

11 AUG 2015

Ref: H201502755

Dear [REDACTED]

### Response to your request for official information

Thank you for your request of 15 July 2015 under the Official Information Act 1982 (the Act) for “copies of the following reports presented to the MARC” with reference to items 4.1.2 to 4.1.5 of the 162<sup>nd</sup> Medicines Adverse Reactions Committee (MARC) meeting minutes. The reports requested are those included in the quarterly report provided by the Centre for Adverse Reactions Monitoring (CARM).

The information relating to this request is itemised below, with a copy of the document attached.

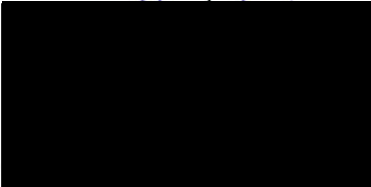
I have decided under sections 9(2)(a) and 9(2)(ba)(i) of the Act to withhold information in order to protect the privacy of natural persons and to protect information which is subject to an obligation of confidence where the making available of the information would be likely to prejudice the supply of similar information.

Request	Response
<i>Copies of the following reports presented to the MARC (items 4.1.2 to 4.1.5 of the 162<sup>nd</sup> MARC meeting)</i>	Attached is: <i>1. Copies of the reports presented to the MARC (items 4.1.2 to 4.1.5 of the 162<sup>nd</sup> MARC meeting).</i>

Please note that the date column of the quarterly report reflects the date that the adverse reaction was reported to CARM, not the date that the adverse reaction occurred. In addition, age in months has been represented in two ways. The first lists age as, for example, 18m which means the patient’s age is 18 months. The second lists age as, for example, 902 indicating that the patient’s age is two months old.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely



Acting Group Manager  
Medsafe

Section 4: Review of Cases in Special Populations (Children and Elderly)

Table 6: Serious cases causally associated with medicines in children under 18 years

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
114914	JAN2015	FEVER CHEST PAIN TACHYCARDIA FLUSHING DIZZINESS	* INTRAGAMP PREDNISON NAPROXEN TRANEXAMIC ACID	16	F	Not yet recovered
115386	MAR2015	MYOCARDITIS	* CLOZAPINE OLANZAPINE	17	M	Not yet recovered
115334	FEB2015	SUICIDE ATTEMPT MEDICATION NON-ADHERENCE HALLUCINATION AUDITORY	* RISPERIDONE	16	F	Unknown outcome

Serious Cases in Children under 18 years.....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
115219	FEB2015	HYPERAESTHESIA	* OXYCODONE	13	F	Not yet recovered
115274	FEB2015	ANAPHYLACTIC REACTION	* IBUPROFEN	11	M	Recovered without sequelae
115040	JAN2015	APNOEA	* SUXAMETHONIUM CHLORIDE	10	M	Recovered without sequelae
115184	FEB2015	RHABDOMYOLYSIS CREATINE PHOSPHOKINASE INCREASED HEPATIC ENZYMES INCREASED	* SUXAMETHONIUM CHLORIDE FENTANYL SEVOFLURANE PARACETAMOL	4	M	Not yet recovered

Serious Cases in Children under 18 years.....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
115472	MAR2015	ANAPHYLACTIC REACTION	* LORATADINE	14	F	Unknown outcome
114858	JAN2015	ERYTHEMA MULTIFORME SERUM SICKNESS-LIKE DISORDER	* AMOXICILLIN	7m	F	Recovered without sequelae
114859	JAN2015	ERYTHEMA MULTIFORME	* AMOXICILLIN	17	F	Recovered without sequelae
115403	MAR2015	ANGIOEDEMA SKIN TEST POSITIVE URTICARIA	* AMOXICILLIN	18m	M	Recovered without sequelae
115468	MAR2015	SYNCOPE UNCONSCIOUSNESS HEADACHE THROAT TIGHTNESS DYSPHAGIA	* AMOXICILLIN COTRIMOXAZOLE METRONIDAZOLE	10	M	Not yet recovered

Serious Cases in Children under 18 years.....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
114857	JAN2015	HYPERSENSITIVITY	* FLUCLOXACILLIN	8	M	Recovered without sequelae
115310	FEB2015	URTICARIA OEDEMA PERIPHERAL SERUM SICKNESS-LIKE DISORDER	* FLUCLOXACILLIN	7	M	Recovered without sequelae
114863	JAN2015	ERYTHEMA MULTIFORME	* AMOXICILLIN/CLAVULANIC ACID	22m	F	Recovered without sequelae
115378	MAR2015	ANAPHYLACTIC REACTION	* AMOXICILLIN/CLAVULANIC ACID FENTANYL PARACETAMOL MORPHINE SULPHATE DEXAMETHASONE	19m	F	Recovered without sequelae
114867	JAN2015	BRONCHOSPASM THROAT TIGHTNESS DIZZINESS TACHYCARDIA HYPOXIA	* CEFTRIAXONE	9	F	Recovered without sequelae

Serious Cases in Children under 18 years.....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
114871	JAN2015	RASH ERYTHEMATOUS	* CEFUROXIME	9	M	Recovered without sequelae
115404	MAR2015	URTICARIA ANGIOEDEMA PRURITUS	* AMOXICILLIN/CLAVULANIC ACID	17m	F	Recovered without sequelae
115170	FEB2015	OEDEMA PERIORBITAL URTICARIA ANGIOEDEMA MACULAR RASH RED MAN SYNDROME	* VANCOMYCIN FLUCLOXACILLIN PARACETAMOL	6	F	Recovered without sequelae
115613	MAR2015	HYPERBILIRUBINAEMIA	* AMPHOTERICIN B PIPERACILLIN/TAZOBACTAM SERTRALINE COTRIMOXAZOLE GCSF nos	14	M	Not yet recovered

Serious Cases in Children under 18 years..... continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
115023	JAN2015	DYSPNOEA THROAT TIGHTNESS RASH	* MISOPROSTOL * NAPROXEN * FENTANYL * MIDAZOLAM	16	F	Recovered without sequelae
114909	JAN2015	CEREBRAL DISORDER	* ECULIZUMAB	23m	M	Died - cause unclassifiable

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Table 7: Serious cases reporting serious AEFI terms with vaccines in children Under 18 years

REPORT	DATE	Severe	REACTIONS	VACCINE	AGE	SEX	OUTCOME
115119	FEB2015	Yes	ANAPHYLACTIC REACTION	* DTaP/IPV * MEASLES-MUMPS-RUBELLA VACCINE	4	F	Recovered without sequelae
114837	JAN2015	Yes Yes Yes Yes	DIARRHOEA VOMITING RASH ERYTHEMATOUS STEVENS JOHNSON SYNDROME	* MEASLES-MUMPS-RUBELLA VACCINE * HAEMOPHILUS B (ACT-HIB) * PNEUMOCOCCAL VACC - 13	17m	M	Not yet recovered
115471	MAR2015	Yes Yes	ENCEPHALITIS PSYCHOSIS	* HPV VACCINE	13	F	Not yet recovered
114985	JAN2015	Yes Yes Yes	ANGIOEDEMA HOARSENESS URTICARIA	* VARICELLA VIRUS VACCINE * MEASLES-MUMPS-RUBELLA VACCINE	22m	M	Recovered without sequelae

Serious AEFIs in Children under 18 years.....continued

REPORT	DATE	Severe	REACTIONS	VACCINE	AGE	SEX	OUTCOME
114860	JAN2015	Yes Yes Yes Yes Yes	CRYING DIARRHOEA VOMITING CRAMP ABDOMINAL GASTROESOPHAGEAL REFUX	* ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	1m	M	Not yet recovered

