

[REDACTED]

Ref: H201603159

Dear [REDACTED]

### Response to your request for official information

Thank you for your request of 3 August 2016 under the Official Information Act 1982 (the Act) for “a copy of this report please – 4.1.6 Special Reports: Annual Review of Fatalities (January 2015 – December 2015)” with reference to item 4.1.6 of the 166<sup>th</sup> Medicines Adverse Reactions Committee (MARC) meeting minutes. The report requested is 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>A copy of the following report presented to the MARC (item 4.1.6 of the 166<sup>th</sup> MARC meeting - Special Reports: Annual Review of Fatalities)</i>	Attached is: <i>1. A copy of the report presented to the MARC (item 4.1.6 of the 166<sup>th</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. Age is listed in years unless specified in months which is identified with ‘m’, for example 6m indicates the patient is six 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

A black rectangular redaction box covering the signature of the sender.

Medsafe

## Section 5: Special Reports

### Annual Review of Fatalities (January 2015 – December 2015)

#### Overview

There were 136 reports of death submitted to CARM in the context of medicine use involving 166 medication administrations (i.e. more than one medication may be implicated in each report). In 70% of cases (n=95) a causal relationship to the medicine(s) identified was assessed as either unrelated (47%) or the cause of death was unclassifiable (23%). In 30% of reports (n=41), the medicine was assessed as potentially contributing to the death (n=28) or resulted in an adverse reaction(s) that likely caused the death (n=13) (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 group of medicines represented by the 166 medicines in the 136 reports was "Nervous System" (n=76). "Blood and Blood forming organs" (n=27), "Antineoplastics and Immunomodulating Agents" (n=26) and "Anti-infectives" (n=17) were the other groups of note. The remaining ATC groups involved 20 medicines collectively with only a few medicines in each class, (Tables 2 & 3). In the Nervous System ATC group 60 of the 76 reports are for clozapine which are from Pharma consequent on a review of their database. Only 3 of the reports could be assigned to the 'may be contributory' causal association with the remainder either documenting events that were unrelated or with too little information to determine an association.

Table 4 illustrates the age distribution of all fatal reports to CARM irrespective of causality. Fifty-six percent of the reports where the age was known, were in patients older than 65 years and 11% were older than 80 years. There were more males (55%) compared to females (45%). There were 5 reports in patients under the age of two. These reports were for 3 cases of sudden death/Sudden Unexpected Death in Infancy in the context of routine childhood immunization schedule with 2 occurring 18 days following the 6 week routine scheduled vaccines, one of which also had developed septicemia and the third 2½ weeks after the 6 month routine scheduled vaccines. The remaining two reports: one was attributed to misoprostol associated Moebius Syndrome following a failed termination in the first trimester and the second, a Pharma report, detailed an unspecified brain injury in a 2 year old who received eculizumab for an off-label indication. The causal association could not be determined. There were 2 deaths in the 2-10 year age group. One report documented a suicide with levetiracetam occurring on changing brands. The potential for severe psychiatric reactions with levetiracetam is well recognized and the brand related association was investigated but was not considered to be a factor. In the other report a 14 year old developed fatal bronchiectasis whilst being treated with tocilizumab. The patient had a long history of bronchiectasis since infancy and although the report had limited information, the underlying condition was thought to be the primary cause of death.

Table 5 lists the 136 reports of fatalities to CARM grouped by ATC group. In 70% of these reports the cause of death was assessed as unrelated or unclassifiable and in the remaining 30% 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 reactions reported most frequently bleeding episodes accounted for 7/13 (54%) of reports where death was assessed as due to the medication and 8/28 (29%) of reports where the medicine may have been contributory. The remainder was of diverse drug/reaction combinations.

