

Case Series Drug Analysis Print

Name: FOI 23/016 - PCV Vaccine Analysis Print

Report Run Date: 02-Feb-2023

Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

FOI 23/016 - PCV All UK spontaneous reports for PCV up to and
Vaccine Analysis Print: including DLP 31/01/2023

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 3 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| <i>Anaemias haemolytic mechanical factor</i> | | |
| Haemolytic uraemic syndrome | 5 | 0 |
| <i>Haematological disorders</i> | | |
| Mastocytosis | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 1 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Leukocytosis | 1 | 0 |
| Lymphocytic infiltration | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Abdominal lymphadenopathy | 1 | 0 |
| Lymphadenitis | 1 | 0 |
| Lymphadenopathy | 5 | 0 |
| <i>Neutropenias</i> | | |
| Febrile neutropenia | 1 | 0 |
| Neutropenia | 1 | 0 |
| <i>Sickle cell trait and disorders</i> | | |
| Sickle cell anaemia with crisis | 1 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 2 | 0 |
| Thrombocytopenia | 5 | 0 |
| Blood disorders SOC TOTAL | 30 | 0 |

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|--|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 1 | 0 |
| Cardiovascular disorder | 3 | 0 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 1 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiomegaly | 1 | 0 |
| Left ventricular dysfunction | 1 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Pericardial effusion | 2 | 0 |
| Pericardial haemorrhage | 1 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 17 | 0 |
| Bradycardia neonatal | 1 | 0 |
| Tachycardia | 17 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 1 | 0 |
| Supraventricular tachycardia | 1 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 13 | 5 |
| Cardio-respiratory arrest | 4 | 1 |
| Ventricular fibrillation | 1 | 0 |
| Ventricular tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 66 | 6 |

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|---|--------------|--------------|
| Congenital disorders | | |
| <i>Cardiac septal defects congenital</i> | | |
| Atrial septal defect | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Hypermobility syndrome | 2 | 0 |
| <i>Gastric disorders congenital</i> | | |
| Pyloric stenosis | 1 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Congenital nystagmus | 1 | 0 |
| Congenital disorders SOC TOTAL | 5 | 0 |

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|--|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear discomfort | 1 | 0 |
| Ear pain | 4 | 0 |
| Ear swelling | 5 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 1 | 0 |
| <i>External ear infections and inflammations</i> | | |
| External ear inflammation | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 5 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Vertigo | 1 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane disorder | 1 | 0 |
| Ear disorders SOC TOTAL | 19 | 0 |

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|--|-----------|----------|
| Eye disorders | | |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Excessive eye blinking | 4 | 0 |
| Eyelid ptosis | 1 | 0 |
| <i>Lacrimation disorders</i> | | |
| Lacrimation increased | 2 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Erythema of eyelid | 1 | 0 |
| Eyelid oedema | 1 | 0 |
| Swelling of eyelid | 3 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 1 | 0 |
| Eye oedema | 2 | 0 |
| Eye swelling | 16 | 0 |
| Periorbital oedema | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye pruritus | 1 | 0 |
| Ocular hyperaemia | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 19 | 0 |
| Gaze palsy | 2 | 0 |
| Strabismus | 3 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| Photophobia | 3 | 0 |
| <i>Orbital structural change, deposit and degeneration</i> | | |
| Lid sulcus deepened | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Anisocoria | 2 | 0 |
| Miosis | 2 | 0 |
| Mydriasis | 4 | 0 |
| Pupil fixed | 2 | 0 |
| <i>Visual disorders NEC</i> | | |
| Photopsia | 1 | 0 |
| Vision blurred | 2 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 2 | 0 |
| Cortical visual impairment | 1 | 0 |
| Visual impairment | 3 | 0 |
| Eye disorders SOC TOTAL | 83 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Gastrointestinal sounds abnormal | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Colitis | 2 | 0 |
| Necrotising colitis | 2 | 1 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 171 | 0 |
| Diarrhoea haemorrhagic | 2 | 0 |
| Diarrhoea neonatal | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 3 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 10 | 0 |
| Faecaloma | 1 | 0 |
| Faeces discoloured | 12 | 0 |
| Faeces hard | 1 | 0 |
| Faeces pale | 1 | 0 |
| Faeces soft | 2 | 0 |
| Mucous stools | 9 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 6 | 0 |
| Flatulence | 10 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Reflux gastritis | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 13 | 0 |
| Abdominal pain upper | 19 | 0 |
| Gastrointestinal pain | 1 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 11 | 0 |
| Gastrooesophageal reflux disease | 10 | 0 |
| Intestinal dilatation | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Gastric disorder | 1 | 0 |
| Gastrointestinal disorder | 2 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Change of bowel habit | 1 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Necrotising enterocolitis neonatal | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 12 | 0 |
| Dysphagia | 1 | 0 |
| Gastrointestinal wall thickening | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Frequent bowel movements | 6 | 0 |
| Irritable bowel syndrome | 1 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intussusception | 1 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia, obstructive | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Infantile vomiting | 4 | 0 |
| Nausea | 16 | 0 |

