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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
226298	5/03/2007	Male	<1	Rotarix (Rotavirus) - Suspect (0 days)	Medication error
231951	14/08/2007	Female	<1	Rotarix (Rotavirus) - Suspect (-)	Diarrhoea
232044	15/08/2007	Female	<1	Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Diarrhoea ; Pyrexia
234134	8/10/2007	Male	<1	Infanrix Penta (Diphtheria toxoid ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (60 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer membrane protein complex) - Concomitant (60 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (60 days); Rotarix (Rotavirus) - Suspect (60 days)	Intussusception
234367	15/10/2007	Female	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (14 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (14 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (14 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (14 days)	Diarrhoea ; Intussusception ; Vomiting
235652	26/11/2007	Unknown	<1	Rotarix (Rotavirus) - Suspect (-)	Intussusception

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
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
237814	12/02/2008	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (1 days); Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Pyrexia ; Rash
237965	15/02/2008	Male	<1	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) - Concomitant (0 days)	Extensive swelling of vaccinated limb ; Injection site reaction
238840	12/03/2008	Male	<1	Rotarix (Rotavirus) - Suspect (0 days)	Crying ; Irritability ; Rash erythematous ; Vomiting
239053	18/03/2008	Female	<1	Diphtheria-tetanus-pertussis Vaccine (Bordetella pertussis ; Diphtheria toxoid ; dried aluminium phosphate ; Tetanus toxoid) - Concomitant (56 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Concomitant (56 days); Rotateq (Rotavirus G1 human-bovine reassortant ;	Intussusception

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (56 days); Trade Name Not Specified (Product not Coded) - Concomitant (56 days)	
239211	25/03/2008	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Concomitant (3 days); DTPa-IPV Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Nephrolithiasis ; Vomiting
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 ;	Rash

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
242517	2/07/2008	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Concomitant (-); Rotarix (Rotavirus) - Suspect (7 days)	Intussusception
242916	14/07/2008	Unknown	<1	Rotarix (Rotavirus) - Suspect (-)	Intussusception
243272	29/07/2008	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Chills ; Hypotonic-hyporesponsive episode ; Vomiting
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-	Pyrexia ; Urticaria

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
245025	1/10/2008	Female	<1	Rotarix (Rotavirus) - Suspect (107 days)	Intussusception
245028	1/10/2008	Male	<1	Rotarix (Rotavirus) - Suspect (51 days)	Intussusception
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
246767	2/12/2008	Female	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (-); Haemophilus Influenzae Type B Vaccine (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (-)	Intussusception

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); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Concomitant (-); Poliomyelitis Virus Vaccine Oral (Poliovirus) - Concomitant (-); Rotarix (Rotavirus) - Suspect (44 days)	
246768	2/12/2008	Male	<1	Rotarix (Rotavirus) - Suspect (108 days)	Intussusception
247242	18/12/2008	Male	<1	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 haemorrhagic
247843	20/01/2009	Female	<1	Rotarix (Rotavirus) - Suspect (81 days)	Intussusception
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
248306	5/02/2009	Female	<1	Rotarix (Rotavirus) - Suspect (43 days)	Intussusception
248307	5/02/2009	Female	<1	Rotarix (Rotavirus) - Suspect (50 days)	Diarrhoea
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	Hypotonic-hyporesponsive episode

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				days)	
249103	6/03/2009	Male	1	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 (211 days)	Abdominal pain ; Diarrhoea ; Intussusception ; Irritability
249259	13/03/2009	Female	<1	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
250734	5/05/2009	Male	<1	Rotarix (Rotavirus) - Suspect (159 days)	Abdominal pain ; Intussusception ; Lethargy ; Pallor ; Vomiting
250736	5/05/2009	Female	<1	Rotarix (Rotavirus) - Suspect (73 days)	Intussusception ; Lethargy ; Pallor ; Vomiting
251540	27/05/2009	Male	-	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 (-); 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 (-); 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 (66 days)	Abdominal distension ; Diarrhoea ; Hypovolaemic shock ; Intussusception ; Rectal haemorrhage ; Vomiting
251542	27/05/2009	Male	-	Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-	Abdominal pain ; Diarrhoea ;

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				bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - 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 (-); 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 (63 days)	Intussusception ; Lethargy ; Vomiting
251864	3/06/2009	Male	<1	Rotarix (Rotavirus) - Suspect (138 days)	Intussusception
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
256549	7/09/2009	Female	<1	Rotarix (Rotavirus) - Suspect (0 days)	Diarrhoea
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
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	Injection site mass

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				toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	
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
260427	27/11/2009	Female	<1	Rotarix (Rotavirus) - Suspect (7 days)	Abdominal distension ; Change of bowel habit ; Irritability
260569	1/12/2009	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Erythema ; Oedema peripheral
261323	22/12/2009	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose	Urticaria