Table 6 is a subset of the data in Table 5

**Table 1: Outcome Overview**

<b>Outcome</b>	<b>Number of Cases</b>	<b>Percentage</b>
Died due to the adverse reaction	13	9.6
Died – drug may be contributory	28	20.6
Died – unrelated to the drug	64	47.0
Died – cause unclassifiable	31	22.8
<b>Total Reports</b>	<b>136</b>	<b>100.0</b>

**Table 2: ATC classification Overview**

<b>ATC High Level Group</b>	<b>No. of Medicines</b>	<b>Percentage</b>
Alimentary	3	1.8
Blood and Blood forming organs	27	16.3
Cardiovascular	7	4.2
Dermatological	0	
Genito Urinary System and Sex Hormones	1	0.6
Systemic Hormones (excl Sex Hormones)	2	1.2
Anti-infectives	17	10.2
Antineoplastics and Immunomodulating Agents	26	15.7
Musculoskeletal	7	4.2
Nervous System	76	45.8
Antiparasitic Products, Insecticides and Repellents	0	
Respiratory System	0	
Sensory Organs	0	
Miscellaneous	0	
<b>Total Suspect Medicines</b>	<b>166</b>	<b>100.0</b>

Table 3: ATC Detailed listing of Medicines

	ATC Group	No. of Medicines	Total
<b>A</b>	<b>Alimentary</b>		<b>3</b>
A02	Misoprostol	1	
	Omeprazole	1	
A04	Ondansetron hydrochloride	1	
<b>B</b>	<b>Blood and Blood forming organs</b>		<b>27</b>
B01	Apixaban	2	
	Dabigatran	15	
	Heparin LMW – Enoxaparin	2	
	Rivaroxaban	3	
	Ticagrelor	2	
	Warfarin	2	
B02	Eptacog alpha	1	
<b>C</b>	<b>Cardiovascular</b>		<b>7</b>
C01	Amiodarone	1	
C03	Frusemide	1	
C09	Cilazapril	2	
	Quinapril	1	
C10	Atorvastatin	1	
	Rosuvastatin	1	
<b>G</b>	<b>Genito Urinary System and Sex Hormones</b>		<b>1</b>
G03	Cyproterone acetate	1	
<b>H</b>	<b>Systemic Hormones (excl Sex Hormones)</b>		<b>2</b>
H02	Prednisone	1	
H05	Teriparatide	1	
<b>J</b>	<b>Anti-infectives</b>		<b>17</b>
J01	Flucloxacillin	1	
	Gentamycin	1	
	Nitrofurantoin	1	
	Trimethoprim	1	
J05	Ganciclovir sodium	1	
J07	DTaP Hexa Vaccine	3	
	Influenza – Trivalent	3	
	Pneumococcal 13	3	
	Rota Virus Vaccine	3	
<b>L</b>	<b>Antineoplastics and Immunomodulating Agents</b>		<b>26</b>
L01	Azacitidine	1	
	Bevacizumab	1	
	Erlotinib	1	
	Ibrutinib	1	
	Methotrexate	1	
	Pembrolizumab	3	
	Rituximab	1	
L02	Abiraterone	1	
	Tamoxifen	1	
L04	Adalimumab	2	
	Eculizumab	1	
	Infliximab	1	
	Lenalidomide	6	
	Thalidomide	3	
	Tocilizumab	2	

	ATC Group	No. of Medicines	Total
<b>M</b>	<b>Musculoskeletal</b>		<b>7</b>
M01	Diclofenac	3	
	Ibuprofen	1	
M03	Rocuronium	1	
M05	Zoledronate	2	
<b>N</b>	<b>Nervous System</b>		<b>76</b>
N01	Fentanyl	1	
N02	Acetylsalicylic acid	2	
N03	Clonazepam	1	
	Lamotrigine	1	
	Levetiracetam	1	
N04	Benzotropine Mesylate	1	
N05	Clozapine	60	
	Haloperidol	1	
	Olanzapine	2	
	Quetiapine	1	
	Risperidone	1	
N06	Fluoxetine	1	
	Paroxetine	2	
	Sertraline	1	
	<b>Total Medicines</b>		<b>166</b>

Table 4: Age group and Gender Overview

Age Group	Female	Male	Unknown	Total
Under 2	2	3		5
02 – 09				
10 – 19		2		2
20 – 29		1		1
30 – 39	2	3		5
40 – 49	6	6		12
50 – 59	10	8		18
60 – 69	10	22		32
70 – 79	18	21		39
80 plus	13	6		19
Unknown		3		3
<b>Total</b>	<b>61</b>	<b>75</b>		<b>136</b>
	45%	55%		

**Table 5: Annual Report Fatal Cases January to December 2015**

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 identified with \*\*\*\*\* below the Report Number. This listing covers the 136 reports, identifying 166 suspect medicines, which resulted in a fatal outcome regardless of causality.