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|---|------------|----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Regurgitation | 1 | 0 |
| Vomiting | 227 | 0 |
| Vomiting projectile | 17 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Haematemesis | 1 | 0 |
| Haematochezia | 13 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Salivary hypersecretion | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Lip pain | 1 | 0 |
| Oral pain | 1 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 12 | 0 |
| Mouth swelling | 2 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Mouth ulceration | 1 | 0 |
| <i>Tongue disorders</i> | | |
| Tongue disorder | 1 | 0 |
| Tongue geographic | 1 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Protrusion tongue | 2 | 0 |
| Swollen tongue | 3 | 0 |
| Tongue blistering | 1 | 0 |
| Tongue discolouration | 2 | 0 |
| Tongue movement disturbance | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 626 | 1 |

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|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site erythema | 1 | 0 |
| Administration site swelling | 1 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site irritation | 1 | 0 |
| Application site papules | 1 | 0 |
| Application site rash | 1 | 0 |
| Application site swelling | 2 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 16 | 0 |
| Decreased activity | 3 | 0 |
| Fatigue | 26 | 0 |
| Malaise | 95 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 1 | 0 |
| Hypothermia | 2 | 0 |
| <i>Death and sudden death</i> | | |
| Brain death | 1 | 0 |
| Death | 19 | 19 |
| Sudden death | 6 | 6 |
| Sudden infant death syndrome | 10 | 10 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 1 | 0 |
| Pyrexia | 567 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 17 | 0 |
| Feeling abnormal | 17 | 0 |
| Feeling cold | 4 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 37 | 0 |
| Thirst | 4 | 0 |
| Thirst decreased | 4 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 12 | 0 |
| Gait inability | 11 | 0 |
| Loss of control of legs | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 11 | 0 |
| Crepitations | 1 | 0 |
| Crying | 196 | 0 |
| Developmental delay | 5 | 0 |
| Developmental regression | 1 | 0 |
| Disease recurrence | 1 | 0 |
| Effusion | 1 | 0 |
| Foaming at mouth | 1 | 0 |
| General physical health deterioration | 2 | 0 |
| Glassy eyes | 5 | 0 |
| High-pitched crying | 18 | 0 |
| Illness | 13 | 0 |
| Induration | 16 | 0 |
| Influenza like illness | 5 | 0 |
| Irritability postvaccinal | 3 | 0 |
| Local reaction | 64 | 0 |

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|---|-------|-------|
| General disorders General disorders cont'd | | |
| Moaning | 2 | 0 |
| Multiple organ dysfunction syndrome | 1 | 0 |
| Peripheral swelling | 107 | 0 |
| Pneumatoxis | 1 | 0 |
| Screaming | 94 | 0 |
| Secretion discharge | 3 | 0 |
| Swelling | 77 | 0 |
| Swelling face | 21 | 0 |
| Inflamations | | |
| Inflammation | 37 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 1 | 0 |
| Injection site bruising | 7 | 0 |
| Injection site cyst | 1 | 0 |
| Injection site discharge | 1 | 0 |
| Injection site discolouration | 5 | 0 |
| Injection site erosion | 1 | 0 |
| Injection site erythema | 134 | 0 |
| Injection site hypersensitivity | 1 | 0 |
| Injection site induration | 14 | 0 |
| Injection site inflammation | 42 | 0 |
| Injection site irritation | 1 | 0 |
| Injection site joint erythema | 1 | 0 |
| Injection site mass | 32 | 0 |
| Injection site movement impairment | 1 | 0 |
| Injection site oedema | 3 | 0 |
| Injection site pain | 25 | 0 |
| Injection site pruritus | 2 | 0 |
| Injection site rash | 14 | 0 |
| Injection site reaction | 66 | 0 |
| Injection site swelling | 110 | 0 |
| Injection site urticaria | 5 | 0 |
| Injection site vesicles | 4 | 0 |
| Injection site warmth | 26 | 0 |
| Mass conditions NEC | | |
| Cyst | 1 | 0 |
| Mass | 6 | 0 |
| Oedema NEC | | |
| Face oedema | 2 | 0 |
| Localised oedema | 2 | 0 |
| Oedema | 3 | 0 |
| Oedema peripheral | 16 | 0 |
| Pain and discomfort NEC | | |
| Chest discomfort | 3 | 0 |
| Chest pain | 2 | 0 |
| Discomfort | 14 | 0 |
| Pain | 60 | 0 |
| Tenderness | 19 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 14 | 0 |
| Adverse reaction | 1 | 0 |
| Drug ineffective | 180 | 0 |
| Immediate post-injection reaction | 1 | 0 |