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**Serious AEFI Terms**

System Organ Class	AEFI
Alimentary	PAROTID ENLARGEMENT
	PAROTITIS
Application Site	ISR ABCESS
	ISR INFLAMMATION (SEVERE)
	ISR ABSCESS STERILE
Endocrine/Metabolic	LARYNGOTRACHEAL OEDEMA
	LARYNX OEDEMA
	ORCHITIS
Haematological	THROMBOCYTOPENIA
Musculoskeletal	ARTHRALGIA
	ARTHRITIS
	ARTHROPATHY
	ARTHROSIS
	OSTEOMYELITIS
Nervous System	CONVULSIONS
	CONVULSIONS GRAND MAL
	ENCEPHALITIS
	ENCEPHALOMYELITIS
	ENCEPHALOPATHY
	FEVER CONVULSIONS
	GUILLAIN-BARRE SYNDROME
	HYPOTONIC-HYPORESPONSIVE EPISODE (HHE)
	MENINGITIS
	MENINGITIS ASEPTIC
	MENINGOENCEPHALITIS
	NEURITIS
	NEURITIS CRANIAL
	NEURITIS MOTOR
	NEURITIS SENSORY
	OEDEMA CEREBRAL
PETIT MAL CONVULSION	
POLIOMYELITIS	

**Serious AEFI Terms**

System Organ Class	AEFI
Others	ALLERGIC REACTION
	ANAPHYLACTIC REACTION
	ANAPHYLACTIC SHOCK
	ANAPHYLACTOID REACTION
	ANAPHYLAXIS
	CRYING ABNORMAL
	DEATH
	FACE OEDEMA
	FEVER $\geq 40^{\circ}$
	LYMPHADENOPATHY
	OEDEMA
	OEDEMA GENERALISED
	TONGUE OEDEMA
Resistance Mechanism Disorders	SEPSIS
	SEPTICAEMIA
	VACCINE FAILURE
Respiratory	APNOEA
	BRONCHOSPASM
	DYSPNOEA
	OEDEMA PULMONARY
Skin and Appendages	ABSCESS
	ACUTE GEN. ECZEMATOUS PUSTULOSIS
	ANGIOEDEMA
	ANGIONEUROTIC OEDEMA
	BULLOUS ERUPTION
	ECZEMA
	EPIDERMAL NECROLYSIS
	ERYTHEMA MULTIFORME
	PRURITUS
	STEVENS JOHNSON SYNDROME
	TOXIC EPIDERMAL NECROLYSIS
URTICARIA	

**Table 8: Serious non-fatal cases causally associated with critical terms in patients over 80 years**

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
115066	JAN2015	TOXIC EPIDERMAL NECROLYSIS	PARACETAMOL/CODEINE HYDROXYCHLOROQUINE OMEPRAZOLE BENDROFLUAZIDE NITROFURANTOIN	90	F	Not yet recovered
114882	JAN2015	GI HAEMORRHAGE HAEMOGLOBIN DECREASED	* DABIGATRAN	82	F	Unknown outcome
115173	FEB2015	LIVER INJURY MIXED	* AMOXICILLIN	82	M	Not yet recovered
115773	MAR2015	HEPATITIS CHOLESTATIC	* AMOXICILLIN/CLAVULANIC ACID * AZITHROMYCIN ATORVASTATIN	84	M	Not yet recovered

Serious Cases in patients Over 80 years.....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>	<u>OUTCOME</u>
115376	MAR2015	DRUG LEVEL INCREASED RENAL FAILURE ACUTE	* GENTAMICIN	81	F	Not yet recovered
115003	JAN2015	NEPHRITIS INTERSTITIAL RENAL FAILURE ACUTE	* NITROFURANTOIN * PANTOPRAZOLE * METFORMIN ACETYLSALICYLIC ACID SIMVASTATIN	85	M	Not yet recovered
114938	JAN2015	HYPOMAGNEAEMIA HYPOCALCAEMIA CONVULSIONS	* OMEPRAZOLE VANCOMYCIN METRONIDAZOLE CEFUROXIME LISINAPRIL	90	M	Recovered without sequelae

Serious Cases in patients Over 80 years.....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX	OUTCOME
115677	MAR2015	HYPOMAGNESAEMIA HYPOCALCAEMIA CEREBELLAR SYNDROME	* PANTOPRAZOLE TRAMADOL DOMPERIDONE DOXAZOSIN CICLOPIROX	81	F	Not yet recovered
115691	MAR2015	HYPOMAGNESAEMIA HYPOCALCAEMIA RENAL FUNCTION ABNORMAL	* PANTOPRAZOLE TRIMETHOPRIM CHOLECALCIFEROL METOPROLOL THYROXINE	92	F	Not yet recovered
114991	JAN2015	ANAPHYLACTIC REACTION	* LATEX * ROCURONIUM * CEPHAZOLIN PROPOFOL REMIFENTANIL	81	M	Recovered without sequelae

## Section 5: Special Reports

### Annual Review of Fatalities (January 2014 – December 2014)

#### *Overview*

There were 162 reports of death submitted to CARM in the context of medicine use involving 245 medications (i.e. more than one medication may be implicated in each report). In 71% of cases (n=115) a causal relationship to the medicine(s) identified was assessed as either unrelated (24%) or the cause of death was unclassifiable (47%). In 29% of reports (n=47), the medicine was assessed as potentially contributing to the death (n=29) or resulted in an adverse reaction(s) that likely caused the death (n=18) (Table 1). Overview of the deaths that are likely due to the medication is discussed under Table 6 below. These proportions are similar to those reported last year.

The most frequent ATC groups of medicines represented by the 245 medicines in the 162 reports were "Nervous System" (n=65), "Blood and Blood forming organs" (n=63), "Antineoplastics and Immunomodulating Agents" (N=44) with "Musculoskeletal" agents (24) and "Anti-infectives" (n=19). The remaining ATC groups involved 30 medicines collectively with only a few medicines in each class, (Tables 2 & 3).

Table 4 illustrates the age distribution of all fatal reports to CARM irrespective of causality. Sixty-six percent of the reports where the age was known, were in patients older than 65 years and 22% are older than 80 years. There were more males (59%) compared to females (41%) There were 6 reports in patients under the age of two. These reports were for 5 reports of sudden death/Sudden Unexpected Death in Infancy in the context of routine childhood immunization schedule occurring in the 3-5 month window in 4 reports and in a 15 month old in the 5<sup>th</sup> report. The sixth report documents a death in a 2 month old from septicemia and fulminating necrotising enterocolitis following the administration of mydriatic and prednisone eye drops post laser surgery for Retinopathy of Prematurity.

Table 5 lists the 162 reports of fatalities to CARM grouped by ATC group. In 71% of these reports the cause of death was assessed as unrelated or unclassifiable and in the remaining 29% the medicine may have contributed to or was likely to have caused the reaction that led to death. For many of the reports of death the cases relate either to reactions that are well recognized and/or involve complex co-morbidity that may have increased the risk of death. Of the 29%, the reactions reported most frequently were bleeding episodes with anticoagulants accounting for 72% (n=13/18) of reports where death was considered due to the drug and 38% (n=11/29) of reports where the drug may have been contributory. This was followed by sepsis/infection episodes accounting for 21% (n=6/29) of reports where the drug may have contributed to the death. Monoclonal antibodies were suspect in 4 of the 6 reports in this group.