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
<u>Alimentary</u>					
115922	APR2015	CONGENITAL ANOMALY NOS	* MISOPROSTOL		F
117072 *****	JUL2015	HYPOTENSION RENAL FAILURE ACUTE BRADYCARDIA CARDIAC ARREST MULTIPLE ORGAN FAILURE	* DICLOFENAC * OMEPRAZOLE * CILAZAPRIL * FRUSEMIDE * SIMVASTATIN	80	M
117433 *****	AUG2015	ABSCESS PERIANAL CONSTIPATION	* AZACITIDINE * ONDANSETRON HYDROCHLORIDE	78	M
<u>Blood and Blood forming organs</u>					
115333	FEB2015	CEREBRAL HAEMORRHAGE ENDOCARDITIS	* APIXABAN	74	M
117020	JUL2015	CARCINOMA COLON	* APIXABAN	85	F
114883	JAN2015	CARDIAC TAMPONADE DISSECTING AORTIC ANEURYSM HAEMORRHAGE INTRACRANIAL	* DABIGATRAN	77	M
115140 *****	FEB2015	GI HAEMORRHAGE RENAL FAILURE ACUTE DRUG LEVEL INCREASED SEPSIS DEATH	* DABIGATRAN * IBUPROFEN * BACLOFEN * METOPROLOL * DIGOXIN	61	M
115340	FEB2015	HAEMORRHAGE STROKE	* DABIGATRAN	69	F
115705 *****	MAR2015	THROMBUS INTRACARDIAC	* DABIGATRAN * WARFARIN	70	M

Blood and Blood forming organs

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
116493	MAY2015	SEPSIS THROMBOSIS CEREBRAL ARTERIAL RECTAL BLEEDING	* DABIGATRAN * OMEPRAZOLE * METOPROLOL * FRUSEMIDE * DILTIAZEM	73	F
117048	JUL2015	HAEMORRHAGE INTRACRANIAL FALL SUBDURAL HAEMATOMA	* DABIGATRAN * DILTIAZEM * METOPROLOL * CHOLECALCIFEROL * ATORVASTATIN	74	F
117107	JUL2015	PULMONARY HAEMORRHAGE VASCULITIS RENAL FAILURE ACUTE DEATH	* DABIGATRAN * DIGOXIN * DILTIAZEM * METOPROLOL	78	F
117247	JUL2015	ANAEMIA MELAENA VOMITING	* DABIGATRAN	91	F
117339	JUL2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN	80	F
117376	AUG2015	NEOPLASM MALIGNANT	* DABIGATRAN	81	M
117413	AUG2015	FRACTURE CEREBRAL HAEMORRHAGE SEPTICAEMIA PNEUMONIA ASPIRATION	* DABIGATRAN * TIOTROPIUM BROMIDE	68	M
118018	SEP2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN * BISOPROLOL * CILAZAPRIL * OMEPRAZOLE * SIMVASTATIN	85	M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT



Blood and Blood forming organs

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
118019 ****	SEP2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN * ACETYLSALICYLIC ACID ATORVASTATIN BISOPROLOL IBUPROFEN	77	F
118093	SEP2015	GI HAEMORRHAGE	* DABIGATRAN	85	M
118266	OCT2015	CEREBRAL HAEMORRHAGE	* DABIGATRAN TERBINAFINE ALENDROMATE + CHOLECALCIFEROL THYROXINE CILAZAPRIL	82	F
118523 ****	NOV2015	HAEMORRHAGE INTRAABDOMINAL	* TICAGRELOR * HEPARIN-LMW - ENOXAPARIN * WARFARIN * ACETYLSALICYLIC ACID DILTIAZEM	67	F
118821	NOV2015	HAEMORRHAGE RETROPERITONEAL DEATH	* HEPARIN-LMW - ENOXAPARIN ACETYLSALICYLIC ACID	68	M
117330	JUL2015	HEADACHE	* RIVAROXABAN	73	F
117486	AUG2015	HAEMORRHAGE INTRACRANIAL	* RIVAROXABAN ALLOPURINOL ATORVASTATIN	75	M
118725	NOV2015	STROKE	* RIVAROXABAN	70	M
117986	SEP2015	RENAL FAILURE CHRONIC	* TICAGRELOR		M
118523 ****	NOV2015	HAEMORRHAGE INTRAABDOMINAL	* TICAGRELOR * HEPARIN-LMW - ENOXAPARIN * WARFARIN * ACETYLSALICYLIC ACID DILTIAZEM	67	F

