>Headaches NEC</i></b>		
Headache	1	0
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Mental impairment	1	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	10	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	1	0
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Hyporesponsive to stimuli	3	0
Infant irritability	1	0
Myoclonus	1	0
Unresponsive to stimuli	25	0
<b><i>Neuromuscular disorders NEC</i></b>		
Hypotonic-hyporesponsive episode	15	0
Muscle spasticity	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	1	0
Epileptic encephalopathy	1	0
Febrile convulsion	9	0
Infantile spasms	2	0
Seizure	13	0
Status epilepticus	1	0
<b><i>Sleep disturbances NEC</i></b>		



## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Poor quality sleep	5	0
Sudden onset of sleep	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	1	0
Speech disorder	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>161</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Gestational age and weight conditions</i>		
Poor weight gain neonatal	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	5	0
<b>null SOC TOTAL</b>	<b>5</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	4	0
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Anxiety	1	0
Nervousness	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Personality change	1	0
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	1	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	6	0
Middle insomnia	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	2	0
Emotional distress	3	0
Irritability	35	0
Mood altered	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	10	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	2	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	2	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	5	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>100</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Anuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	12	0
Dyspnoea	11	0
Hypopnoea	3	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	3	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	3	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Cyanosis central	1	0
Respiratory acidosis	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	9	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonia aspiration	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
<i><b>Neonatal hypoxic conditions</b></i>		
Infantile apnoea	3	0
Neonatal hypoxia	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Use of accessory respiratory muscles	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking	1	0
Dysphonia	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	4	0
<b>Respiratory disorders SOC TOTAL</b>	<b>71</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021  
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 15-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	2	0
Hyperhidrosis	3	0
<i><b>Bullous conditions</b></i>		
Blister	4	0
Dermatitis bullous	1	0
Pemphigoid	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	3	0
Papule	2	0
Skin burning sensation	1	0
Skin discolouration	13	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	1	0
Skin plaque	1	0
Skin reaction	1	0
Skin warm	6	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	1	0
Dermatitis allergic	3	0
Dermatitis atopic	1	0
Dermatitis diaper	1	0
Eczema	9	0
Eczema infantile	1	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i><b>Erythemas</b></i>		
Erythema	30	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	6	0
<i><b>Purpura and related conditions</b></i>		
Petechiae	9	0
Purpura	2	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	45	0
Rash erythematous	10	0
Rash macular	11	0
Rash papular	3	0
Rash pruritic	2	0
Rash vesicular	5	0
<i><b>Skin and subcutaneous tissue ulcerations</b></i>		
Skin erosion	1	0
<i><b>Skin vasomotor conditions</b></i>		
Livedo reticularis	9	0
Lividity	1	0
<i><b>Urticarias</b></i>		
Urticaria	18	0
Urticaria chronic	1	0
Urticaria pressure	1	0
<b>Skin disorders SOC TOTAL</b>	<b>213</b>	<b>0</b>



## Case Series Drug Analysis Print

### Name: FOI 21/181: Infanrix Hexa Drug Analysis Print (DAP)

Report Run Date: 16-Mar-2021

Data Lock Date: 15-Mar-2021 19:00:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Arterial infections and inflammations</b></i>		
Kawasaki's disease	1	1
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	2	0
<i><b>Haemorrhages NEC</b></i>		
Haemorrhage	1	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Fibromuscular dysplasia	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	8	0
Flushing	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	35	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>54</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1423</b>	<b>16</b>
<b>TOTAL REPORTS</b>	<b>483</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>16</b>