

Table 1a - A line listing of UK spontaneous suspected adverse reaction reports in association with specified batch numbers up to and including 29/04/2021

Case	Drug ingredient	Drug name as classified	Dose	Dose Unit	Onset first dose (days)	Route of administration	Reaction	Reaction outcome	Past medical history
1	BACILLUS CALMETTE GUERIN	BCG	0.1 ml		1	INTRADERMAL USE	Hypotension, Nausea, Malaise, Vision blurred, Hyperhidrosis, Dizziness	Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved	
2	BACILLUS CALMETTE GUERIN	BCG	0.05 ml		1	INTRADERMAL USE	Thrombocytopenia, Tachycardia, Respiratory rate increased, Petechiae, Neutropenia, Respiratory tract congestion, Pallor	Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved	
3	BACILLUS CALMETTE GUERIN	BCG	0.5 ml			INTRADERMAL USE	Lymphadenitis, Wrong technique in product usage process	Not recovered/not resolved, Unknown	
4	RUBELLA VIRUS, MUMPS VIRUS, MEASLES VIRUS	PRIORIX			1	INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR	Erythema, Swelling	Recovering/resolving, Recovering/resolving	
5	RUBELLA VIRUS, MUMPS VIRUS, MEASLES VIRUS	MMR VACCINE				UNKNOWN, UNKNOWN,	Rash morbilliform, Pyrexia, Eye swelling	Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved	
6	RUBELLA VIRUS, MUMPS VIRUS, MEASLES VIRUS, HEPATITIS B VIRUS	HBVAXPRO, MMR VACCINE	10 µg		1	INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR	Urinary tract infection, Rash, Swelling face, Syncope, Oropharyngeal pain, Urticaria	Not recovered/not resolved, Recovered/resolved, Unknown, Unknown, Not recovered/not resolved, Unknown	
7	BACILLUS CALMETTE GUERIN	BCG	0.05 ml		81	INTRADERMAL USE	Axillary pain, Lymphadenopathy, Injection site scar	Unknown, Recovering/resolving, Unknown	Premature baby
8	ROTAVIRUS, HUMAN ROTAVIRUS, STREPTOCOCCUS PNEUMONIAE, POLIOMYELITIS VIRUS, HAEMOPHILUS INFLUENZAE TYPE B, CORYNEBACTERIUM DIPHTHERIAE, CLOSTRIDIUM TETANI, BORDETELLA PERTUSSIS, BORDETELLA PERTUSSIS, NEISSERIA MENINGITIDIS, NEISSERIA MENINGITIDIS, NEISSERIA MENINGITIDIS, NEISSERIA MENINGITIDIS	BEXSERO, INFANRIX IPV HIB, PREVENAR 13, ROTARIX			1	UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, UNKNOWN, ORAL USE, ORAL USE	Pyrexia, Death	Unknown, Fatal	Jaundice, Constipation, Premature baby
9	RUBELLA VIRUS, MUMPS VIRUS, MEASLES VIRUS, POLIOMYELITIS VIRUS, CORYNEBACTERIUM DIPHTHERIAE, CLOSTRIDIUM TETANI, BORDETELLA PERTUSSIS, BORDETELLA PERTUSSIS	REPEVAX, M-M-R II/MMR II	0.5 ml		0	INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR	Respiratory rate decreased, Hypotonia, Heart rate decreased, Cold sweat, Unresponsive to stimuli, Hypotension	Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved, Recovered/resolved	
10	STREPTOCOCCUS PNEUMONIAE, NEISSERIA MENINGITIDIS, HAEMOPHILUS INFLUENZAE TYPE B	MENITORIX, PREVENAR 13			1	PARENTERAL, PARENTERAL, PARENTERAL	Pyrexia, Dizziness postural, Diarrhoea	Not recovered/not resolved, Not recovered/not resolved, Not recovered/not resolved	Illness, Asthma, Seasonal allergy
11	RUBELLA VIRUS, RUBELLA VIRUS, MUMPS VIRUS, MUMPS VIRUS, MEASLES VIRUS, MEASLES VIRUS	M-M-RVAXPRO			6	INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR, INTRAMUSCULAR	Rash morbilliform	Recovering/resolving, Recovered/resolved with sequelae, Recovered/resolved, Recovered/resolved, Not recovered/not resolved, Recovered/resolved, Not recovered/not resolved	
12	RUBELLA VIRUS, MUMPS VIRUS, MEASLES VIRUS	MMR VACCINE				PARENTERAL, PARENTERAL, PARENTERAL	Hypersensitivity, Peripheral swelling, Erythema, Blood aluminium increased, Pyrexia, Scar	Recovered/resolved, Not recovered/not resolved	

Table 1b - Aggregated patient data:

Patient Sex	Total
Female	6
Male	6
Total	12

Table 1c - Aggregated patient age:

Patient Age Group	Total
<1	4
01-02	4
03-12	2
13-17	0
18-35	2
36-65	0
66+	0
Total	12