The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
84537	17/05/1993	Female	<1	Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (-)	Constipation
87508	6/09/1993	Male	2	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days)	Apnoea ; Crying ; Diarrhoea ; Hypotonia ; Pyrexia ; Seizure ; Vomiting
88646	22/10/1993	Unknown	77	Broncostat (Haemophilus influenzae) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-); Trade Name Not Specified (Sulindac) - Suspect (-)	Acute kidney injury ; Haemolytic anaemia
94674	29/07/1994	Female	1	Emla Cream (lidocaine (lignocaine) ; Prilocaine) - Suspect (5 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (5 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (5 days); Trade Name Not Specified (Paracetamol) - Suspect (5 days)	Bronchospasm ; Leukocytosis ; Pyrexia ; Upper respiratory tract infection
98715	3/02/1995	Female	<1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (-)	Sudden death

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
115131	11/01/1997	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days); Triple Antigen (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (-)	Sudden death
118770	2/07/1997	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Sabin Vaccine (Poliovirus) - Suspect (-); Triple Antigen (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Concomitant (-)	Pneumonia
121980	28/10/1997	Male	1	Hibtiter (Diphtheria CRM197 protein ; Haemophilus type B polysaccharide) - Suspect (6 days); Infanrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (6 days)	Erythema multiforme ; Rash
129229	16/07/1998	Male	2	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Infanrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis	Sudden death

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				toxoid ; Tetanus toxoid) - Suspect (1 days); Sabin Vaccine (Poliovirus) - Suspect (1 days)	
136757	1/02/1999	Unknown	<1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (0 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days)	Sudden death
137174	1/03/1999	Unknown	-	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (1 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (1 days)	Sudden death
156251	14/08/2000	Female	1	Hibtiter (Diphtheria CRM197 protein ; Haemophilus type B polysaccharide) - Suspect (-); Infanrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (-); Sabin Vaccine (Poliovirus) - Suspect (-)	Apnoea ; Cyanosis ; Hypothermia

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
158174	27/09/2000	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (-)	Quadriplegia
158176	27/09/2000	Female	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (-)	Eyelid ptosis ; Hypotonia ; Rash ; Weight decreased
158438	10/10/2000	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Infanrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Sabin Vaccine (Poliovirus) - Suspect (0 days)	Brain oedema ; Circulatory collapse ; Crying ; Nervousness ; Pyrexia ; Selective eating disorder

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
158694	19/10/2000	Male	<1	Infanrix-Hep B (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (1 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (1 days)	Sudden death
161048	29/01/2001	Male	<1	Infanrix-Hep B (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (7 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (7 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (7 days)	Sudden death
161136	1/02/2001	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days)	Agitation ; Crying ; Decreased appetite ; Pyrexia ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
164545	15/05/2001	Male	<1	Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (-)	Injection site inflammation ; Rash erythematous
164709	18/05/2001	Unknown	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (1 days); Trade Name Not Specified (Product not Coded) - Suspect (1 days)	Sudden death
171374	21/12/2001	Female	-	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (0 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days)	Sudden death
175901	3/06/2002	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Apnoea ; Gastrooesophageal reflux disease

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
180840	19/12/2002	Male	1	Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (-); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Trade Name Not Specified (Aspirin) - Concomitant (-)	Injection site abscess
181397	10/01/2003	Female	<1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (0 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Injection site reaction
181398	10/01/2003	Female	<1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (0 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days)	Rash ; Screaming

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
183086	21/01/2003	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-); Trade Name Not Specified (live varicella vaccine) - Suspect (1 days)	Cardiac arrest ; Clonus ; Respiratory arrest ; Seizure
183709	3/03/2003	Female	1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (14 days)	Drug ineffective ; Influenza
184592	2/04/2003	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Rash
189473	13/08/2003	Male	2	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (379 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (379 days)	Deafness neurosensory

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
189670	19/08/2003	Female	1	Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (21 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (21 days)	Body temperature increased ; Influenza like illness ; Myelitis transverse ; Paralysis ; Rash
190050	1/09/2003	Male	<1	Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Poliomyelitis Virus Vaccine Injection (Poliovirus) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Abnormal behaviour ; Encephalitis ; Lethargy ; Poor feeding infant ; Pyrexia ; Rash papular
190246	4/09/2003	Female	1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (115 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (115 days)	Clonic convulsion ; Encephalitis viral ; Seizure