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|---|-------------|-----------|
| General disorders General disorders cont'd | | |
| Therapeutic product ineffective | 231 | 0 |
| Vaccination failure | 31 | 0 |
| Ulcers NEC | | |
| Ulcer | 1 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 3 | 0 |
| Vaccination site bruising | 6 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 48 | 0 |
| Vaccination site haematoma | 2 | 0 |
| Vaccination site haemorrhage | 1 | 0 |
| Vaccination site induration | 17 | 0 |
| Vaccination site inflammation | 9 | 0 |
| Vaccination site joint erythema | 1 | 0 |
| Vaccination site joint movement impairment | 1 | 0 |
| Vaccination site joint pain | 1 | 0 |
| Vaccination site mass | 25 | 0 |
| Vaccination site movement impairment | 3 | 0 |
| Vaccination site pain | 27 | 0 |
| Vaccination site pruritus | 2 | 0 |
| Vaccination site rash | 10 | 0 |
| Vaccination site reaction | 7 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site swelling | 39 | 0 |
| Vaccination site urticaria | 1 | 0 |
| Vaccination site vesicles | 2 | 0 |
| Vaccination site warmth | 14 | 0 |
| General disorders SOC TOTAL | 2853 | 35 |

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|---|--------------|--------------|
| Hepatic disorders | | |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 2 | 0 |
| Jaundice cholestatic | 1 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatomegaly | 1 | 0 |
| Hepatic disorders SOC TOTAL | 4 | 0 |

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|---|------------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Allergy to metals | 1 | 0 |
| Hypersensitivity | 40 | 0 |
| Multiple allergies | 2 | 0 |
| Serum sickness-like reaction | 1 | 0 |
| Type III immune complex mediated reaction | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 1 | 0 |
| Drug hypersensitivity | 1 | 0 |
| Food allergy | 3 | 0 |
| Milk allergy | 6 | 0 |
| Reaction to excipient | 1 | 0 |
| Rubber sensitivity | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 32 | 1 |
| Anaphylactic shock | 2 | 0 |
| Anaphylactoid reaction | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Decreased immune responsiveness | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 1 | 0 |
| Immune system disorder | 2 | 0 |
| Immune-mediated adverse reaction | 1 | 0 |
| Immunisation reaction | 4 | 0 |
| Sensitisation | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Hypogammaglobulinaemia | 1 | 0 |
| Immunodeficiency | 3 | 0 |
| Immune system disorders SOC TOTAL | 107 | 1 |

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|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Gastroenteritis | 2 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenovirus infection | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 4 | 0 |
| Bacterial infection | 1 | 0 |
| Bacterial sepsis | 4 | 0 |
| Cellulitis | 33 | 0 |
| Injection site cellulitis | 5 | 0 |
| Meningitis bacterial | 3 | 0 |
| Pneumonia bacterial | 1 | 0 |
| Pyomyositis | 1 | 0 |
| Skin bacterial infection | 3 | 0 |
| Vaccination site cellulitis | 6 | 0 |
| <i>Bone and joint infections</i> | | |
| Intervertebral discitis | 1 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 2 | 0 |
| <i>Candida infections</i> | | |
| Candida infection | 1 | 0 |
| Oral candidiasis | 3 | 0 |
| <i>Cardiac infections</i> | | |
| Endocarditis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Brain empyema | 1 | 0 |
| Cavernous sinus thrombosis | 1 | 0 |
| Encephalitis | 8 | 1 |
| Meningitis | 14 | 0 |
| Meningitis aseptic | 7 | 0 |
| Subdural abscess | 1 | 0 |
| <i>Coronavirus infections</i> | | |
| COVID-19 | 2 | 0 |
| <i>Cytomegaloviral infections</i> | | |
| Cytomegalovirus infection | 1 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Gingivitis | 1 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 10 | 0 |
| Mastoiditis | 3 | 0 |
| Otitis media | 3 | 0 |
| Otitis media acute | 1 | 0 |
| Otitis media chronic | 1 | 0 |
| <i>Enteroviral infections NEC</i> | | |
| Hand-foot-and-mouth disease | 1 | 0 |
| Meningitis enteroviral | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 2 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 7 | 0 |
| Eye infection | 1 | 0 |
| <i>Haemophilus infections</i> | | |