OFFICIALLY RELEASED UNDER THE  
 INFORMATION ACT

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
115705 *****	MAR2015	THROMBUS INTRACARDIAC	* DABIGATRAN * WARFARIN	70	M
116523 *****	NOV2015	HAEMORRHAGE INTRAABDOMINAL	* TIGARELOR * HEPARIN-LMW - ENOXAPARIN * WARFARIN * ACETYLSALICYLIC ACID * DILTIAZEM	67	F
116646	JUN2015	HAEMATEMESIS ASPIRATION PNEUMONITIS RESPIRATORY FAILURE	* EPTACOG ALPHA	71	M
<u>Cardiovascular</u>					
115320	FEB2015	RASH HEPATIC ENZYMES INCREASED BILIRUBINAEMIA THYROID DISORDER SOMNOLENCE	* AMIODARONE * THYROXINE * ACETYLSALICYLIC ACID * CARVEDILOL * CILAZAPRIL	60	M
117072 *****	JUL2015	HYPOTENSION RENAL FAILURE ACUTE BRADYCARDIA CARDIAC ARREST MULTIPLE ORGAN FAILURE	* DICLOFENAC * OMEPRAZOLE * CILAZAPRIL * FRUSEMIDE * SIMVASTATIN	80	M
117737 *****	SEP2015	ANAPHYLACTIC SHOCK DEATH	* ROCURONIUM * CILAZAPRIL * PROPOFOL * FENTANYL * MIDAZOLAM	69	F
118130	OCT2015	MULTIPLE ORGAN FAILURE PANCREATITIS	* QUINAPRIL * ATORVASTATIN * ZOPICLONE * PROCHLORPERAZINE * VARICELLA VACCINE - SHINGLES	71	M
119100	DEC2015	INTERSTITIAL LUNG DISEASE	* ROSUVASTATIN	65	M

REPORT \_\_\_\_\_ DATE \_\_\_\_\_ REACTIONS \_\_\_\_\_ DRUGS \_\_\_\_\_ AGE \_\_\_\_\_ SEX \_\_\_\_\_

Genito-urinary System and Sex Hormones

116292      MAY2015      HEPATIC FAILURE  
HEPATORENAL SYNDROME

79      M

\* CYPROTERONE ACETATE

Systemic Hormones (excl Sex Hormones)

115499      MAR2015      GI HAEMORRHAGE  
\*\*\*\*\*      SEPSIS SECONDARY  
                 UNCONSCIOUSNESS  
                 ATRIAL FIBRILLATION  
                 CROHN'S DISEASE AGGRAVATED