Table 6 is a subset of the data in Table 5



Table 1: Outcome Overview

Outcome	Number of Cases	Percentage
Died due to the adverse reaction	18	11.1
Died – drug may be contributory	29	17.9
Died – unrelated to the drug	39	24.1
Died – cause unclassifiable	76	46.9
<b>Total Reports</b>	<b>162</b>	

Table 2: ATC classification Overview

ATC High Level Group	No. of Medicines	Percentage
Alimentary	4	1.6
Blood and Blood forming organs	63	25.7
Cardiovascular	12	4.9
Dermatological	1	0.4
Genito Urinary System and Sex Hormones	2	0.8
Systemic Hormones (excl Sex Hormones)	4	1.6
Anti-infectives	19	7.8
Antineoplastics and Immunomodulating Agents	44	18.0
Musculoskeletal	24	9.8
Nervous System	65	26.5
Antiparasitic Products, Insecticides, and Repellents	1	0.4
Respiratory System	2	0.8
Sensory Organs	1	0.4
Miscellaneous	3	1.2
<b>Total Suspect Medicines</b>	<b>245</b>	

Table 3: ATC Detailed listing of Medicines

	ATC Group	No. of Medicines	Total
<b>A</b>	<b>Alimentary</b>		<b>4</b>
A02	Coloxyl/Senna	1	
A10	Insulin Aspart	1	
	Insulin Lispro / Protamine	1	
	Metformin	1	
<b>B</b>	<b>Blood and Blood forming organs</b>		<b>63</b>
B01	Abciximab	1	
	Alteplase	6	
	Clopidogrel	5	
	Dabigatran	25	
	Dipyridamole	1	
	Heparin – Unfractionated	1	
	Heparin LMW – Enoxaparin	3	
	Rivaroxaban	1	
	Tenecteplase	2	
	Ticagrelor	6	
	Warfarin	3	
B02	Eptacog alpha	1	
	Tranexamic acid	1	
B03	Erythropoietin	2	
B05	Dianeal (NOS)	1	
	Icodextrin	3	
	Physioneal	1	
<b>C</b>	<b>Cardiovascular</b>		<b>12</b>
C01	Amiodarone	2	
	Digoxin	2	
C02	Bosentan	2	
C03	Spironolactone	1	
C05	Prednisolone	1	
C07	Metoprolol	1	
C09	ACE Inhibitor (NOS)	1	
	Cilazapril/hydrochlorothiazide	1	
	Quinapril	1	
<b>D</b>	<b>Dermatological</b>		<b>1</b>
D04	Oxybuprocaine hydrochloride	1	
<b>G</b>	<b>Genito Urinary System and Sex Hormones</b>		<b>2</b>
G03	Cyproterone	1	
	Oestradiol	1	
<b>H</b>	<b>Systemic Hormones (excl Sex Hormones)</b>		<b>4</b>
H02	Dexamethasone	1	
	Prednisone	3	
<b>J</b>	<b>Anti-infectives</b>		<b>19</b>
J01	Cotrimoxazole	1	
	Ertapenem	1	
	Vancomycin	1	
J05	Intragam P	1	
	Ribavirin	2	
J07	DTaP-Hexa Vaccine	4	
	Haemophilus B	1	
	Influenza – Trivalent	1	
	Measles-Mumps-Rubella Vaccine	1	
	Pneumococcal 10	4	
	Pneumococcal 7	1	
	Rota Virus Vaccine	1	

	ATC Group	No. of Medicines	Total
<b>L</b>	<b>Antineoplastics and Immunomodulating Agents</b>		<b>44</b>
L01	Antineoplastic Agent (NOS)	1	
	Bevacizumab	2	
	Capecitabine	1	
	Cyclophosphamide	2	
	Dacarbazine	1	
	Doxorubicin hydrochloride	2	
	Erlotinib	2	
	Fluorouracil	1	
	Imatinib	2	
	Methotrexate	1	
	Nilotinib	2	
	Rituximab	6	
	Sorafenib	2	
	Sunitinib	1	
	Trastuzumab	1	
	Vincristine	2	
	Vorinostat	1	
L03	Glatiramer acetate	1	
	Peginterferon alpha 2A	4	
L04	Adalimumab	4	
	Cyclosporin	1	
	Etanercept	1	
	Lenalidomide	1	
	Thalidomide	1	
	Tocilizumab	1	
<b>M</b>	<b>Musculoskeletal</b>		<b>24</b>
M01	Diclofenac	1	
	Parecoxib	1	
M04	Allopurinol	2	
	Benzbromarone	1	
	Colchicine	2	
	Febuxostat	1	
M05	Alendronate	1	
	Zoledronate	15	
<b>N</b>	<b>Nervous System</b>		<b>65</b>
N01	General Anaesthetics unclassified	1	
N02	Acetylsalicylic acid	7	
	Codeine	1	
	Morphine sulphate	2	
	Oxycodone	3	
	Paracetamol	1	
	Tramadol	1	
N03	Clonazepam	1	
N04	Entacapone	2	
	Levodopa/Carbidopa (100/25)	1	
	Ropinirole	1	
	Rotigotine	4	
	Selegiline	1	
N05	Anisulpride	1	
	Chlorpromazine	1	
	Clozapine	22	
	Diazepam	1	
	Midazolam	1	
	Olanzapine	5	
	Risperidone	1	

	ATC Group	No. of Medicines	Total
N06	Amitriptyline	2	
	Bupropion hydrochloride	1	
	Citalopram	1	
	Escitalopram	1	
	Paroxetine	1	
	Venlafaxine	1	
<b>P</b>	<b>Parasitic Products, insecticides and Repellents</b>		<b>1</b>
P01	Quinine	1	
<b>R</b>	<b>Respiratory System</b>		<b>2</b>
R01	Phenylephrine	1	
R06	Cyclizine	1	
<b>S</b>	<b>Sensory Organs</b>		<b>1</b>
S01	Cyclopentolate	1	
<b>V</b>	<b>Miscellaneous</b>		<b>3</b>
V03	Alcohol (Ethyl)	1	
	Deferasirox	1	
V08	Iohexol	1	
	<b>Total Medicines</b>		<b>245</b>

Table 4: Age group and Gender Overview

Age Group	Female	Male	Unknown	Total
Under 2	2	4		6
02 – 09		1		1
10 – 19		1		1
20 – 29	1	2		3
30 – 39	3	7		10
40 – 49	6	5		11
50 – 59	7	9		16
60 – 69	10	13		23
70 – 79	19	27		46
80 plus	12	19		31
Unknown	6	7	1	14
<b>Total</b>	<b>66</b>	<b>95</b>	<b>1</b>	<b>162</b>

**Table 5: Annual Report Fatal Cases January to December 2012**

Reports are grouped according to the ATC classification of the suspect agent(s). Cases where there is more than one suspect agent are listed once in each relevant ATC classification and those cases appearing in more than one ATC classification are indicated with \*\*\*\* indicated below the Report Number. This listing covers the 162 reports, identifying 245 suspect medicines, which resulted in a fatal outcome regardless of causality.

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
<u>Alimentary</u>					
111139 ****	APR2014	MULTIPLE ORGAN FAILURE RESPIRATORY DISTRESS TONGUE ULCERATION RENAL FAILURE AGGRAVATED DIARRHOEA	* FEBUXOSTAT * COLCHICINE * COLOXYL/SENNA	66	M
110701	MAR2014	MEDICATION ERROR	* INSULIN ASPART	83	M
109850	JAN2014	HYPOGLYCAEMIA MEDICATION ERROR FALL SUBDURAL HAEMATOMA	* INSULIN LISPRO / PROTAMINE INSULIN GLARGINE MICONAZOLE AQUEOUS CREAM	68	F
114359	NOV2014	RENAL FAILURE ACUTE ACIDOSIS LACTIC HYPOGLYCAEMIA	* METFORMIN PANGREATIC ENZYMES FRUSEMIDE CARVEDILOL SERETIDE	67	M
<u>Blood and Blood forming organs</u>					
113664 ****	SEP2014	CEREBRAL HAEMORRHAGE DEATH	* ABCIXIMAB * TICAGRELOR * ACETYLSALICYLIC ACID * HEPARIN - UNFRACTIONATED GLYCERYL TRINITRATE	59	F
110350 ****	FEB2014	CEREBRAL HAEMORRHAGE CONVULSIONS HAEMORRHAGE NOS DEATH	* ALTEPLASE * ACETYLSALICYLIC ACID * DIPYRIDAMOLE * HEPARIN-LMW - ENOXAPARIN	70	M