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
191527	23/10/2003	Female	1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (349 days); Hibtiter (Diphtheria CRM197 protein ; Haemophilus type B polysaccharide) - Suspect (349 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (23 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (349 days)	Blister ; Coeliac disease ; Cough ; Crying ; Diarrhoea ; Food allergy ; Irritability ; Lymphadenopathy ; Rash ; Thirst
192408	21/11/2003	Female	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Rash
196123	31/03/2004	Male	<1	Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (1 days); Trade Name Not Specified (Product not Coded) - Suspect (1 days)	Irritability ; Pyrexia ; Urticaria

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
196313	6/04/2004	Male	<1	Infanrix-Hep B (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days)	Eye movement disorder
196404	13/04/2004	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Suspect (215 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (215 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (149 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-25 days); Poliomyelitis Virus Vaccine Injection (Poliovirus) - Suspect (215 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (215 days)	Abnormal behaviour ; Eczema ; Sleep disorder

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
198058	11/06/2004	Unknown	3	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Suspect (1380 days); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (680 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1077 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (-); Sabin Vaccine (Poliovirus) - Suspect (1380 days); Sabin Vaccine (Poliovirus) - Suspect (680 days)	Attention deficit/hyperactivity disorder ; Oppositional defiant disorder
198923	14/07/2004	Male	<1	Infanrix-Hep B (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (3 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Sabin Vaccine (Poliovirus) - Suspect (3 days)	Death ; Upper respiratory tract infection

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
199097	16/07/2004	Female	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (6 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (6 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (6 days); Trade Name Not Specified (Product not Coded) - Suspect (6 days)	Death
200527	3/09/2004	Male	13	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-)	Arthralgia
201106	23/09/2004	Male	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Cardio-respiratory arrest ; Death ; Hypotonia ; Pallor ; Vomiting
213307	10/11/2005	Female	1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (7 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (-)	Death

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
214601	5/01/2006	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days)	Cyanosis ; Dyskinesia ; Eye movement disorder ; Injection site erythema ; Lymphadenopathy ; Musculoskeletal stiffness ; Seizure
214629	5/01/2006	Female	1	Liquid Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Meningitec (Diphtheria CRM197 protein ; Meningococcal polysaccharide group C) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Unevaluable event
216284	6/03/2006	Female	3	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (0 days)	Injection site reaction

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
216285	6/03/2006	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Rash
219329	20/06/2006	Male	<1	Infanrix-Hep B (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Liquid Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Decreased appetite ; Pyrexia ; Rash

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
219364	21/06/2006	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Cardio-respiratory arrest
221139	28/08/2006	Male	1	Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Liquid Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Sabin Vaccine (Poliovirus) - Suspect (1 days)	Pyrexia ; Rash ; Vomiting
221987	27/09/2006	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Sudden infant death syndrome

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
222199	5/10/2006	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Injection site reaction ; Vomiting
222950	7/11/2006	Male	1	Meningitec (Diphtheria CRM197 protein ; Meningococcal polysaccharide group C) - Suspect (0 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Flushing ; Rash erythematous ; Urticaria
225189	30/01/2007	Male	<1	Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Irritability ; Rash papular ; Weight gain poor

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
225957	20/02/2007	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); DTPa-IPV Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Eye movement disorder ; Hypotonia ; Hypotonic-hyporesponsive episode ; Pallor
229386	5/06/2007	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Decreased appetite ; Screaming ; Somnolence

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
230112	25/06/2007	Female	1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (1 days)	Generalised erythema ; Periorbital oedema ; Rash
231680	8/08/2007	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-)	Emotional distress ; Irritability ; Rash erythematous

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
232044	15/08/2007	Female	<1	Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Diarrhoea ; Pyrexia
234064	3/10/2007	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); DTPa-IPV Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (2 days)	Urticaria

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
234134	8/10/2007	Male	<1	Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (60 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Concomitant (60 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (60 days); Rotarix (Rotavirus) - Suspect (60 days)	Intussusception
234367	15/10/2007	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (14 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (14 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (14 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (14 days)	Diarrhoea ; Intussusception ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
234529	17/10/2007	Male	1	Menjugate (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (10 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (10 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (10 days); VAQTa Hepatitis A Vaccine Inactivated (Hepatitis a virus antigen) - Suspect (10 days)	Generalised oedema ; Rash generalised ; Tongue oedema
235327	15/11/2007	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Apnoea ; Bradycardia ; Oxygen saturation decreased
236417	19/12/2007	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Bradycardia ; Hypoxia ; Pallor