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				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)	
261637	6/01/2010	Male	<1	DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (3 days); Pneumococcal Vaccine (Pneumococcal purified capsular polysaccharides) - Concomitant (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Diarrhoea ; Haematochezia
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
268163	27/05/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose	Apnoea ; Sudden infant

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	death syndrome
269147	15/06/2010	Male	<1	Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotarix (Rotavirus) - Suspect (3 days)	Cardiac arrest neonatal
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
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	Confusional state ; Hypotonia ; Pallor

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				days)	
271976	10/08/2010	Male	1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Abdominal discomfort ; Diarrhoea ; Vomiting
272553	23/08/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotarix (Rotavirus) - Suspect (3 days)	Brain injury ; Cardiac arrest
272815	31/08/2010	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Concomitant (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Vaccination error
273400	15/09/2010	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Hypotonic-hyporesponsive episode

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
273608	21/09/2010	Male	<1	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
275295	5/11/2010	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Death
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	Abnormal behaviour ; Crying

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
278483	9/02/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Eye movement disorder ; Floppy infant ; Pyrexia
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
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
279529	7/03/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Constipation ; Crying ; Diarrhoea ; Hypophagia ;

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	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
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
280692	31/03/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Coordination abnormal ; Diarrhoea

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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	Crying ; Floppy infant

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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-hypo-responsive 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
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 ;	Seizure

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
283844	7/06/2011	Male	<1	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 ; Diarrhoea haemorrhagic ; Faeces discoloured ; Mucous stools ; 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 ;	Diarrhoea ; Irritability ; Rash macular ; Screaming ; Vomiting

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
286515	27/07/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotarix (Rotavirus) - Suspect (-)	Death
287352	12/08/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Crying ; Irritability
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	Decreased appetite ; Pyrexia ; Vomiting

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				days)	
287437	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia
287447	15/08/2011	Male	<1	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia
287451	15/08/2011	Unknown	-	Comvax (Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Neisseria meningitidis outer membrane protein complex) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Apnoea ; Bradycardia
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	Pyrexia ; Tremor ; Vomiting

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
288726	9/09/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Rash erythematous
289653	28/09/2011	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (6 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (6 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (6 days)	Death
289908	4/10/2011	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (-)	Injection site mass ; Injection site reaction
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	Hypotonic-hyporesponsive episode

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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 (-)	
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 G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
295460	6/02/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8]	Petechiae ; Pyrexia

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				human-bovine reassortant) - Suspect (1 days)	
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
297048	7/03/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Irritability ; Opisthotonus ; Pyrexia
297318	14/03/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
297786	23/03/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Rash

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
302116	14/06/2012	Male	<1	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); Trade Name Not Specified (Product not Coded) - Suspect (1 days)	Pyrexia ; Rhinorrhoea ; Vomiting
302425	21/06/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Concomitant (1 days)	Blister ; Decreased appetite ; Pyrexia ; Sleep disorder ; Urticaria
302783	27/06/2012	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8]	Diarrhoea ; Hypotonic-hypo-responsive episode ; 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 and/or was reported as part of a clinical trial or individual patient access.

Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				human-bovine reassortant) - Suspect (-)	
302829	28/06/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypersensitivity ; Urticaria
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 G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (6 days)	Intussusception
304714	3/08/2012	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Hypotonic- hyposensitive

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	episode ; Injection site reaction ; Purpura
305795	23/08/2012	Unknown	-	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 (-)	Gastroenteritis
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
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	No adverse event

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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]	Diarrhoea ; Mucous stools ; Pyrexia ; Vomiting

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				human-bovine reassortant) - Suspect (5 days)	
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
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
319131	6/05/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Abdominal pain ; Crying ; Haematochezia

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
322011	24/06/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Apnoeic attack ; Hypotonia
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
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	Hypotonia ; Lethargy ; Pallor ; Vomiting

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
328026	3/10/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Unresponsive to stimuli
328330	9/10/2013	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
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	Erythema ; Swelling

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	
328998	22/10/2013	Unknown	-	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
331361	20/11/2013	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Choking ; Cough ; Dysphagia ; Pallor ; Salivary hypersecretion ; Unresponsive to stimuli ; Vomiting
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 human-bovine reassortant ; Rotavirus G3 human-	Apnoeic attack

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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 G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Diarrhoea ; Haematochezia
334026	24/01/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Concomitant (-); Prevenar (Corynebacterium diphtheriae ; Pneumococcal purified capsular 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	Blister ; Injection site reaction ; Rash

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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-	Apnoeic attack