75      M

\* INFliximab  
\* PREDNisone  
WARFARIN  
VITAMIN D

118728      NOV2015      FRACTURE  
                 OSTEOPOROSIS

84      F

\* TERIPARATIDE

Antiinfectives

118417      OCT2015      HEPATIC FAILURE  
                 RENAL TUBULAR NECROSIS  
                 DEATH

78      M

\* FLUCLOXACILLIN

114877      JAN2015      RENAL FAILURE AGGRAVATED  
                 MEDICATION ERROR  
                 DEATH

87      M

\* GENTAMICIN

118722      NOV2015      MEDICATION ERROR  
                 PNEUMONIA INTERSTITIAL

81      F

\* NITROFURANTOIN

117076      JUL2015      TOXIC EPIDERMAL NECROLYSIS  
                 MEDICATION ERROR  
                 DEATH

80      F

\* TRIMETHOPRIM

117415      AUG2015      PULMONARY HAEMORRHAGE  
                 PNEUMONITIS

52      F

\* GANCICLOVIR SODIUM

RELEASED UNDER THE OFFICIAL INFORMATION ACT

OFFICIAL INFORMATION ACT  
 RELEASED UNDER THE

Anti-infectives

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117961 *****	SEP2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	2m	M
118270 *****	OCT2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	6m	M
119094 *****	DEC2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	1m	F
116202	MAY2015	PROGRESSION OF DISEASE EMBOLISM PULMONARY GI HAEMORRHAGE THROMBOPHLEBITIS VENA CAVA INF	* INFLUENZA - TRIVALENT FELODIPINE CHOLECALCIFEROL LACTULOSE MORPHINE SULPHATE	78	F
116573	MAY2015	SUDDEN DEATH	* INFLUENZA - TRIVALENT ALENDRONATE + CHOLECALCIFEROL ACETYLSALICYLIC ACID METOPROLOL FRUSEMIDE	96	F
118820	NOV2015	SARCOMA	* INFLUENZA - TRIVALENT	46	M
117961 *****	SEP2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	2m	M
118270 *****	OCT2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	6m	M
119094 *****	DEC2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	1m	F

Anti-infectives

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117961 *****	SEP2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	2m	M
118270 *****	OCT2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	6m	M
119094 *****	DEC2015	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 13	1m	F
<u>Antineoplastics and Immunomodulating Agents</u>					
117433 *****	AUG2015	ABSCESS PERIANAL CONSTIPATION	* AZACITIDINE * ONDANSETRON HYDROCHLORIDE	78	M
118529	NOV2015	PULMONARY HAEMORRHAGE	* BEVACIZUMAB PACLITAXEL CARBOPLATIN	43	M
117006	JUL2015	PULMONARY HAEMORRHAGE	* ERLOTINIB SORAFENIB MORPHINE SULPHATE DOCUSATE SODIUM ATENOLOL	44	M
119010	DEC2015	ATRIAL FIBRILLATION RENAL FAILURE ACUTE PULMONARY DISORDERS CARDIAC HYPERTROPHY PROGRESSION OF DISEASE	* IBRUTINIB	73	M
117321	JUL2015	MEDICATION ERROR PULMONARY CARCINOMA	* METHOTREXATE	57	F

Antineoplastics and Immunomodulating Agents

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
118422	OCT2015	PROGRESSION OF DISEASE	* PEMBROLIZUMAB	42	F
118423	OCT2015	PROGRESSION OF DISEASE	* PEMBROLIZUMAB	69	M
118424	OCT2015	PROGRESSION OF DISEASE	* PEMBROLIZUMAB	51	M
116486	MAY2015	GINEOPLASM MALIGNANT	* RITUXIMAB	72	F
117552 *****	AUG2015	DEAFNESS PROGRESSION OF DISEASE BONE METASTASES	* ABIRATERONE * ZOLEDRONATE * FENTANYL * HALOPERIDOL * SERTRALINE	78	M
115253 *****	FEB2015	PROGRESSION OF DISEASE DRUG INTERACTION THERAPEUTIC RESPONSE DECREASED	TAMOXIFEN   FLUOXETINE	39	F
117245	JUL2015	MYOCARDIAL INFARCTION	* ADALIMUMAB GABAPENTIN OXYCODONE AMITRIPTYLINE CILAZAPRIL	68	F
117370	AUG2015	PULMONARY CARCINOMA PSORIASIS AGGRAVATED	* ADALIMUMAB		M
114909	JAN2015	CEREBRAL DISORDER	* ECULIZUMAB	23m	M
115499 *****	MAR2015	GI HAEMORRHAGE SEPSIS SECONDARY UNCONSCIOUSNESS ATRIAL FIBRILLATION CROHN'S DISEASE AGGRAVATED	* INFlixIMAB * PREDNISONE WARFARIN VITAMIN D	75	M
115622	MAR2015	PROGRESSION OF DISEASE	* LENALIDOMIDE	55	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Antineoplastics and Immunomodulating Agents