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
236727	7/01/2008	Unknown	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); DTPa-IPV Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Hypotonia ; Pallor
237764	11/02/2008	Unknown	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotarix (Rotavirus) - Suspect (3 days)	Abdominal pain ; Decreased appetite ; Flatulence ; Insomnia ; Screaming

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
237814	12/02/2008	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Pyrexia ; Rash

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
239211	25/03/2008	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Concomitant (3 days); DTPa-IPV Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Nephrolithiasis ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
240082	16/04/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Rash
242376	30/06/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
242517	2/07/2008	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Concomitant (-); Rotarix (Rotavirus) - Suspect (7 days)	Intussusception
243272	29/07/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Chills ; Hypotonic-hyporesponsive episode ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
244287	2/09/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Pyrexia ; Urticaria
244742	19/09/2008	Female	<1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Apnoeic attack ; Bradycardia

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
245032	1/10/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Diarrhoea ; Hypotonic-hyporesponsive episode ; Lethargy
245056	2/10/2008	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode ; Irritability

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
245316	9/10/2008	Female	26	DTPa-HIB Vaccine (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (-); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (-)	Extensive swelling of vaccinated limb ; Injection site reaction ; Skin exfoliation
245756	23/10/2008	Female	4	Liquid Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (6 days); Meningitec (Diphtheria CRM197 protein ; Meningococcal polysaccharide group C) - Suspect (6 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (6 days)	Angioedema ; Pyrexia ; Rash
245763	23/10/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Bradycardia ; Oxygen saturation decreased ; Pyrexia
245880	28/10/2008	Female	26	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (5 days); Pneumovax	Extensive swelling of vaccinated limb ;

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				(Pneumococcal purified capsular polysaccharides) - Suspect (5 days)	Injection site reaction ; Pyrexia
246767	2/12/2008	Female	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Concomitant (-); Rotarix (Rotavirus) - Suspect (44 days)	Intussusception
247121	12/12/2008	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (-); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-)	Urticaria

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
248103	29/01/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Hypotonic-hyporesponsive episode ; Pyrexia
248319	5/02/2009	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
255849	24/08/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Mencevax Ac (Meningococcal polysaccharide group A ; Meningococcal polysaccharide group C) - Concomitant (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Intussusception
257310	29/09/2009	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Irritability ; Sleep disorder ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
257730	8/10/2009	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Hypotonic-hyporesponsive episode ; Screaming
258079	13/10/2009	Male	3	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (3 days)	Extensive swelling of vaccinated limb ; Pyrexia
258575	21/10/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Erythema

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
258576	21/10/2009	Female	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Injection site mass
258972	28/10/2009	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (8 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (8 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (8 days)	Diarrhoea ; Haematochezia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
260569	1/12/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Erythema ; Oedema peripheral
261083	15/12/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Apnoea ; Bradycardia ; Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
261323	22/12/2009	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days); Synflorix (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Urticaria
261388	23/12/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Apnoea ; Bradycardia ; Hypotonic-hyporesponsive episode
261400	23/12/2009	Female	5	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Cyanosis ; Hypotension ; Hypotonia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
261718	8/01/2010	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (0 days)	Injection site reaction
262073	21/01/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Dry skin ; Injection site reaction ; Irritability ; Pyrexia ; Screaming

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
262100	21/01/2010	Unknown	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Cyanosis ; Peripheral coldness ; Unresponsive to stimuli
262555	8/02/2010	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (7 days); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (7 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (7 days); Panvax H1N1 influenza vaccine Junior (Influenza virus haemagglutinin) - Suspect (7 days)	Cough ; Eye discharge ; Pyrexia ; Rash
264295	25/03/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Crying ; Pyrexia ; Screaming ; Tachycardia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
267282	14/05/2010	Female	1	Fluvax Junior (Influenza virus haemagglutinin) - Suspect (0 days); Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days)	Cold sweat ; Delirium ; Diarrhoea ; Dysarthria ; Pallor ; Pyrexia ; Tremor ; Vomiting
267497	17/05/2010	Male	1	Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Febrile convulsion
267744	21/05/2010	Male	1	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (1 days)	Febrile convulsion ; Irritability ; Pyrexia ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
268163	27/05/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoea ; Sudden infant death syndrome
269658	23/06/2010	Female	1	Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Dyspnoea ; Pyrexia