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|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Haemophilus bacteraemia | 1 | 0 |
| Haemophilus sepsis | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Herpes simplex | 1 | 0 |
| Herpes virus infection | 1 | 0 |
| Herpes zoster | 1 | 0 |
| Human herpesvirus 6 infection | 2 | 0 |
| Oral herpes | 1 | 0 |
| Varicella | 1 | 0 |
| Varicella zoster virus infection | 1 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 2 | 0 |
| Abscess limb | 1 | 0 |
| Empyema | 62 | 0 |
| Febrile infection | 1 | 0 |
| Infection | 9 | 0 |
| Injection site abscess | 3 | 0 |
| Injection site infection | 3 | 0 |
| Localised infection | 1 | 0 |
| Vaccination site abscess | 5 | 0 |
| Vaccination site infection | 3 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 5 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 4 | 0 |
| Infectious pleural effusion | 1 | 0 |
| Lower respiratory tract infection | 25 | 0 |
| Pneumonia | 58 | 0 |
| Pneumonia necrotising | 1 | 0 |
| <i>Mumps viral infections</i> | | |
| Mumps | 2 | 0 |
| <i>Neisseria infections</i> | | |
| Meningococcal infection | 2 | 0 |
| Meningococcal sepsis | 1 | 0 |
| <i>Parainfluenzae viral infections</i> | | |
| Parainfluenzae virus infection | 1 | 0 |
| <i>Respiratory syncytial viral infections</i> | | |
| Respiratory syncytial virus bronchiolitis | 4 | 0 |
| Respiratory syncytial virus infection | 2 | 0 |
| <i>Rhinoviral infections</i> | | |
| Rhinovirus infection | 1 | 0 |
| <i>Rotaviral infections</i> | | |
| Gastroenteritis rotavirus | 1 | 0 |
| <i>Rubella viral infections</i> | | |
| Rubella | 1 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 2 | 0 |
| <i>Salmonella infections</i> | | |
| Salmonellosis | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Bacteraemia | 21 | 0 |
| Sepsis | 34 | 0 |
| Septic shock | 1 | 0 |

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|--|------------|-----------|
| Infections | | |
| Infections cont'd | | |
| Urosepsis | 1 | 1 |
| <i>Skin structures and soft tissue infections</i> | | |
| Eczema infected | 1 | 0 |
| Skin infection | 3 | 0 |
| <i>Staphylococcal infections</i> | | |
| Staphylococcal infection | 1 | 0 |
| Staphylococcal sepsis | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Meningitis pneumococcal | 48 | 2 |
| Pharyngitis streptococcal | 1 | 0 |
| Pneumococcal bacteraemia | 17 | 0 |
| Pneumococcal infection | 340 | 11 |
| Pneumococcal sepsis | 26 | 2 |
| Pneumonia pneumococcal | 23 | 1 |
| Pneumonia streptococcal | 17 | 0 |
| Septic arthritis streptococcal | 1 | 0 |
| Streptococcal bacteraemia | 1 | 0 |
| Streptococcal sepsis | 2 | 0 |
| Tonsillitis streptococcal | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Croup infectious | 4 | 0 |
| Epiglottitis | 1 | 0 |
| Nasopharyngitis | 13 | 0 |
| Pharyngitis | 1 | 0 |
| Rhinitis | 8 | 0 |
| Tonsillitis | 7 | 0 |
| Upper respiratory tract infection | 11 | 0 |
| <i>Urinary tract infections</i> | | |
| Kidney infection | 1 | 0 |
| Urinary tract infection | 3 | 0 |
| <i>Viral infections NEC</i> | | |
| Bronchiolitis | 8 | 0 |
| Gastroenteritis viral | 1 | 0 |
| Viral infection | 5 | 0 |
| Viral rash | 1 | 0 |
| Viral upper respiratory tract infection | 3 | 0 |
| Infections SOC TOTAL | 958 | 18 |

Case Series Drug Analysis Print

Name: FOI 23/016 - PCV Vaccine Analysis Print

Report Run Date: 02-Feb-2023
Earliest Reaction Date: 21-Sep-2001

Data Lock Date: 31-Jan-2023 18:30:04
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Injuries | | |
| <i>Cerebral injuries NEC</i> | | |
| Craniocerebral injury | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure via breast milk | 1 | 0 |
| Maternal exposure during breast feeding | 1 | 0 |
| Maternal exposure during pregnancy | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 10 | 0 |
| Product use in unapproved indication | 3 | 0 |
| Wrong technique in product usage process | 2 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Muscle injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Injury | 1 | 0 |
| Wound secretion | 2 | 0 |
| <i>Product administration errors and issues</i> | | |
| Extra dose administered | 1 | 0 |
| Inappropriate schedule of product administration | 12 | 0 |
| Incomplete course of vaccination | 1 | 0 |
| Incorrect dose administered | 2 | 0 |
| Incorrect route of product administration | 2 | 0 |
| Product administered at inappropriate site | 2 | 0 |
| Product administered to patient of inappropriate age | 7 | 0 |
| Product administration error | 4 | 0 |
| Wrong product administered | 1 | 0 |
| <i>Product prescribing errors and issues</i> | | |
| Product prescribing error | 1 | 0 |
| Product prescribing issue | 1 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 3 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 15 | 0 |
| Scar | 1 | 0 |
| Scratch | 1 | 0 |
| Skin injury | 1 | 0 |
| Skin laceration | 1 | 0 |
| <i>Vaccination related complications</i> | | |
| Post vaccination syndrome | 1 | 0 |
| Vaccination complication | 1 | 0 |
| Injuries SOC TOTAL | 81 | 0 |