Blood and Blood forming organs .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
110351	FEB2014	RESPIRATORY FAILURE	* ALTEPLASE	92	M
110983	APR2014	HAEMORRHAGE STROKE	* ALTEPLASE	83	M
111783 *****	MAY2014	ANGIOEDEMA	* ALTEPLASE * ACE INHIBITOR (NOS)	41	M
111784	MAY2014	HAEMORRHAGE INTRACRANIAL	* ALTEPLASE	78	F
114452	NOV2014	HAEMORRHAGE INTRACRANIAL	* ALTEPLASE	73	M
109395 *****	JAN2014	HAEMORRHAGE SUBDURAL HAEMORRHAGE CEREBELLAR DEATH	* CLOPIDOGREL * ACETYLSALICYLIC ACID * ATORVASTATIN * METOPROLOL	50	M
110700 *****	MAR2014	CEREBRAL HAEMORRHAGE MEDICATION ERROR DEATH	* TENECTEPLASE * CLOPIDOGREL * HEPARIN-LMW - ENDXAPARIN * ACETYLSALICYLIC ACID	72	M
112017	MAY2014	HAEMORRHAGE INTRACRANIAL	* CLOPIDOGREL * ACETYLSALICYLIC ACID	58	F
112180 *****	JUN2014	SUICIDE ABDOMINAL PAIN	* CLOPIDOGREL * AMITRIPTYLINE * ESCITALOPRAM * SIMVASTATIN * METOPROLOL	73	M
112673	JUL2014	HAEMORRHAGE INTRACRANIAL	* CLOPIDOGREL * SIMVASTATIN * ALLOPURINOL * TERAZOSIN	76	M

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Blood and Blood forming organs .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
110359	FEB2014	ABDOMINAL PAIN DIARRHOEA RECTAL BLEEDING COAGULATION DISORDER HAEMOGLOBIN DECREASED	* DABIGATRAN	81	M
111276	APR2014	STROKE SUBDURAL HAEMATOMA	* DABIGATRAN SIMVASTATIN DIGOXIN METOPROLOL FRUSEMIDE	71	F
111277	APR2014	CEREBRAL INFARCTION	* DABIGATRAN SIMVASTATIN FELODIPINE METOPROLOL	88	F
111278 *****	APR2014	GI HAEMORRHAGE	* DABIGATRAN CITALOPRAM CANDESARTAN GLIPIZIDE FRUSEMIDE	86	M
111279	APR2014	CEREBRAL INFARCTION ASPIRATION PNEUMONITIS RESPIRATORY DISTRESS MESENTERIC ARTERY THROMBOSIS INTESTINAL ISCHAEMIA	* DABIGATRAN DIGOXIN DILTIAZEM QUINAPRIL BUDESONIDE/EFORMOTEROL	67	M
111280	APR2014	HAEMORRHAGE INTRACRANIAL	* DABIGATRAN DIGOXIN SIMVASTATIN TAMSULOSIN FRUSEMIDE	77	M
111281 *****	APR2014	PNEUMONIA MULTIPLE ORGAN FAILURE DIGITALIS TOXICITY	* DABIGATRAN * ALLOPURINOL * DIGOXIN METFORMIN SIMVASTATIN	72	F

Blood and Blood forming organs .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111282	APR2014	GI HAEMORRHAGE RENAL FAILURE NOS MELAENA VAGINAL HAEMORRHAGE	* DABIGATRAN FRUSEMIDE METOPROLOL QUINAPRIL DIGOXIN	54	F
111469	APR2014	CARDIAC FAILURE	* DABIGATRAN	97	F
111470	APR2014	HAEMORRHAGE NOS	* DABIGATRAN	84	M
111471	APR2014	DYSPEPSIA SUDDEN DEATH	* DABIGATRAN	78	M
111598	APR2014	CEREBRAL INFARCTION	* DABIGATRAN	74	M
111706	MAY2014	CEREBRAL INFARCTION	* DABIGATRAN BISOPROLOL ATORVASTATIN CILZAPRIL ACETYLSALICYLIC ACID	78	M
112134	MAY2014	MEDICATION ERROR HAEMATEMESIS HAEMORRHAGE CEREBELLAR DEATH	* DABIGATRAN METOPROLOL LOSARTAN/HYDROCHLOROTHIAZIDE	79	F
112355	JUN2014	FALL SUDDEN DEATH	* DABIGATRAN	95	F
112009	MAY2014	STROKE	* DABIGATRAN WARFARIN	91	M
112010	MAY2014	CEREBRAL INFARCTION	* DABIGATRAN CITALOPRAM FRUSEMIDE SIMVASTATIN RISPERIDONE	87	F



Blood and Blood forming organs .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
112011	MAY2014	SUDDEN DEATH	* DABIGATRAN METOPROLOL ATENOLOL SIMVASTATIN	75	F
112012 *****	MAY2014	RENAL FAILURE ACUTE RECTAL BLEEDING DRUG LEVEL INCREASED	* DABIGATRAN DIGOXIN FRUSEMIDE TAMSULOSIN ZOPICLONE	84	M
112013	MAY2014	MYOCARDIAL ISCHAEMIA	* DABIGATRAN ACETYLSALICYLIC ACID	56	M
112979	AUG2014	CEREBRAL HAEMORRHAGE	* DABIGATRAN OMEPRAZOLE DILTIAZEM CILAZAPRIL ATORVASTATIN	75	M
112980	AUG2014	MEDICATION ERROR STROKE	* DABIGATRAN ACETYLSALICYLIC ACID METFORMIN CILAZAPRIL GABAPENTIN	80	M
113376	SEP2014	HAEMORRHAGE INTRACRANIAL DEATH	* DABIGATRAN	75	M
113535	SEP2014	HAEMORRHAGE STROKE	* DABIGATRAN	F	
113538	SEP2014	HAEMORRHAGE INTRACRANIAL	* DABIGATRAN	75	M
112433 *****	JUN2014	SPINAL HAEMATOMA MEDICATION ERROR DEATH SUBARACHNOID HAEMORRHAGE	* HEPARIN-LMW - ENOXAPARIN * TICAGRELOR * ACETYLSALICYLIC ACID SIMVASTATIN METFORMIN	68	F

Blood and Blood forming organs .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111609 *****	MAY2014	GI HAEMORRHAGE DEATH	* RIVAROXABAN * ACETYLSALICYLIC ACID	60	F
112466	JUN2014	CEREBRAL HAEMORRHAGE MEDICATION ERROR DEATH	* TENECTEPLASE	77	M
110333	FEB2014	THROMBOSIS	* TICAGRELOR	F	F
110334	FEB2014	MYOCARDIAL INFARCTION THROMBOSIS	* TICAGRELOR * CLOPIDOGREL	F	F
110984	FEB2014	SUICIDE	* TICAGRELOR	70	M
113613	SEP2014	PNEUMONIA	* TICAGRELOR	67	M
109523	JAN2014	HAEMORRHAGE SUBDURAL DEATH	* WARFARIN	71	F
112019	MAY2014	HAEMORRHAGE INTRACRANIAL DEATH	* WARFARIN * INSULIN	79	M
113043	AUG2014	MEDICINE INEFFECTIVE HAEMORRHAGE INTRACRANIAL	* EPTACOG ALPHA * COAGULATION FACTOR, HUMAN	7	M
114392 *****	NOV2014	CEREBRAL INFARCTION	* PARECOXIB * TRANEXAMIC ACID	67	M
110596	MAR2014	MYOCARDIAL INFARCTION	* ERYTHROPOIETIN * AMLODIPINE * ATORVASTATIN * METOPROLOL * GLIPIZIDE	75	M

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Blood and Blood forming organs .....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
110601	MAR2014	STROKE GI HAEMORRHAGE	* ERYTHROPOIETIN		M
110120	FEB2014	VOMITING DIARRHOEA UNCLASSIFIED REACTION	* DIANEAL NOS * ICODEXTRIN	31	F
110122	FEB2014	PERITONITIS	* ICODEXTRIN * PHYSIONEAL	75	M
111965	MAY2014	INTESTINAL ISCHAEMIA DIARRHOEA MULTIPLE ORGAN FAILURE PANCREATITIS NECROTISING	* ICODEXTRIN	55	M
<u>Cardiovascular</u>					
113259	AUG2014	PULMONARY FIBROSIS	* AMIODARONE * THYROXINE * EZETIMIBE * FRUSEMIDE * ALLOPURINOL		M
114302	NOV2014	ALVEOLITIS FIBROSING DEATH	* AMIODARONE	79	M
111281 *****	APR2014	PNEUMONIA MULTIPLE ORGAN FAILURE DIGITALIS TOXICITY	* DABIGATRAN * ALLOPURINOL * DIGOXIN * METFORMIN * SIMVASTATIN	72	F
112012 *****	MAY2014	RENAL FAILURE ACUTE RECTAL BLEEDING DRUG LEVEL INCREASED	* DABIGATRAN * DIGOXIN * FRUSEMIDE * TAMBUSOLIN * ZOPICLONE	84	M