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
269768	24/06/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (2 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Intussusception
269916	28/06/2010	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Pyrexia ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
270371	7/07/2010	Male	-	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Injection site erythema ; Injection site swelling
270377	7/07/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Confusional state ; Hypotonia ; Pallor

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
270425	7/07/2010	Male	1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Concomitant (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Injection site reaction ; Swelling face
271976	10/08/2010	Male	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Abdominal discomfort ; Diarrhoea ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
272553	23/08/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotarix (Rotavirus) - Suspect (3 days)	Brain injury ; Cardiac arrest
272815	31/08/2010	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Vaccination error

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
273400	15/09/2010	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
275295	5/11/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
276921	20/12/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Abnormal behaviour ; Crying
278483	9/02/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Eye movement disorder ; Floppy infant ; Pyrexia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
278881	18/02/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Crying
279018	22/02/2011	Female	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (2 days)	Stevens-Johnson syndrome

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
279198	25/02/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Angioedema ; Hypotonic-hyporesponsive episode ; Rash ; Vomiting
279349	1/03/2011	Female	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (2 days)	Blister ; Conjunctivitis ; Eating disorder ; Erythema ; Eye swelling ; Increased upper airway secretion ; Irritability ; Lethargy ; Measles ; Mucosal inflammation ; Rash ; Skin exfoliation ; Stevens-Johnson syndrome ; Tachypnoea

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
279529	7/03/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Constipation ; Crying ; Diarrhoea ; Hypophagia ; Insomnia ; Malaise ; Vomiting projectile
280046	18/03/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Lip swelling

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
280218	23/03/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Hypotonic-hyporesponsive episode ; Irritability ; Pyrexia
280446	25/03/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Hypotonia ; Seizure ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
280692	31/03/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (5 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (5 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (5 days)	Coordination abnormal ; Diarrhoea
280700	31/03/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Decreased appetite ; Injection site reaction ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
280785	4/04/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (1 days)	Rash
281008	7/04/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Crying ; Floppy infant

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
281948	28/04/2011	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (1 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); VAQTa Hepatitis A Vaccine Inactivated (Hepatitis a virus antigen) - Suspect (1 days)	Diarrhoea ; Pyrexia ; Rash ; Vomiting
283063	20/05/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
283424	30/05/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Seizure ; Vomiting
283461	30/05/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
283537	31/05/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Muscle twitching
285401	4/07/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (6 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (6 days); Trade Name Not Specified (Product not Coded) - Suspect (6 days)	Fluid intake reduced ; Haematochezia ; Intussusception ; Lethargy ; Malaise ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
285586	8/07/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Pyrexia
286424	26/07/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Diarrhoea ; Irritability ; Rash macular ; Screaming ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
286515	27/07/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotarix (Rotavirus) - Suspect (-)	Death
287352	12/08/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Crying ; Irritability

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
287393	15/08/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Decreased appetite ; Pyrexia ; Vomiting
287433	15/08/2011	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Apnoea ; Bradycardia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
287435	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Apnoea ; Bradycardia
287437	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia
287447	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
287451	15/08/2011	Unknown	-	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia
287452	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Apnoea ; Bradycardia
287593	18/08/2011	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Apnoea ; Bradycardia ; Diabetic ketoacidosis

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
287648	19/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Apnoea ; Bradycardia
288358	5/09/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Pyrexia ; Tremor ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
288726	9/09/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Rash erythematous
289653	28/09/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (6 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (6 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (6 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
289908	4/10/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Injection site mass ; Injection site reaction
289925	5/10/2011	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Pruritus ; Rash erythematous ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
290981	26/10/2011	Female	1	Hepatitis A Vaccine (Hepatitis a virus antigen) - Concomitant (154 days); Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (154 days); Synflorix (Pneumococcal purified capsular polysaccharides) - Concomitant (154 days); Trade Name Not Specified (live varicella vaccine) - Concomitant (154 days); Vaxigrip (Influenza virus haemagglutinin) - Suspect (147 days)	Influenza ; Vaccination failure
291037	27/10/2011	Female	4	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1235 days)	Bordetella test negative
291383	4/11/2011	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (6 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (6 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (6 days)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
292096	18/11/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Device malfunction
292368	25/11/2011	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (14 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (14 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (14 days)	Febrile convulsion
292592	30/11/2011	Female	10	Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Concomitant (-); Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
293045	8/12/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days)	Febrile convulsion
293290	14/12/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Injection site reaction
293703	21/12/2011	Male	4	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days)	Injection site reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
293792	22/12/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Trade Name Not Specified (Product not Coded) - Suspect (3 days)	Sudden infant death syndrome
294490	12/01/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
294557	13/01/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Seizure
294667	17/01/2012	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Crying ; Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
294731	18/01/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
295460	6/02/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Petechiae ; Pyrexia