Case Series Drug Analysis Print

Name: FOI 23/016 - PCV Vaccine Analysis Print

Report Run Date: 02-Feb-2023

Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Streptococcus test positive | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 20 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose fluctuation | 1 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 1 | 0 |
| <i>Central nervous system histopathology procedures</i> | | |
| Biopsy brain abnormal | 1 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF white blood cell count increased | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Inflammatory marker increased | 2 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| Coagulation test abnormal | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate abnormal | 3 | 0 |
| Heart rate decreased | 2 | 0 |
| Heart rate increased | 13 | 0 |
| Pulse abnormal | 1 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test abnormal | 2 | 0 |
| Antibody test negative | 2 | 0 |
| Tryptase increased | 1 | 0 |
| <i>Metabolism tests NEC</i> | | |
| Blood ketone body increased | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood magnesium decreased | 1 | 0 |
| Blood sodium decreased | 2 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |
| Intraocular pressure increased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature | 1 | 0 |
| Body temperature abnormal | 4 | 0 |
| Body temperature decreased | 3 | 0 |
| Body temperature fluctuation | 3 | 0 |
| Body temperature increased | 66 | 0 |
| Breath sounds abnormal | 3 | 0 |
| Respiratory rate decreased | 1 | 0 |
| Respiratory rate increased | 3 | 0 |
| Weight decreased | 3 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count increased | 3 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 17 | 0 |
| <i>Red blood cell analyses</i> | | |
| Haemoglobin decreased | 3 | 0 |
| <i>Renal function analyses</i> | | |
| Blood creatinine decreased | 1 | 0 |
| Blood urea decreased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine present | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 02-Feb-2023

Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Investigations | | |
| Investigations cont'd | | |
| White blood cells urine | 1 | 0 |
| Urinary tract function analyses NEC | | |
| Urine output decreased | 4 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure decreased | 1 | 0 |
| Capillary nail refill test abnormal | 1 | 0 |
| Virus identification and serology | | |
| Coronavirus test positive | 1 | 0 |
| White blood cell analyses | | |
| Eosinophil count increased | 1 | 0 |
| Lymphocyte count increased | 1 | 0 |
| Neutrophil count decreased | 1 | 0 |
| White blood cell count decreased | 1 | 0 |
| White blood cell count increased | 5 | 0 |
| Investigations SOC TOTAL | 187 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 02-Feb-2023
Earliest Reaction Date: 21-Sep-2001

Data Lock Date: 31-Jan-2023 18:30:04
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 2 | 0 |
| Decreased appetite | 99 | 0 |
| Food refusal | 2 | 0 |
| Hypophagia | 6 | 0 |
| Increased appetite | 1 | 0 |
| <i>Cell metabolism disorders NEC</i> | | |
| Mitochondrial cytopathy | 1 | 0 |
| <i>Chloride imbalance</i> | | |
| Hyperchloraemia | 1 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 2 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 1 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Dairy intolerance | 3 | 0 |
| Food intolerance | 3 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 1 | 0 |
| Failure to thrive | 1 | 0 |
| Feeding disorder | 8 | 0 |
| Food aversion | 4 | 0 |
| Poor feeding infant | 53 | 0 |
| Weight gain poor | 4 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 1 | 0 |
| <i>Metabolic acidoses (excl diabetic acidoses)</i> | | |
| Metabolic acidosis | 3 | 0 |
| <i>Potassium imbalance</i> | | |
| Hyperkalaemia | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 2 | 0 |
| <i>Sugar intolerance (excl glucose intolerance)</i> | | |
| Lactose intolerance | 2 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 6 | 0 |
| Metabolic disorders SOC TOTAL | 207 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 02-Feb-2023
Earliest Reaction Date: 21-Sep-2001