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Cardiovascular .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
110981	APR2014	PROGRESSION OF DISEASE	* BOSENTAN	74	F
111966	MAY2014	CARDIAC FAILURE RIGHT	* BOSENTAN	77	F
110621 *****	MAR2014	BREAST NEOPLASM MALIGNANT-MALE METASTASES NOS MEDICATION ERROR	* OESTRADIOL * CYPROTERONE ACETATE * SPIRONOLACTONE * AMISULPRIDE * RISPERIDONE	43	F
111811 *****	MAY2014	CONVULSIONS ENTEROCOLITIS INTESTINAL NECROSIS SEPSIS	* OXYBUPROCAINE HYDROCHLORIDE * PREDNISOLONE * CYCLOPENTOLATE * PHENYLEPHRINE * GEN ANAESTHETICS UNCLASSIFIED	902	F
112055 *****	MAY2014	STROKE	* CLOZAPINE * ROPINIROLE * METOPROLOL * ALLOPURINOL * FRUSEMIDE	80	M
111783 *****	MAY2014	ANGIOEDEMA	* ALTEPLASE * ACE INHIBITOR (NOS)	41	M
113686	SEP2014	SYNCOPE CUSHINGS SYNDROME PULMONARY CARCINOMA RENAL FAILURE NOS ATRIAL FIBRILLATION	* CILAZAPRIL/HYDROCHLOROTHIAZIDE DILTIAZEM DOXAZOSIN RESVERATROL NOS VITAMIN B COMPLEX	74	F
111882 *****	MAY2014	INTESTINAL ISCHAEMIA	* ROTIGOTINE * ENTACAPONE * SELEGILINE * ACETYLSALICYLIC ACID * QUINAPRIL	69	M

REPORT DATE REACTIONS DRUGS AGE SEX

Dermatological

111811 *****	MAY2014	CONVULSIONS ENTEROCOLITIS INTESTINAL NECROSIS SEPSIS	* OXYBUPROCAINE HYDROCHLORIDE * PREDNISOLONE * CYCLOPENTOLATE * PHENYLEPHRINE * GEN ANAESTHETICS UNCLASSIFIED	902 F
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Genito-urinary System and Sex Hormones

110621 *****	MAR2014	BREAST NEOPLASM MALIGNANT, MALE METASTASES NOS MEDICATION ERROR	* OESTRADIOL * CYPROTERONE ACETATE * SPIRONOLACTONE * AMISULPRIDE * RISPERIDONE	43 F
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Systemic Hormones (excl Sex Hormones)

109618 *****	JAN2014	EMBOLISM PULMONARY	* LENALIDOMIDE * BLINDED STUDY-MEDICINE * DEXAMETHASONE * ATORVASTATIN * PARACETAMOL	71 M
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110899 *****	MAR2014	LOWER RESP TRACT INFECTION PNEUMOCYSTIS CARINII INFECTION SEPSIS MYALGIA MULTIPLE ORGAN FAILURE	* TOCILIZUMAB * PREDNISONE * OMEPRAZOLE * NORTRIPTYLINE	53 F
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110903 *****	MAR2014	NEUTROPENIA SEPSIS	* RITUXIMAB * CYCLOPHOSPHAMIDE * DOXORUBICIN HYDROCHLORIDE * VINCRIStINE * PREDNISONE	69 F
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111328 *****	APR2014	NAUSEA GASTRO-INTESTINAL DISORDER NOS FRACTURE PATHOLOGICAL	* ADALIMUMAB * ALENDRONATE * PREDNISONE	68 M
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AGE SEX

REPORT DATE REACTIONS DRUGS

Antimicrobials

112556	JUL2014	LEUKOCYTOSIS CONVULSIONS FEVER VOMITING	* * * *	COTRIMOXAZOLE QUINAPRIL FRUSEMIDE OMEPRAZOLE METOPROLOL	97	F
112135	MAY2014	TOXIC EPIDERMAL NECROLYSIS MULTIPLE ORGAN FAILURE DEATH	* *	VANCOMYCIN ERTAPENEM	29	M
113662	SEP2014	CARDIAC ARREST	*	INTRAGAM.P GENTAMICIN NOREFOXACIN AMOXICILLIN/CLAVULANIC ACID COLCHICINE	64	F
110603 ****	MAR2014	SUICIDE	* *	PEGINTERFERON alpha 2A RIBAVIRIN	43	M
110849 ****	MAR2014	THROMBOCYTOPENIA	* *	PEGINTERFERON alpha 2A RIBAVIRIN	49	M
109482	JAN2014	SUDDEN INFANT DEATH SYNDROME	* *	DTaP-Hexa PNEUMOCOCCAL VACC - 10	905	M
113129	AUG2014	SUDDEN DEATH	* *	DTaP-Hexa PNEUMOCOCCAL VACC - 10	904	F
113290	AUG2014	SUDDEN DEATH	* * *	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 10	903	M
114809	DEC2014	SUDDEN INFANT DEATH SYNDROME	* *	DTaP-Hexa PNEUMOCOCCAL VACC - 10	904	M
112848	JUL2014	SUDDEN DEATH	* * *	MEASLES-MUMPS-RUBELLA VACCINE HAEMOPHILUS B (HIBERIX) PNEUMOCOCCAL VACC - 7	915	M

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Antifungals .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111827	MAY2014	CARDIAC ARREST	* INFLUENZA - TRIVALENT CHOLECALCIFEROL DIPYRIDAMOLE THYROXINE ALLOPURINOL	81	M
<b>Antineoplastics and Immunomodulating Agents</b>					
114176 *****	OCT2014	PANCTOPENIA PROGRESSION OF DISEASE	* CLOZAPINE * ANTINEOPLASTIC AGENT(S) NOS * PARACETAMOL * AMOXICILLIN/CLAVULANIC ACID * ATORVASTATIN * BEVACIZUMAB * FLUOROURACIL	61	M
112748	JUL2014	GASTRIC ULCER METASTASES NOS PROGRESSION OF DISEASE	* BEVACIZUMAB * FLUOROURACIL	32	M
113365	AUG2014	PROGRESSION OF DISEASE	* BEVACIZUMAB * CISPLATIN * GEMCITABINE	42	F
113726	SEP2014	MUCOSITIS NOS BONE MARROW DEPRESSION DIARRHOEA DEATH	* CAPECITABINE	38	M
110903 *****	MAR2014	NEUTROPENIA SEPSIS	* RITUXIMAB * CYCLOPHOSPHAMIDE * DOXORUBICIN HYDROCHLORIDE * VINCISTINE * PREDNISONNE	69	F
111989	MAY2014	AGRANULOCYTOSIS	* RITUXIMAB * CYCLOPHOSPHAMIDE * DOXORUBICIN HYDROCHLORIDE * VINCISTINE * PREDNISONNE		M