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
296244	20/02/2012	Male	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Febrile convulsion
296249	20/02/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Cough ; Diarrhoea ; Pyrexia ; Rash ; Vomiting
296256	21/02/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Febrile convulsion

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
297048	7/03/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Irritability ; Opisthotonus ; Pyrexia
297318	14/03/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
297786	23/03/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash
297933	26/03/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (16 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (16 days); Trade Name Not Specified (Product not Coded) - Suspect (16 days)	Diarrhoea haemorrhagic

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
299788	2/05/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Synflorix (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Trade Name Not Specified (Product not Coded) - Suspect (1 days)	Diarrhoea ; Hypoglycaemia ; Hypotonia ; Metabolic acidosis ; Pneumonia ; Pyrexia ; Respiratory rate increased ; Respiratory syncytial virus infection ; Vomiting
300541	17/05/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (10 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (10 days); Trade Name Not Specified (Product not Coded) - Suspect (10 days)	Seizure

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
302425	21/06/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (1 days)	Blister ; Decreased appetite ; Pyrexia ; Sleep disorder ; Urticaria
302783	27/06/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Diarrhoea ; Hypotonic-hyporesponsive episode ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
302786	27/06/2012	Female	6	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Injection site reaction ; Pyrexia
302829	28/06/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypersensitivity ; Urticaria
303272	9/07/2012	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (0 days); Varilrix (live varicella vaccine) - Suspect (0 days)	No adverse event ; Vaccination error

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
303596	13/07/2012	Male	1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-)	VIth nerve disorder
303710	17/07/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Abdominal pain ; Diarrhoea ; Faeces discoloured ; Pyrexia ; Screaming

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
304607	2/08/2012	Unknown	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (6 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (6 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (6 days)	Intussusception
304714	3/08/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode ; Injection site reaction ; Purpura

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
307024	18/09/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Hypotonic-hyporesponsive episode
307114	19/09/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
308425	16/10/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (2 days); Rotarix (Rotavirus) - Concomitant (2 days)	Vaccination error
308575	18/10/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	No adverse event

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
308664	19/10/2012	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Injection site nodule ; Injection site reaction
308906	25/10/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Muscle twitching ; Pallor

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
309230	31/10/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Diarrhoea
309857	13/11/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (5 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (5 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (5 days)	Diarrhoea ; Mucous stools ; Pyrexia ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
309926	14/11/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (1 days)	Injection site reaction
310822	4/12/2012	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Meningitec (Diphtheria CRM197 protein ; Meningococcal polysaccharide group C) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Urticaria
311781	24/12/2012	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (2 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (2 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (2 days)	Hypotonic-hyporesponsive episode ; Pyrexia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
313182	31/01/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Diarrhoea ; Injection site reaction ; Pyrexia ; Somnolence ; Swelling
314194	19/02/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (24 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (24 days); Trade Name Not Specified (Product not Coded) - Suspect (24 days)	Crying ; Screaming

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
314733	27/02/2013	Female	3	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days)	Injection site reaction
315274	8/03/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Pyrexia ; Swelling face
315929	20/03/2013	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (3 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (3 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (3 days)	Rash generalised

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
315931	20/03/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Rash papular
316162	25/03/2013	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days)	Decreased appetite ; Rash macular ; Rhinorrhoea
317452	10/04/2013	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Meningitec (Diphtheria CRM197 protein ; Meningococcal polysaccharide group C) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Meningitis bacterial ; Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
317456	10/04/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Hypotonic-hyporesponsive episode
318004	17/04/2013	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (1 days)	Pyrexia ; Rash papular
318339	22/04/2013	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Concomitant (1 days)	Injection site reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
318917	2/05/2013	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (2 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (2 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (2 days)	Rash generalised
319131	6/05/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Abdominal pain ; Crying ; Haematochezia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
319141	6/05/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Apnoeic attack
322011	24/06/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoeic attack ; Hypotonia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
322260	27/06/2013	Female	2	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (14 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (14 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (14 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (14 days)	Cardiac arrest ; Pharyngitis ; Pyrexia
323229	16/07/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (8 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (8 days)	Viral infection