Data Lock Date: 31-Jan-2023 18:30:04
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 1 | 0 |
| Polyarthritis | 1 | 0 |
| <i>Extremity deformities</i> | | |
| Foot deformity | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Periarthritis | 2 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 19 | 0 |
| Joint effusion | 1 | 0 |
| Joint range of motion decreased | 1 | 0 |
| Joint swelling | 6 | 0 |
| Joint warmth | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 11 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle disorder | 1 | 0 |
| Muscle spasms | 4 | 0 |
| Muscle tightness | 1 | 0 |
| Muscle twitching | 9 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Floppy infant | 32 | 0 |
| Muscle rigidity | 7 | 0 |
| Trismus | 1 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 4 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Limb mass | 1 | 0 |
| Musculoskeletal stiffness | 19 | 0 |
| Posture abnormal | 2 | 0 |
| Toe walking | 1 | 0 |
| Weight bearing difficulty | 11 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Limb discomfort | 6 | 0 |
| Musculoskeletal chest pain | 1 | 0 |
| Musculoskeletal discomfort | 1 | 0 |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 2 | 0 |
| Pain in extremity | 65 | 0 |
| <i>Tendon disorders</i> | | |
| Tendonitis | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 214 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>Leukaemias acute lymphocytic</i> | | |
| Acute lymphocytic leukaemia | 2 | 0 |
| <i>Myelodysplastic syndromes</i> | | |
| Myelodysplastic syndrome | 1 | 0 |
| <i>Nervous system neoplasms unspecified malignancy NEC</i> | | |
| Astrocytoma | 1 | 0 |
| <i>Rhabdomyosarcomas</i> | | |
| Rhabdomyosarcoma | 1 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Neoplasm skin | 1 | 0 |
| Neoplasms SOC TOTAL | 6 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 21-Sep-2001

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 10 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebral infarction | 1 | 0 |
| Intraventricular haemorrhage | 1 | 0 |
| Ruptured cerebral aneurysm | 1 | 0 |
| <i>Central nervous system vascular disorders NEC</i> | | |
| Brain hypoxia | 1 | 0 |
| <i>Cerebrovascular venous and sinus thrombosis</i> | | |
| Cerebral venous thrombosis | 1 | 0 |
| Superior sagittal sinus thrombosis | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Balance disorder | 5 | 0 |
| Coordination abnormal | 1 | 0 |
| Dysstasia | 1 | 0 |
| Hand-eye coordination impaired | 1 | 0 |
| Nystagmus | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 4 | 0 |
| Dyspraxia | 2 | 0 |
| Sensory processing disorder | 2 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Depressed level of consciousness | 6 | 0 |
| Lethargy | 61 | 0 |
| Loss of consciousness | 17 | 0 |
| Sedation | 1 | 0 |
| Somnolence | 82 | 0 |
| Syncope | 16 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 26 | 0 |
| Fine motor delay | 1 | 0 |
| Hypokinesia | 3 | 0 |
| Motor dysfunction | 1 | 0 |
| Movement disorder | 3 | 0 |
| Psychomotor hyperactivity | 3 | 0 |
| <i>Dystonias</i> | | |
| Dystonia | 1 | 0 |
| Opisthotonus | 3 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 16 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 17 | 0 |
| Tension headache | 2 | 0 |
| <i>Hydrocephalic conditions</i> | | |
| Hydrocephalus | 2 | 0 |
| <i>Increased intracranial pressure disorders</i> | | |
| Brain oedema | 3 | 0 |
| <i>Intellectual disabilities</i> | | |
| Intellectual disability | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 02-Feb-2023

Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 2 | 0 |
| Disturbance in attention | 3 | 0 |
| <i>Migraine headaches</i> | | |
| Migraine with aura | 1 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypertonia | 1 | 0 |
| Hypotonia | 67 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Hypersomnia | 11 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Brain stem syndrome | 1 | 0 |
| Nervous system disorder | 5 | 0 |
| Neurodegenerative disorder | 1 | 0 |
| Subdural effusion | 3 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Cerebrospinal fluid leakage | 1 | 0 |
| Dizziness | 9 | 0 |
| Dizziness postural | 1 | 0 |
| Drooling | 2 | 0 |
| Exaggerated startle response | 2 | 0 |
| Fontanelle bulging | 6 | 0 |
| Grimacing | 1 | 0 |
| Hyporesponsive to stimuli | 5 | 0 |
| Inability to crawl | 1 | 0 |
| Infant irritability | 3 | 0 |
| Meningism | 1 | 0 |
| Myoclonus | 1 | 0 |
| Neurological decompensation | 1 | 0 |
| Neurological symptom | 1 | 0 |
| Pleocytosis | 3 | 0 |
| Presyncope | 4 | 0 |
| Unresponsive to stimuli | 67 | 0 |
| <i>Neuromuscular disorders NEC</i> | | |
| Hypotonic-hypo-responsive episode | 10 | 0 |
| Muscle spasticity | 1 | 0 |
| Neuromyopathy | 1 | 0 |
| <i>Paraesthesias and dysaesthesias</i> | | |
| Burning sensation | 2 | 0 |
| Hyperaesthesia | 2 | 0 |
| Hypoaesthesia | 3 | 0 |
| Paraesthesia | 3 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Monoplegia | 2 | 0 |
| Paralysis | 2 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 10 | 0 |
| Epileptic encephalopathy | 1 | 0 |
| Febrile convulsion | 48 | 0 |
| Infantile spasms | 1 | 0 |
| Partial seizures | 9 | 0 |
| Seizure | 81 | 0 |
| Seizure anoxic | 1 | 0 |