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
335304	19/02/2014	Female	<1	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 ; Vomiting projectile
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
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
336405	14/03/2014	Male	<1	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)	Expired product administered ; No adverse event
337050	24/03/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose	Rotavirus infection ;

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	Vaccination failure
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
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	Hypotonic-hyporesponsive episode

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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-hypo-responsive episode
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-	Rash

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (8 days)	
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
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	Sepsis

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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 (-)	
349541	30/10/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Pneumococcal Polysaccharide Conjugate Vaccine, 13-valent adsorbed (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Sudden infant death syndrome
349811	4/11/2014	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (3 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (3 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (3 days)	Death
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	Anaphylactic reaction

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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 (-)	
350605	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Anaphylactic reaction ; Dyspnoea ; Eye swelling ; Foaming at mouth ; Lip swelling ; Rash erythematous ; Wheezing
350613	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Death
350626	21/11/2014	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-	Anaphylactic reaction

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	
352677	13/01/2015	Female	<1	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 ; Vomiting
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
355328	2/03/2015	Female	<1	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
355334	2/03/2015	Female	<1	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
355725	9/03/2015	Unknown	-	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
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	Botulism

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
356644	25/03/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Botulism ; Irritability ; Paralysis ; Poor feeding infant
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
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 ;	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 and/or was reported as part of a clinical trial or individual patient access.

Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
358162	24/04/2015	Unknown	<1	Rotarix (Rotavirus) - Suspect (-)	Intussusception
358947	6/05/2015	Female	<1	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)	Vomiting
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
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	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 and/or was reported as part of a clinical trial or individual patient access.

Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	
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 (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Arthralgia ; Joint swelling ; Lip swelling ; Wheezing
361405	12/06/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus	Abnormal behaviour

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
362236	24/06/2015	Male	<1	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 ; Vaccination error
363955	16/07/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Irritability ; Lethargy ; Pyrexia ; Rash macular
364234	20/07/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (10 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (10 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (10 days)	Rash generalised
366847	3/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Death

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
366865	4/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Diarrhoea
367814	23/09/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Urticaria
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

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
370842	17/11/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Death
371341	25/11/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Death
371457	26/11/2015	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Hypotonic-hyporesponsive episode
371681	1/12/2015	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus	Sudden infant death syndrome

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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
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-	Death neonatal

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				bovine reassortant ; Rotavirus G4 human-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 G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Abdominal pain ; Crying
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	Angioedema ; Pruritus

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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]	Injection site reaction

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				human-bovine reassortant) - Suspect (0 days)	
401119	21/12/2016	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (2 days)	Irritability ; Pain
401897	10/01/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Concomitant (0 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (0 days)	Febrile convulsion
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
402940	31/01/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ;	Flushing ; Rash macular

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
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
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
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	Hypotonic-hyporesponsive episode

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	
406676	6/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Central nervous system infection ; Cerebral disorder ; Hypotension ; Hypoxia ; Meningeal disorder ; Tonic clonic movements
406839	10/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (-)	Seizure
406925	10/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotateq (Rotavirus G1 human-bovine reassortant ; Rotavirus G2 human-bovine reassortant ; Rotavirus G3 human-bovine reassortant ; Rotavirus G4 human-bovine reassortant ; Rotavirus P1 [8] human-bovine reassortant) - Suspect (1 days)	Cardiac disorder ; Hypotension ; Hypoxia ; Seizure
407737	24/04/2017	Female	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose	Concomitant disease

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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)	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-hypo-responsive episode
408199	28/04/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (13 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (13 days); Rotarix (Rotavirus) - Suspect (13 days)	Irritability ; Nystagmus ; Poor feeding infant
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

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
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
423141	30/11/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Sudden infant death syndrome
423177	1/12/2017	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (0 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (0 days)	Sudden death ; Unresponsive to stimuli
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	Rash ; Screaming

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				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 (-)	
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
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
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]	Dehydration ; Diarrhoea

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Case No.	Report Date	Sex	Age	Medicine (Onset Time)	Reaction
				human-bovine reassortant) - Suspect (9 days)	
463814	30/04/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (1 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Rotarix (Rotavirus) - Suspect (1 days)	Death
464371	6/05/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (-); Rotarix (Rotavirus) - Suspect (-)	Sudden infant death syndrome
464393	6/05/2019	Male	<1	Infanrix HEXA (Diphtheria toxoid ; Haemophilus influenza type B polyribose ribitol phosphate ; Hepatitis B surface antigen recombinant ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; Tetanus toxoid) - Suspect (-); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Rotarix (Rotavirus) - Suspect (-)	Decreased appetite ; Moaning ; Pyrexia ; Sudden infant death syndrome