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Antineoplastics and Immunomodulating Agents .....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
110452	MAR2014	AGRANULOCYTOSIS PNEUMONIA	* DACARBAZINE SIMVASTATIN METOPROLOL OMEPRAZOLE CANDESARTAN	84	M
110846	MAR2014	STOMACH PERFORATION ABDOMINAL PAIN DIARRHOEA DIVERTICULITIS CHEST PAIN	* ERLOTINIB DOMPERIDONE LAXSOL MORPHINE SULPHATE OMEPRAZOLE	77	M
112259	JUN2014	PROGRESSION OF DISEASE	* ERLOTINIB		F
110447	MAR2014	SUDDEN DEATH	* IMATINIB	66	F
111724	MAY2014	PROGRESSION OF DISEASE	* IMATINIB	78	M
113875	OCT2014	BILE DUCT CARCINOMA	* METHOTREXATE * CYCLOSPORIN	46	M
109466	JAN2014	SUDDEN DEATH	* NILOTINIB	74	M
109693	JAN2014	SUDDEN DEATH	* NILOTINIB		F
110871	MAR2014	NEUTROPENIA SUDDEN DEATH	* RITUXIMAB CLOPIDOGREL FLECAINIDE METHOTREXATE PANTOPRAZOLE	65	F
110901	MAR2014	RESPIRATORY FAILURE	* RITUXIMAB	52	M
110902	MAR2014	METASTASES NOS	* RITUXIMAB	36	F

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Antineoplastics and Immunomodulating Agents .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111004	APR2014	LOWER RESP TRACT INFECTION INFECTION FUNGAL	* RITUXIMAB HYDROXYCHLOROQUINE OMEPRAZOLE DOMPERIDONE CHOLECALCIFEROL	80	F
113918	OCT2014	PROGRESSION OF DISEASE	* SORAFENIB	52	F
113920	OCT2014	PROGRESSION OF DISEASE HYPERTENSION MACULAR RASH PALMAR-PLANTAR ERYTHRODYSAESTH.	* SORAFENIB	64	M
109806	JAN2014	SUDDEN DEATH PROGRESSION OF DISEASE	* SUNITINIB		F
113685	SEP2014	PROGRESSION OF DISEASE	* TRASTUZUMAB	40	F
109611	JAN2014	SUDDEN DEATH	* VORINOSTAT	68	M
109828	JAN2014	PANCREATITIS SEPTICAEMIA	* GLATIRAMER ACETATE LITHIUM CARBONATE NORTRIPTYLINE TRAMADOL OMEPRAZOLE	35	F
110603 *****	MAR2014	SUICIDE	* PEGINTERFERON alpha 2A * RIBAVIRIN	43	M
110849 *****	MAR2014	THROMBOCYTOPENIA	* PEGINTERFERON alpha 2A * RIBAVIRIN	49	M
110869	MAR2014	THROMBOCYTOPENIA SEPSIS MULTIPLE ORGAN FAILURE	* PEGINTERFERON alpha 2A	55	F

Antineoplastics and Immunomodulating Agents .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111986	MAY2014	HEPATIC NEOPLASM MALIGNANT WEIGHT DECREASE TIREDNESS	* PEGINTERFERON alpha 2A RIBAVIRIN	60	M
109938	FEB2014	RESPIRATORY FAILURE	* ADALIMUMAB	52	M
109942	FEB2014	TOOTH ABSCESS	* ADALIMUMAB		U
110584	MAR2014	SUICIDE	* ADALIMUMAB	31	M
111328 ****	APR2014	NAUSEA GASTRO-INTESTINAL DISORDER NOS FRACTURE PATHOLOGICAL	* ADALIMUMAB * ALENDRONATE * PREDNISON	68	M
109730	JAN2014	SUDDEN DEATH	* ETANERCEPT * OMEPRAZOLE TRAMADOL * AMITRIPTYLINE ACETYLSALICYLIC ACID	70	M
109618 ****	JAN2014	EMBOLISM PULMONARY	* LENALIDOMIDE * BLINDED STUDY MEDICINE * DEXAMETHASONE * ATORVASTATIN PARACETAMOL	71	M
109621	JAN2014	SUDDEN DEATH	* THALIDOMIDE	76	F
110899 ****	MAR2014	LOWER RESP TRACT INFECTION PNEUMOCYSTIS CARINII INFECTION SEPSIS MYALGIA MULTIPLE ORGAN FAILURE	* TOCILIZUMAB * PREDNISON * OMEPRAZOLE NORTRIPTYLINE	53	F

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AGE SEX

REPORT	DATE	REACTIONS	DRUGS
<u>Musculoskeletal</u>			
114788 *****	DEC2014	LEG PAIN SYNCOPE SKIN COLD/CLAMMY DYSPNOEA GASTRITIS	* DICLOFENAC * PARACETAMOL
114392 *****	NOV2014	CEREBRAL INFARCTION	* PARECOXIB * TRANEXAMIC ACID
111281 *****	APR2014	PNEUMONIA MULTIPLE ORGAN FAILURE DIGITALIS TOXICITY	* DABIGATRAN * ALLOPURINOL * DIGOXIN * METFORMIN * SIMVASTATIN
112222	JUN2014	FACE OEDEMA STOMATITIS RASH ERYTHEMATOUS RENAL FAILURE AGGRAVATED PNEUMONIA	* ALLOPURINOL
112288	JUN2014	HAEMORRHAGE NOS	* BENZBROMARONE ALLOPURINOL COLCHICINE QUINAPRIL FERROUS SULPHATE
111139 *****	APR2014	MULTIPLE ORGAN FAILURE RESPIRATORY DISTRESS TONGUE ULCERATION RENAL FAILURE AGGRAVATED DIARRHOEA	* FEBUXOSTAT * COLCHICINE * COLOXYLUSENNA
111561 *****	APR2014	RENAL FAILURE ACUTE ACIDOSIS METABOLIC MEDICATION NON-ADHERENCE DEATH	* COLCHICINE * QUININE ALCOHOL (ETHYL) PREDNISONE PARACETAMOL/CODEINE

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Musculoskeletal .....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
111328 ****	APR2014	NAUSEA GASTRO-INTESTINAL DISORDER NOS FRACTURE-PATHOLOGICAL	* ADALIMUMAB * ALENDRONATE * PREDNISONE	68	M
109468	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	73	F
109474	JAN2014	STROKE	* ZOLEDRONATE	70	F
109475	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	86	M
109476	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	94	M
109659	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	90	F
109664	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	78	F
109666	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	84	F
109671	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	75	F
109682	JAN2014	STROKE	* ZOLEDRONATE QUINAPRIL ANASTROZOLE OMEPRAZOLE METOPROLOL	92	F
109687	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	86	F
109688	JAN2014	SUDDEN DEATH	* ZOLEDRONATE	90	M
110443	MAR2014	SUDDEN DEATH	* ZOLEDRONATE	69	M

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Musculoskeletal .....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
110444	MAR2014	SUDDEN DEATH	* ZOLEDRONATE	87	M
110446	MAR2014	NEOPLASM MALIGNANT	* ZOLEDRONATE	77	F
114479	NOV2014	SUDDEN DEATH	* ZOLEDRONATE * OMEPRAZOLE * PREDNISONE * SPIRONOLACTONE * MEBEVERINE	73	F
<u>Nervous System</u>					
111811 ****	MAY2014	CONVULSIONS ENTEROCOLITIS INTESTINAL NECROSIS SEPSIS	* OXYBUPROCAINE HYDROCHLORIDE * PREDNISOLONE * CYCLOPENTHOLATE * PHENYLEPHRINE * GEN ANAESTHETICS UNCLASSIFIED	902	F
109395 ****	JAN2014	HAEMORRHAGE SUBDURAL HAEMORRHAGE CEREBELLAR DEATH	* CLOPIDOGREL * ACETYLSALICYLIC ACID * ATORVASTATIN * METOPROLOL	50	M
110350 ****	FEB2014	CEREBRAL HAEMORRHAGE CONVULSIONS HAEMORRHAGE NOS DEATH	* ALTEPLASE * ACETYLSALICYLIC ACID * DIPYRIDAMOLE * HEPARIN-LMW - ENOXAPARIN	70	M
110700 ****	MAR2014	CEREBRAL HAEMORRHAGE MEDICATION ERROR DEATH	* TENECTEPLASE * CLOPIDOGREL * HEPARIN-LMW - ENOXAPARIN * ACETYLSALICYLIC ACID	72	M
111609 ****	MAY2014	GI HAEMORRHAGE DEATH	* RIVAROXABAN * ACETYLSALICYLIC ACID	60	F