Case Series Drug Analysis Print

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Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Seizure cluster | 2 | 0 |
| Seizure like phenomena | 1 | 0 |
| Status epilepticus | 4 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Restless legs syndrome | 1 | 0 |
| Sensory disturbance | 1 | 0 |
| <i>Sleep disturbances NEC</i> | | |
| Sleep deficit | 1 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Speech disorder | 3 | 0 |
| Speech disorder developmental | 3 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Radiculopathy | 1 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 25 | 0 |
| Nervous system disorders SOC TOTAL | 723 | 0 |

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---------------------------------------|----------|----------|
| Pregnancy conditions | | |
| <i>Newborn complications NEC</i> | | |
| Neonatal disorder | 4 | 0 |
| Pregnancy conditions SOC TOTAL | 4 | 0 |

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 2 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product quality issue | 4 | 0 |
| null SOC TOTAL | 6 | 0 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 21 | 0 |
| Behaviour disorder | 1 | 0 |
| Breath holding | 11 | 0 |
| Regressive behaviour | 1 | 0 |
| Staring | 10 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder | 1 | 0 |
| <i>Affect alterations NEC</i> | | |
| Flat affect | 1 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Separation anxiety disorder | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 9 | 0 |
| Anxiety | 4 | 0 |
| Stress | 1 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 1 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 3 | 0 |
| Disturbance in social behaviour | 1 | 0 |
| Personality change | 4 | 0 |
| Social avoidant behaviour | 1 | 0 |
| <i>Communications disorders</i> | | |
| Mutism | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 1 | 0 |
| Disorientation | 3 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 2 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Initial insomnia | 1 | 0 |
| Insomnia | 25 | 0 |
| Middle insomnia | 3 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 7 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 3 | 0 |
| Selective eating disorder | 5 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Emotional distress | 30 | 0 |
| Emotional poverty | 1 | 0 |
| Irritability | 161 | 0 |
| Mood altered | 7 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear of eating | 1 | 0 |
| Social fear | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 5 | 0 |
| Hallucination, auditory | 1 | 0 |
| Hallucinations, mixed | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 31 | 0 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 3 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressed mood | 5 | 0 |
| Tearfulness | 1 | 0 |
| <i>Mood disorders NEC</i> | | |
| Apathy | 1 | 0 |
| Listless | 9 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Obsessive-compulsive symptom | 1 | 0 |
| <i>Parasomnias</i> | | |
| Sleep terror | 4 | 0 |
| <i>Personality disorders with anxious behaviour (Cluster C)</i> | | |
| Dependent personality disorder | 1 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 18 | 0 |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 1 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Decreased eye contact | 4 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 18 | 0 |
| <i>Somatic symptom disorders</i> | | |
| Conversion disorder | 1 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Lack of spontaneous speech | 1 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Head banging | 3 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Self-injurious ideation | 1 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 434 | 0 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Micturition urgency | 1 | 0 |
| Urinary retention | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Nephrotic syndrome | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 3 | 0 |
| Anuria | 1 | 0 |
| Oliguria | 1 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Kidney enlargement | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Haematuria | 1 | 0 |
| Urine abnormality | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 11 | 0 |

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Reproductive & breast disorders | | |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Genital blister | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital rash | 1 | 0 |
| Genital swelling | 1 | 0 |
| <i>Scrotal disorders NEC</i> | | |
| Scrotal swelling | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular pain | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 5 | 0 |

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Earliest Reaction Date: 21-Sep-2001

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 36 | 0 |
| Apnoeic attack | 7 | 0 |
| Dyspnoea | 52 | 0 |
| Grunting | 5 | 0 |
| Hyperventilation | 1 | 0 |
| Hypopnoea | 9 | 0 |
| Hypoventilation | 2 | 0 |
| Irregular breathing | 1 | 0 |
| Respiration abnormal | 2 | 0 |
| Respiratory arrest | 19 | 1 |
| Respiratory distress | 11 | 0 |
| Tachypnoea | 8 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 3 | 0 |
| Wheezing | 26 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 0 |
| Cyanosis central | 1 | 0 |
| Hypoxia | 3 | 1 |
| Respiratory acidosis | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 44 | 0 |
| Haemoptysis | 1 | 0 |
| Productive cough | 6 | 0 |
| Sputum discoloured | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Stridor | 4 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Pneumonitis | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Pleuritic pain | 1 | 0 |
| Pulmonary haemorrhage | 3 | 1 |
| Rales | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 5 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 2 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Infantile apnoea | 5 | 0 |
| Neonatal hypoxia | 3 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Lung consolidation | 3 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal erythema | 7 | 0 |
| Pharyngeal inflammation | 1 | 0 |
| Pharyngeal swelling | 1 | 0 |
| Pharyngeal ulceration | 1 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Pleurisy | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 16 | 0 |
| Pneumothorax | 3 | 0 |