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117954 *****	SEP2015	HAEMOPTYSIS RESPIRATORY ARREST PROGRESSION OF DISEASE	* THALIDOMIDE * LENALIDOMIDE	65	M
118078	SEP2015	MYELOMATOSIS MULTIPLE PROGRESSION OF DISEASE	* LENALIDOMIDE	50	M
118079	SEP2015	MYELOMATOSIS MULTIPLE PROGRESSION OF DISEASE	* LENALIDOMIDE	82	M
118080	SEP2015	MYELOMATOSIS MULTIPLE SEPSIS BRONCHIECTASIS RENAL IMPAIRMENT PROGRESSION OF DISEASE	* LENALIDOMIDE	73	F
118311	OCT2015	INFECTION FUNGAL BRONCHOPNEUMONIA SEPSIS PROGRESSION OF DISEASE NEUTROPENIA	* LENALIDOMIDE MORPHINE SULPHATE	73	M
114954	JAN2015	PROGRESSION OF DISEASE FRACTURE PATHOLOGICAL	* THALIDOMIDE DEXAMETHASONE MORPHINE SULPHATE FRUSEMIDE ALLOPURINOL	74	M
115767	MAR2015	PANCYTOPENIA PROGRESSION OF DISEASE	* THALIDOMIDE ANTINEOPLASTIC AGENT(S) NOS MELPHALAN PREDNISONE	55	F
117954 *****	SEP2015	HAEMOPTYSIS RESPIRATORY ARREST PROGRESSION OF DISEASE	* THALIDOMIDE * LENALIDOMIDE	65	M
116551	MAY2015	BRONCHIECTASIS	* TOCILIZUMAB	14	M

Antineoplastics and immunomodulating Agents

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
118528	NOV2015	INFECTION VIRAL MULTIPLE ORGAN FAILURE LIVEDO RETICULARIS SKIN NODULE	* TOCIZUMAB	67	M
<b>Musculoskeletal</b>					
117072 *****	JUL2015	HYPOTENSION RENAL FAILURE ACUTE BRADYCARDIA CARDIAC ARREST MULTIPLE ORGAN FAILURE	* DICLOFENAC * OMEPRAZOLE * CILAZAPRIL * FRUSEMIDE * SIMVASTATIN	80	M
117892 *****	SEP2015	LYMPHOMA MALIGNANT RENAL FAILURE CHRONIC	* CLOZAPINE * DICLOFENAC	62	M
118819	NOV2015	GI HAEMORRHAGE DUODENAL ULCER HAEMORRHAGIC MEDICATION ERROR DEATH	* DICLOFENAC	73	F
115140 *****	FEB2015	GI HAEMORRHAGE RENAL FAILURE ACUTE DRUG LEVEL INCREASED SEPSIS DEATH	* DABIGATRAN * IBUPROFEN * BACLOFEN * METOPROLOL * DIGOXIN	61	M
117737 *****	SEP2015	ANAPHYLACTIC SHOCK DEATH	* ROCURONIUM * CILAZAPRIL * PROPOFOL * FENTANYL * MIDAZOLAM	69	F
117552 *****	AUG2015	DEAFNESS PROGRESSION OF DISEASE BONE METASTASES	* ABIRATERONE * ZOLEDRONATE * FENTANYL * HALOPERIDOL * SERTRALINE	78	M

RELEASED UNDER THE OFFICIAL INFORMATION ACT



Musculoskeletal

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117773	SEP2015	RENAL FAILURE ACUTE MEDICATION ERROR HYPOCALCAEMIA URINARY TRACT INFECTION HAEMATURIA	* ZOLEDRONATE GLUCLAZIDE METOPROLOL SIMVASTATIN DIPYRIDAMOLE	84	F