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
112433 *****	JUN2014	SPINAL HAEMATOMA MEDICATION ERROR DEATH SUBARACHNOID HAEMORRHAGE	* HEPARIN-LMW - ENOXAPARIN * TICAGRELOL * ACETYLSALICYLIC ACID * SIMVASTATIN * METFORMIN	68	F
111862 *****	MAY2014	INTESTINAL ISCHAEMIA	* ROTIGOTINE * ENTACAPONE * SELEGILINE * ACETYLSALICYLIC ACID * QUINAPRIL	69	M
113664 *****	SEP2014	CEREBRAL HAEMORRHAGE DEATH	* ABCIXIMAB * TICAGRELOL * ACETYLSALICYLIC ACID * HEPARIN - UNFRACTIONATED * GLYCERYL TRINITRATE	59	F
113489 *****	SEP2014	DRUG LEVEL INCREASED DEATH MEDICATION ERROR	* TRAMADOL * AMTRIPTYLINE * CODEINE * CYCLIZINE * OXYCODONE	58	F
113003	AUG2014	ASPIRATION PNEUMONIA	* CLOZAPINE * MIDAZOLAM * MORPHINE SULPHATE * NORTRIPTYLINE * OMEPRAZOLE	80	F
114404	NOV2014	DROWSINESS MEDICATION ERROR	* MORPHINE SULPHATE	91	M
109612	JAN2014	ACCIDENTAL OVERDOSE	* DIAZEPAM * OXYCODONE * CLONAZEPAM	39	M

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Nervous System .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
112015	MAY2014	INTESTINAL OBSTRUCTION SEPSIS MULTIPLE ORGAN FAILURE	* OXYCODONE FELODIPINE QUINAPRIL	68	F
114788 ****	DEC2014	LEG PAIN SYNCOPE SKIN COLD CLAMMY DYSPNOEA GASTRITIS	* DICLOFENAC * PARACETAMOL	49	M
111793	MAY2014	DYSKINESIA FALL CONFUSION	* ROTIGOTINE * ENTACAPONE * LEVODOPA/CARBIDOPA (100/25) PARACETAMOL DOMPERIDONE	79	F
112055 ****	MAY2014	STROKE	* CLOZAPINE * ROPINIROLE * METOPROLOL ALLOPURINOL FRUSEMIDE	80	M
111792	MAY2014	VOMITING DIARRHOEA CHOKING ASPIRATION PNEUMONITIS	* ROTIGOTINE	83	M
111794	MAY2014	FALL	* ROTIGOTINE LEVODOPA/CARBIDOPA (100/25) LEVODOPA/CARBIDOPA (200/50) CR	79	M
110621 ****	MAR2014	BREAST NEOPLASM MALIGNANT MALE METASTASES NOS MEDICATION ERROR	* OESTRADIOL * CYPROTERONE ACETATE * SPIRONOLACTONE * AMISULPRIDE * RISPERIDONE	43	F

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Nervous System .....continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111555	APR2014	MEDICATION ERROR	* CHLORPROMAZINE ANTIBIOTICS UNCLASSIFIED	15	M
109488	JAN2014	GASTRIC CARCINOMA	* CLOZAPINE	41	F
109529	JAN2014	PANCYTOPENIA FOLIC ACID DEFICIENCY PARKINSONISM AGGRAVATED PNEUMONIA	* CLOZAPINE * OLANZAPINE LEVODOPA/CARBIDOPA (100/25) PILOCARPINE VALPROATE SODIUM	65	M
109532	JAN2014	PHARYNGITIS SUDDEN DEATH INFECTION	* CLOZAPINE DESMOPRESSIN CITALOPRAM CLONAZEPAM OXYBUTYRIN	30	M
109635	JAN2014	SUDDEN DEATH	* CLOZAPINE	39	M
109639	JAN2014	EMBOLISM PULMONARY THROMBOSIS VENOUS DEEP	* CLOZAPINE	43	F
109645	JAN2014	SUDDEN DEATH	* CLOZAPINE	50	M
109861	JAN2014	PNEUMONIA	* OLANZAPINE * CLOZAPINE		M
110968	APR2014	DRUG LEVEL INCREASED	* CLOZAPINE		M
110972 ****	APR2014	SUDDEN DEATH	* CLOZAPINE * ALCOHOL (ETHYL)		M
111199	APR2014	AORTIC STENOSIS AGITATION CONFUSION SYNCOPE	* CLOZAPINE	71	M

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Nervous System ..... continued

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111203	APR2014	PROGRESSION OF DISEASE INFECTION MULTIPLE ORGAN FAILURE	* CLOZAPINE SENNA PREPARATIONS TRIMETHOPRIM OMEPRAZOLE VITAMIN B12	71	M
111212	APR2014	SUDDEN DEATH	* CLOZAPINE	64	F
111392	APR2014	LEUKOCYTOSIS NEUTROPHILIA	* CLOZAPINE	39	M
111422	APR2014	SYNCOPE UNCONSCIOUSNESS CHOKING	* CLOZAPINE MIRTAZAPINE DIAZEPAM PARACETAMOL LAXSOL	70	F
111426	APR2014	PNEUMONIA ASPIRATION	* CLOZAPINE	58	M
111427	APR2014	CONSTIPATION CARCINOMA COLON INTESTINAL OBSTRUCTION INTESTINAL PERFORATION	* CLOZAPINE VALPROATE SODIUM	68	F
111429	APR2014	PULMONARY CARCINOMA BRAIN METASTASES RESPIRATORY FAILURE CONVULSIONS CONFUSION	* CLOZAPINE * OLANZAPINE * PAROXETINE	28	F
111433	APR2014	CHRONIC OBSTRUCT AIRWAYS DISEASE RESPIRATORY FAILURE CONSCIOUSNESS DECREASED	* CLOZAPINE MADOPAR FRUSEMIDE CLOPIDOGREL CHOLECALCIFEROL	77	F

Nervous System .....continued

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
113248	AUG2014	SUDDEN DEATH	* CLOZAPINE * OLANZAPINE * BUPROPION HYDROCHLORIDE	25	M
114176 *****	OCT2014	PANCTOPENIA PROGRESSION OF DISEASE	* CLOZAPINE * ANTINEOPLASTIC AGENT(S) NOS PARACETAMOL AMOXICILLIN/CLAVULANIC ACID ATORVASTATIN	61	M
109858	JAN2014	SUDDEN DEATH	* OLANZAPINE * ZOPICLONE * VALPROATE SODIUM	51	M
112180 *****	JUN2014	SUICIDE ABDOMINAL PAIN	* CLOPIDOGREL * AMITRIPTYLINE * ESCITALOPRAM * SIMVASTATIN * METOPROLOL	73	M
111278 *****	APR2014	GI HAEMORRHAGE	* DABIGATRAN * CITALOPRAM * CANDESARTAN * GLIPIZIDE * FRUSEMIDE	86	M
109753	JAN2014	SUICIDE	* VENLAFAXINE	70	M
<u>Antiparasitic Products, insecticides and repellents</u>					
111561 *****	APR2014	RENAL FAILURE ACUTE ACIDOSIS METABOLIC MEDICATION NON-ADHERENCE DEATH	* COLCHICINE * QUININE * ALCOHOL (ETHYL) * PREDNISON * PARACETAMOL/CODEINE	55	M

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REPORT DATE REACTIONS DRUGS

Respiratory System

111811  
\*\*\*\*\*  
MAY2014  
CONVULSIONS )  
ENTEROCOLITIS  
INTESTINAL NECROSIS  
SEPSIS  
\* OXYBUPROCAINE HYDROCHLORIDE  
\* PREDNISOLONE  
\* CYCLOPENTOLATE  
\* PHENYLEPHRINE  
\* GEN ANAESTHETICS UNCLASSIFIED