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
324271	31/07/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoea
325707	26/08/2013	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days)	Pyrexia ; Rash maculo-papular ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
325916	29/08/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Hypotonia ; Lethargy ; Pallor ; Vomiting
326007	30/08/2013	Female	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Urticaria
326706	11/09/2013	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (17 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (17 days)	Exanthema subitum ; Febrile convulsion ; Lethargy ; Pyrexia ; Rash macular ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
328026	3/10/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Unresponsive to stimuli
328330	9/10/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
328355	9/10/2013	Female	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Urinary tract infection
328356	9/10/2013	Female	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-)	Urinary tract infection
328411	10/10/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal	Erythema ; Swelling

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	
328541	14/10/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (0 days); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days)	Vaccination error
330364	7/11/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Erythema

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
330378	7/11/2013	Male	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (2 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (2 days)	Rash
331361	20/11/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Choking ; Cough ; Dysphagia ; Pallor ; Salivary hypersecretion ; Unresponsive to stimuli ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
331412	21/11/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Diarrhoea ; Irritability ; Pyrexia ; Rash generalised
331740	27/11/2013	Male	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Wrong drug administered
332897	23/12/2013	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (-); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	No adverse event ; Product packaging issue ; Wrong technique in product usage process

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
332899	23/12/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoeic attack
332911	23/12/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Oxygen saturation decreased ; Vaccination error

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
332912	23/12/2013	Male	4	Fluarix (Influenza virus haemagglutinin) - Suspect (3 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (3 days)	No adverse event
334015	23/01/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Diarrhoea ; Haematochezia
334026	24/01/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular	No adverse event ; Wrong drug administered

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				polysaccharides) - Concomitant (-); Rotarix (Rotavirus) - Suspect (-)	
334290	19/12/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (2 days)	Blister ; Injection site reaction ; Rash

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
334333	31/01/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Seizure
334446	4/02/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Hypotonia ; Pallor ; Pyrexia ; Unresponsive to stimuli

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
334549	5/02/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoeic attack
335347	20/02/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Apnoeic attack ; Unresponsive to stimuli

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
335474	25/02/2014	Female	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days)	Otitis media ; Pharyngitis
335476	25/02/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (9 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (9 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (9 days)	Febrile convulsion
335847	4/03/2014	Female	1	Fluarix (Influenza virus haemagglutinin) - Suspect (1 days); Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
337050	24/03/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Rotavirus infection ; Vaccination failure
338234	9/04/2014	Female	43	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Vaxigrip (Influenza virus haemagglutinin) - Suspect (1 days)	Pain in extremity ; Pyrexia ; Rash erythematous ; Vomiting
338476	11/04/2014	Male	<1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-)	Arthritis bacterial

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
340889	21/05/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
342382	23/06/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash generalised

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
342782	30/06/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
345449	6/08/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
346202	20/08/2014	Female	<1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Rash
346733	29/08/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (4 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (4 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (4 days)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
347841	23/09/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (8 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (8 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (8 days)	Rash
347970	26/09/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
348800	16/10/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
349131	22/10/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Febrile convulsion ; Lethargy

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
349290	27/10/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Sudden infant death syndrome
349321	28/10/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Sepsis

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
349541	30/10/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Pneumococcal Polysaccharide Conjugate Vaccine, 13-valent adsorbed (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Sudden infant death syndrome
349811	4/11/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
349999	11/11/2014	Male	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days); Priorix-Tetra (live varicella vaccine ; Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days)	Crying ; Nightmare ; Stubbornness
350326	17/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Anaphylactic reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
350605	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Anaphylactic reaction ; Dyspnoea ; Eye swelling ; Foaming at mouth ; Lip swelling ; Rash erythematous ; Wheezing
350613	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
350626	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Anaphylactic reaction
354087	9/02/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (7 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (7 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (7 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
354764	19/02/2015	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Rash generalised
355351	2/03/2015	Male	1	Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Diarrhoea ; Haematochezia ; Injection site reaction ; Lethargy ; Vomiting
356277	17/03/2015	Male	2	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Injection site reaction
356279	17/03/2015	Female	4	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days)	Injection site reaction

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
356520	23/03/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Botulism
356644	25/03/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Botulism ; Irritability ; Paralysis ; Poor feeding infant

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
356645	25/03/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Anaphylactic reaction
356652	25/03/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-)	Anaphylactic reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
356735	27/03/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Anaphylactic reaction
357639	15/04/2015	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (7 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (7 days)	Concomitant disease progression ; Lethargy ; Pyrexia ; Seizure ; Vomiting
357925	20/04/2015	Female	1	Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Injection site erythema ; Pruritus

