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
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
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

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
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

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
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
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

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
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

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
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
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

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
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
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

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
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
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
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	Injection site mass

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	
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
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) -	Erythema ; Oedema peripheral

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				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)	
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
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	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
				toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	
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
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
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	Apnoea ; Sudden infant death syndrome

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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 ;	Injection site erythema ; Injection site swelling

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				Pneumococcal purified capsular polysaccharides) - Suspect (0 days)	
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
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	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
				reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
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	Vaccination error

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	
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 ;	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
				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 (-)	
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) -	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
				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)	
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 ;	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
				Pneumococcal purified capsular polysaccharides) - Suspect (2 days)	
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
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
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

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
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
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

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
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
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	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
				reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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	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
				reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	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
				filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-)	
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
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) -	Rash erythematous

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
				Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	
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
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	Injection site mass ; 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
				reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	
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

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
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
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	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
				days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	
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
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	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
				human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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
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-	Irritability ; Opisthotonus ; 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
				bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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
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

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
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
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	Hypersensitivity ; 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
				human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	Intussusception

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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (6 days)	
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
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

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
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
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

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
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
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
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

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
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
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

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
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
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	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
				human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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-	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
				bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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	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
				(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)	
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
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 purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	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
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
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-	Choking ; Cough ; Dysphagia ; Pallor ; Salivary hypersecretion ; 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
				bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	Apnoeic attack

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
				human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	
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 polysaccharides) - Concomitant (-); Rotarix (Rotavirus) - Suspect (-)	No adverse event ; Wrong drug administered
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

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
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
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
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

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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
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
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

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
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
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

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
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
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	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
				human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
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	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
				(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)	
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
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	Anaphylactic reaction ; Dyspnoea ; Eye swelling ; Foaming at mouth ; Lip swelling ; Rash erythematous ; Wheezing

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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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
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	Botulism ; Irritability ; Paralysis ; Poor feeding 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
				human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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
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	Arthralgia ; Joint swelling ; Lip swelling ; Wheezing

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				(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)	
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
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	Irritability ; Lethargy ; Pyrexia ; Rash macular

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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
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
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	Urticaria

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				(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)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	
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
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	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
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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

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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
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
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-	Death neonatal

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (4 days)	
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
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	Abdominal pain ; Crying

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
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
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	Angioedema ; Pruritus

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	
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
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

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
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
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

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
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
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	No adverse event

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days)	
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

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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
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
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

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
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
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

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
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
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	Irritability ; Nystagmus ; Poor feeding infant

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Case Number	Report Entry Date	Gender	Age	Medicine reported as being taken	MedDRA Reaction terms
				polysaccharides) - Suspect (13 days); Rotarix (Rotavirus) - Suspect (13 days)	
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 haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-)	Nervous system disorder
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
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

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
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
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	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
				toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	
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
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	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
				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 (-)	
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 ; 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
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
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

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
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 (Ibuprofen) - Concomitant (-); Panadol (Paracetamol) - Suspect (1 days)	Blood glucose decreased ; Diarrhoea ; Faeces discoloured ; Fluid intake reduced ; Giardiasis ; Malaise ; Off label use ; 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
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
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	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
				polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (-)	
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