113489  
\*\*\*\*\*  
SEP2014  
DRUG LEVEL INCREASED  
DEATH  
MEDICATION ERROR  
\* TRAMADOL  
\* AMITRIPTYLINE  
\* CODEINE  
\* CYCLIZINE  
\* OXYCODONE

Sensory Organs

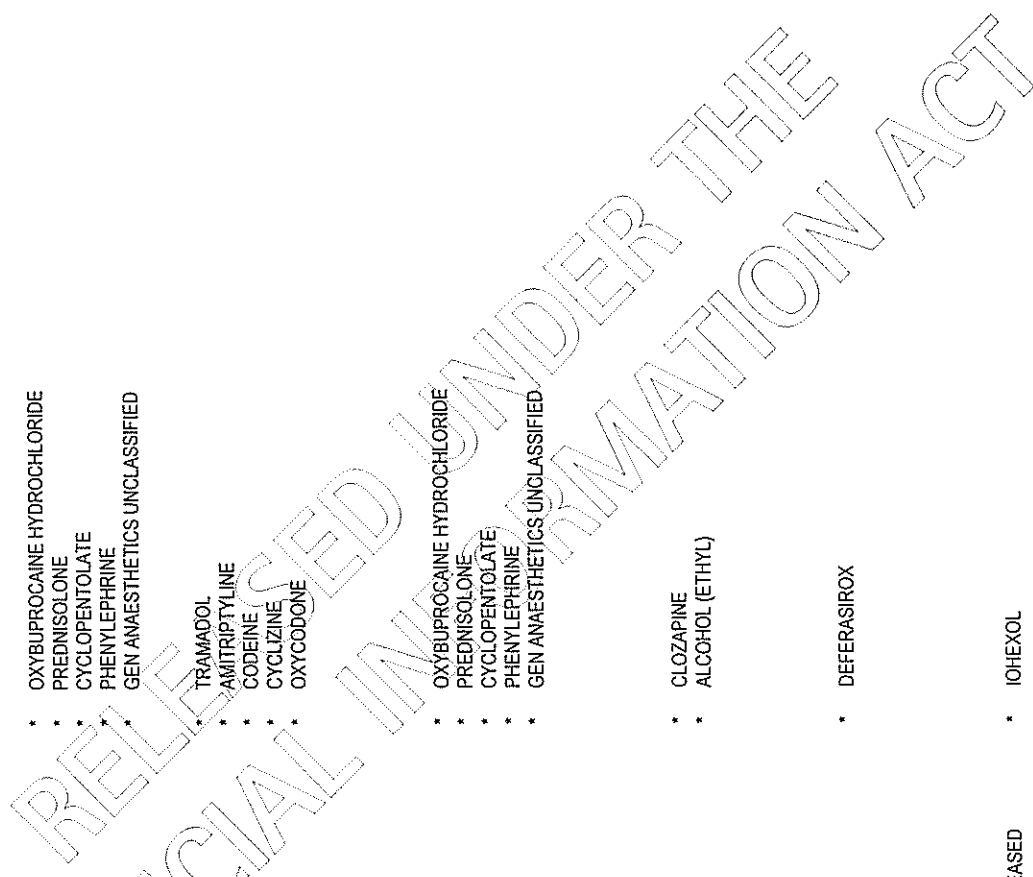
111811  
\*\*\*\*\*  
MAY2014  
CONVULSIONS  
ENTEROCOLITIS  
INTESTINAL NECROSIS  
SEPSIS  
\* OXYBUPROCAINE HYDROCHLORIDE  
\* PREDNISOLONE  
\* CYCLOPENTOLATE  
\* PHENYLEPHRINE  
\* GEN ANAESTHETICS UNCLASSIFIED

Miscellaneous

110972  
\*\*\*\*\*  
APR2014  
SUDDEN DEATH  
\* CLOZAPINE  
\* ALCOHOL (ETHYL)

110954  
M  
APR2014  
SUDDEN DEATH  
\* DEFERASIROX

114270  
F  
NOV2014  
OXYGEN SATURATION DECREASED  
PULMONARY OEDEMA  
TACHYCARDIA  
HYPERTENSION  
PLEURAL EFFUSION  
\* IOHEXOL



**Table 6:**

These cases are extracted separately here for comment but also appear in the overall listing by Medicine Classification ATC code. Case summary and CARM comment are as presented to the various MARC meetings.

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	AGE	SEX
109395		JAN2014	HAEMORRHAGE SUBDURAL HAEMORRHAGE CEREBELLAR DEATH	* CLOPIDOGREL * ACETYSALICYLIC ACID * ATORVASTATIN * METOPROLOL	50	M
109523		JAN2014	HAEMORRHAGE SUBDURAL DEATH	* WARFARIN	71	F
110350 <small>****</small>		FEB2014	CEREBRAL HAEMORRHAGE CONVULSIONS HAEMORRHAGE NOS DEATH	* ALTEPLASE * ACETYSALICYLIC ACID * DIPYRIDAMOLE * HEPARIN-LMW - ENOXAPARIN	70	M
110700		MAR2014	CEREBRAL HAEMORRHAGE MEDICATION ERROR DEATH	* TENECTEPLASE * CLOPIDOGREL * HEPARIN-LMW - ENOXAPARIN * ACETYSALICYLIC ACID	72	M

REPORT DATE REACTIONS DRUGS AGE SEX

111278 APR2014 GI HAEMORRHAGE DEATH \* DABIGATRAN \* CITALOPRAM CANDESARTAN GLIPIZIDE FRUSEMIDE 86 M

111282 APR2014 GI HAEMORRHAGE RENAL FAILURE NOS MELAENA VAGINAL HAEMORRHAGE DEATH \* DABIGATRAN FRUSEMIDE METOPROLOL QUINAPRIL DIGOXIN 54 F

111561 APR2014 RENAL FAILURE ACUTE ACIDOSIS METABOLIC MEDICATION NON-ADHERENCE DEATH \* COLCHICINE \* QUININE ALCOHOL (ETHYL) PREDNISONO PARACETAMOL/CODEINE 55 M

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REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
111609	MAY2014	GI HAEMORRHAGE DEATH	* RIVAROXABAN * ACETYLSALICYLIC ACID	60	F
112019	MAY2014	HAEMORRHAGE INTRACRANIAL DEATH	* WARFARIN INSULIN	79	M
112134	MAY2014	MEDICATION ERROR HAEMATEMESIS HAEMORRHAGE CEREBELLAR DEATH	* DABIGATRAN METOPROLOL LOSARTANHYDROCHLOROTHAZIDE	79	F
112135	MAY2014	TOXIC EPIDERMAL NECROLYSIS MULTIPLE ORGAN FAILURE DEATH	* VANCOMYCIN * ERTAPENEM	29	M

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REPORT DATE REACTIONS DRUGS AGE SEX

68 F

- \* HEPARIN-LMW - ENOXAPARIN
- \* TICAGRELOR
- \* ACETYLSALICYLIC ACID

SPINAL HAEMATOMA  
MEDICATION ERROR  
DEATH  
SUBARACHNOID HAEMORRHAGE

JUN2014

112433

77 M

- \* TENECTEPLASE

CEREBRAL HAEMORRHAGE  
MEDICATION ERROR  
DEATH

JUN2014

112466

75 M

- \* DABIGATRAN

HAEMORRHAGE INTRACRANIAL  
DEATH

SEP2014

113376

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REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
113489	SEP2014	DRUG LEVEL INCREASED DEATH	* TRAMADOL * AMITRIPTYLINE * CODEINE * CYGLIZINE * OXYCODONE	58	F
113664	SEP2014	CEREBRAL HAEMORRHAGE DEATH	* ABCIXIMAB * TICAGRELOR * ACETYLSALICYLIC ACID * HEPARIN - UNFRACTIONATED * GLYCERYLTRINITRATE	59	F
113726	SEP2014	MUCOSITIS NOS BONE MARROW DEPRESSION DIARRHOEA DEATH	* CAPECITABINE	38	M
114302	NOV2014	ALVEOLITIS FIBROSING DEATH	* AMIODARONE	79	M

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