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
359345	13/05/2015	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (8 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (8 days)	Pyrexia ; Rash
359813	20/05/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Lethargy ; Pallor ; Rash
359824	20/05/2015	Male	1	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (6 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (6 days)	Decreased appetite ; Pyrexia ; Rash generalised ; Somnolence

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
359848	21/05/2015	Unknown	-	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (-)	Seizure
359850	21/05/2015	Unknown	-	Trade Name Not Specified (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	Intussusception
359858	21/05/2015	Unknown	-	Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-); Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-)	Immune thrombocytopenic purpura

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
360102	26/05/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Death
360543	1/06/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
360625	1/06/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Hypotonic-hyporesponsive episode ; Petechiae
360752	2/06/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
360991	5/06/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Arthralgia ; Joint swelling ; Lip swelling ; Wheezing
361405	12/06/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (8 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (8 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (8 days)	Abnormal behaviour

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
363955	16/07/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Irritability ; Lethargy ; Pyrexia ; Rash macular
364234	20/07/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (10 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (10 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (10 days)	Rash generalised

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
365170	6/08/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Rash
366337	26/08/2015	Female	1	Measles Mumps Rubella Vaccine (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Angioedema ; Mouth ulceration ; Pyrexia ; Vomiting
366847	3/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
366865	4/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Diarrhoea
367814	23/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
369947	2/11/2015	Male	<1	Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	Autism spectrum disorder ; Injection site inflammation ; Pyrexia ; Rash
370839	17/11/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Tachycardia

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
370842	17/11/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Death
371341	25/11/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
371457	26/11/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
371681	1/12/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Sudden infant death syndrome

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
373253	16/12/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Injection site nodule ; Pyrexia ; Somnolence
373254	16/12/2015	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Rash
374970	27/01/2016	Male	<1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Injection site erythema ; Irritability postvaccinal ; Rash

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
375757	12/02/2016	Male	3	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Body temperature increased ; Flushing ; Rash ; Syncope
376609	1/03/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
377175	10/03/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash erythematous ; Rash maculo-papular
377370	15/03/2016	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Concomitant (0 days)	Injection site reaction
385294	29/03/2016	Unknown	-	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-)	Device defective

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
385852	5/04/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (4 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (4 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (4 days)	Death neonatal
388625	24/05/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Abdominal pain ; Irritability

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
390087	15/06/2016	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Urticaria
390180	16/06/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Abdominal pain ; Crying
391385	8/07/2016	Male	12	H-B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (1 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Febrile convulsion ; Viral infection

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
391824	18/07/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Bradycardia ; Infantile apnoea ; Lethargy ; Oxygen saturation decreased
393277	11/08/2016	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Injection site reaction
394058	26/08/2016	Female	<1	Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (0 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Trade Name Not Specified (Product not Coded) - Suspect (0 days)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
394539	5/09/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Angioedema ; Pruritus
395248	15/09/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Apnoea

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
395273	15/09/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
396720	11/10/2016	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Wheezing
397236	20/10/2016	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (3 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (3 days)	Rash

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
398464	4/11/2016	Male	<1	Ipol (Poliovirus) - Suspect (-); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (-)	Myositis ; Osteomyelitis ; Pain ; Pyrexia
398700	10/11/2016	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Injection site reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
401119	21/12/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Irritability ; Pain
401897	10/01/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Febrile convulsion

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
402027	12/01/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Pallor
402046	12/01/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	No adverse event

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
402940	31/01/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Flushing ; Rash macular
402987	1/02/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Injection site reaction

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
403538	13/02/2017	Male	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Concomitant (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (159 days)	Injection site infection ; Injection site vesicles
404128	23/02/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (5 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (5 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (5 days)	Sudden infant death syndrome

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
404394	28/02/2017	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (3 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (3 days)	Rash
405859	24/03/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
406676	6/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Central nervous system infection ; Cerebral disorder ; Hypotension ; Hypoxia ; Meningeal disorder ; Tonic clonic movements
406839	10/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Seizure

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
406925	10/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Cardiac disorder ; Hypotension ; Hypoxia ; Seizure
407737	24/04/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (15 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (15 days); Rotarix (Rotavirus) - Suspect (15 days)	Concomitant disease progression