Case Series Drug Analysis Print

Name: FOI 23/016 - PCV Vaccine Analysis Print

Report Run Date: 02-Feb-2023

Data Lock Date: 31-Jan-2023 18:30:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Pulmonary oedemas</i> | | |
| Acute respiratory distress syndrome | 1 | 0 |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 2 | 1 |
| Respiratory failure | 2 | 1 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Use of accessory respiratory muscles | 1 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Lung disorder | 1 | 1 |
| Respiratory disorder | 6 | 0 |
| Respiratory tract oedema | 1 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal disorder | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Choking | 5 | 0 |
| Dysphonia | 3 | 0 |
| Nasal discomfort | 1 | 0 |
| Nasal obstruction | 1 | 0 |
| Oropharyngeal pain | 12 | 0 |
| Rhinorrhoea | 18 | 0 |
| Sneezing | 1 | 0 |
| Throat irritation | 1 | 0 |
| Respiratory disorders SOC TOTAL | 357 | 6 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| <i>Angioedemas</i> | | |
| Angioedema | 5 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 11 | 0 |
| Hyperhidrosis | 17 | 0 |
| Miliaria | 1 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 16 | 0 |
| Dermatitis bullous | 1 | 0 |
| Erythema multiforme | 9 | 0 |
| Pemphigoid | 3 | 0 |
| Stevens-Johnson syndrome | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 8 | 0 |
| Macule | 2 | 0 |
| Pain of skin | 4 | 0 |
| Papule | 8 | 0 |
| Scab | 3 | 0 |
| Skin burning sensation | 3 | 0 |
| Skin discolouration | 37 | 0 |
| Skin discomfort | 1 | 0 |
| Skin disorder | 3 | 0 |
| Skin induration | 3 | 0 |
| Skin lesion | 7 | 0 |
| Skin odour abnormal | 1 | 0 |
| Skin plaque | 1 | 0 |
| Skin reaction | 12 | 0 |
| Skin tightness | 4 | 0 |
| Skin warm | 30 | 0 |
| Skin weeping | 1 | 0 |
| Yellow skin | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 1 | 0 |
| Dermatitis allergic | 21 | 0 |
| Dermatitis atopic | 2 | 0 |
| Dermatitis diaper | 7 | 0 |
| Eczema | 20 | 0 |
| Eczema infantile | 1 | 0 |
| Eczema weeping | 1 | 0 |
| Skin irritation | 1 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 1 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 286 | 0 |
| <i>Exfoliative conditions</i> | | |
| Skin exfoliation | 3 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair growth abnormal | 1 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 23 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Henoch-Schonlein purpura | 2 | 0 |
| Petechiae | 36 | 0 |
| Purpura | 21 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 279 | 0 |
| Rash erythematous | 43 | 0 |
| Rash macular | 74 | 0 |
| Rash maculo-papular | 16 | 0 |
| Rash morbilliform | 14 | 0 |
| Rash papular | 26 | 0 |
| Rash pruritic | 7 | 0 |
| Rash rubelliform | 2 | 0 |
| Rash vesicular | 4 | 0 |
| <i>Skin and subcutaneous conditions NEC</i> | | |
| Cellulite | 1 | 0 |
| Skin mass | 6 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 24 | 0 |
| <i>Urticarias</i> | | |
| Urticaria | 117 | 0 |
| Urticaria pigmentosa | 1 | 0 |
| Urticaria pressure | 1 | 0 |
| Skin disorders SOC TOTAL | 1237 | 0 |

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| Reaction Name | Total | Fatal |
|---------------------------------------|----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Immobile | 2 | 0 |
| Social circumstances SOC TOTAL | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Surgical & medical procedures | | |
| <i>Inner ear therapeutic procedures</i> | | |
| Cochlea implant | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Medical device removal | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Vascular disorders | | |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 1 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Kawasaki's disease | 1 | 1 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 7 | 0 |
| Hypoperfusion | 1 | 0 |
| Shock | 6 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 1 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Venous thrombosis | 1 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Fibromuscular dysplasia | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Capillary fragility | 1 | 0 |
| Superficial vein prominence | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 38 | 0 |
| Flushing | 9 | 0 |
| Hot flush | 3 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 9 | 0 |
| Poor peripheral circulation | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 124 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 1 | 0 |
| Vascular disorders SOC TOTAL | 208 | 1 |
| TOTAL REACTIONS FOR DRUG | 8435 | 68 |
| TOTAL REPORTS | 2937 | |
| TOTAL FATAL OUTCOME REPORTS | | 68 |