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
407769	24/04/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
408199	28/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (13 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (13 days); Rotarix (Rotavirus) - Suspect (13 days)	Irritability ; Nystagmus ; Poor feeding infant
411253	6/06/2017	Female	2	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous	Nervous system disorder

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-)	
413884	12/07/2017	Male	1	FluQuadri Junior (Influenza virus haemagglutinin) - Suspect (0 days); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Death
414556	21/07/2017	Male	1	FluQuadri Junior (Influenza virus haemagglutinin) - Suspect (-); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-)	Death
415058	31/07/2017	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (23 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (23 days)	Pruritus ; Rash generalised
415063	31/07/2017	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (21 days); Menitorix (Haemophilus influenza type B	Urticaria

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (21 days)	
416648	22/08/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Rash maculo-papular
418110	14/09/2017	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Anaphylactic reaction
418236	15/09/2017	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Anaphylactic reaction ; Hypotonia ; Somnolence ; Swelling face ; Urticaria

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
421081	1/11/2017	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (306 days)	Generalised tonic-clonic seizure ; Pyrexia ; Vomiting
422365	21/11/2017	Unknown	-	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Anaphylactic reaction ; Crying ; Dyspnoea ; Epistaxis
422821	28/11/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Sudden death

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
423112	30/11/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Pallor
423141	30/11/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Sudden infant death syndrome
423177	1/12/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Sudden death ; Unresponsive to stimuli

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
424840	3/01/2018	Female	3	Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-)	Nonspecific reaction
425371	11/01/2018	Male	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days)	Anaphylactic reaction
425781	22/01/2018	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (3653 days); Rotarix (Rotavirus) - Suspect (0 days)	Dyskinesia
425959	23/01/2018	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotarix (Rotavirus) - Concomitant (0 days)	Movement disorder

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
426032	24/01/2018	Female	1	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (14 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Concomitant (14 days)	Encephalitis
426990	7/02/2018	Female	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Rash ; Screaming

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
427237	12/02/2018	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Rash
436788	27/06/2018	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	Hypotonia ; Pallor ; Respiratory distress ; Somnolence ; Unresponsive to stimuli ; Vomiting

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN.

Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
438423	19/07/2018	Male	<1	FluQuadri Junior (Influenza virus haemagglutinin) - Suspect (6 days); Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (6 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (6 days)	Sudden infant death syndrome
438723	24/07/2018	Male	3	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days)	Epistaxis ; Pyrexia
445907	9/10/2018	Unspecified	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ;	Hypotonic-hyporesponsive episode

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
445913	9/10/2018	Unspecified	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Hypotonic-hyporesponsive episode
452997	12/12/2018	Unknown	2	M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-); Menitorix (Haemophilus influenza type B	Febrile convulsion

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-)	
454336	7/01/2019	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Periorbital swelling ; Pyrexia ; Rash
456710	8/02/2019	Unknown	-	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-)	Product quality issue
457627	19/02/2019	Male	1	Act-HIB (Haemophilus type B polysaccharide ; Tetanus protein) - Suspect (1 days); Infanrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (1 days); Priorix-Tetra (live varicella vaccine ; Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days)	Injection site reaction

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
459173	8/03/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (9 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (12 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (9 days)	Dehydration ; Diarrhoea
459850	18/03/2019	Male	<1	Bexsero (Neisseria meningitidis Group B Factor H Binding Protein fusion protein ; Neisseria meningitidis Group B Neisseria Adhesin A protein ; Neisseria meningitidis Group B Neisseria Heparin Binding Antigen fusion protein ; Neisseria meningitidis serogroup B outer membrane vesicles) - Suspect (-); Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Nurofen	Blood glucose decreased ; Diarrhoea ; Faeces discoloured ; Fluid intake reduced ; Giardiasis ; Malaise ; Off label use ; Vomiting

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
				(Ibuprofen) - Concomitant (-); Panadol (Paracetamol) - Suspect (1 days)	
461035	29/03/2019	Unknown	-	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (-)	Product quality issue
461082	29/03/2019	Unknown	-	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-)	Product quality issue

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
463814	30/04/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Death
464371	6/05/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotarix (Rotavirus) - Suspect (-)	Sudden infant death syndrome
464393	6/05/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (-)	Decreased appetite ; Moaning ; Pyrexia ; Sudden infant death syndrome

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction Terms
476165	10/09/2019	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Hypotonic-hyporesponsive episode
476726	16/09/2019	Unknown	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Hypotonic-hyporesponsive episode