Nervous System

117552 *****	AUG2015	DEAFNESS PROGRESSION OF DISEASE BONE METASTASES	* ABIRATERONE * ZOLEDRONATE * FENTANYL * HALOPERIDOL * SERTRALINE	78	M
118019 *****	SEP2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN * ACETYLSALICYLIC ACID * ATORVASTATIN * BISOPROLOL * IBUPROFEN	77	F
118523 *****	NOV2015	HAEMORRHAGE INTRAABDOMINAL	* TICAGRELOR * HEPARIN-LMW - ENOXAPARIN * WARFARIN * ACETYLSALICYLIC ACID * DILTIAZEM	67	F
117946 *****	SEP2015	SUICIDE	* LAMOTRIGINE * CLONAZEPAM * PAROXETINE	29	M
118368	OCT2015	IRRITABILITY MOOD DISORDER SUICIDE ATTEMPT SUICIDE BRAND SWITCH	* LEVETIRACETAM	17	M
118629 *****	NOV2015	FALL HEART DISORDER HYPERTENSION	* CLOZAPINE * BENZTROPINE MESYLATE	54	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
115450	MAR2015	PNEUMONIA HAEMOGLOBIN DECREASED LEUKAEMIA AGRANULOCYTOSIS	* CLOZAPINE PARACETAMOL SIMVASTATIN VEKILAFAXINE CLONAZEPAM	64	M
116233	MAY2015	NEUTROPENIA PROGRESSION OF DISEASE PULMONARY CARCINOMA THROMBOCYTOPENIA ANAEMIA	* CLOZAPINE CITALOPRAM ACETYLSALICYLIC ACID ATORVASTATIN METFORMIN	55	M
117516	AUG2015	MYOCARDIAL INFARCTION LOWER RESP TRACT INFECTION	* CLOZAPINE	83	F
117517	AUG2015	CARDIAC FAILURE MYOCARDIAL INFARCTION UPPER RESP TRACT INFECTION	* CLOZAPINE CYPROTERONE ACETATE FLUOXETINE QUETIAPINE	40	M
117518	AUG2015	CARDIAC FAILURE RESPIRATORY FAILURE OVARIAN CARCINOMA METASTASES NOS	* CLOZAPINE	37	F
117519	AUG2015	PNEUMONIA CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE	68	F
117520	AUG2015	CEREBRAL HAEMORRHAGE CARCINOMA COLON BRAIN METASTASES CARDIAC ARREST	* CLOZAPINE	54	F
117521	AUG2015	CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE	49	F
117522	AUG2015	PNEUMONIA	* CLOZAPINE	54	M
117523	AUG2015	PARKINSONISM	* CLOZAPINE	74	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
117524	AUG2015	CARCINOMA RESPIRATORY DISORDER	* CLOZAPINE	42	M
117553	AUG2015	UTERINE CARCINOMA METASTASES NOS	* CLOZAPINE CLONAZEPAM METOCLOPRAMIDE PARACETAMOL	75	F
117554	AUG2015	PULMONARY CARCINOMA METASTASES NOS PNEUMONIA HEPATITIS B GOUT	* CLOZAPINE	58	M
117555	AUG2015	INTESTINAL OBSTRUCTION CONSTIPATION PNEUMONIA	* CLOZAPINE	73	M
117556	AUG2015	DEMENTIA PSYCHOSIS	* CLOZAPINE	73	M
117557	AUG2015	PYELONEPHRITIS DEMENTIA SEPSIS	* CLOZAPINE	67	M
117558	AUG2015	BREAST NEOPLASM MALIGNANT FEMALE METASTASES NOS	* CLOZAPINE	53	F
117559	AUG2015	DEMENTIA PARKINSONISM DEPRESSION	* CLOZAPINE	77	F
117560	AUG2015	MYOCARDIAL INFARCTION MENORRHAGIA ANAEMIA	* CLOZAPINE SIMVASTATIN METFORMIN GLYCERYL TRINITRATE ACETYLSALICYLIC ACID	50	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

<u>REPORT</u>	<u>DATE</u>	<u>REACTIONS</u>	<u>DRUGS</u>	<u>AGE</u>	<u>SEX</u>
117561	AUG2015	CARDIAC ARREST DEMENTIA PNEUMONIA	* CLOZAPINE	69	F
117562	AUG2015	PNEUMONIA DEMENTIA	* CLOZAPINE	68	M
117667	AUG2015	CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE	59	F
117668	AUG2015	PULMONARY CARCINOMA BRAIN METASTASES	* CLOZAPINE	43	F
117669	AUG2015	BREAST NEOPLASM MALIGNANT FEMALE METASTASES NOS	* CLOZAPINE	43	F
117670	AUG2015	RENAL FAILURE ACUTE DEHYDRATION DEMENTIA INFECTION VIRAL	* CLOZAPINE	72	F
117671	AUG2015	STROKE BRAIN METASTASES CHRONIC OBSTRUCT AIRWAYS DISEASE DIABETES MELLITUS NIDDM	* CLOZAPINE	64	M
117672	AUG2015	PANCREAS NEOPLASM MALIGNANT METASTASES NOS STROKE HEPATITIS	* CLOZAPINE	59	M
117673	AUG2015	MYOCARDIAL INFARCTION ATHEROSCLEROSIS DIABETES MELLITUS OBESITY	* CLOZAPINE	72	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117674	AUG2015	RENAL FAILURE ACUTE DEHYDRATION ANOREXIA DIABETES MELLITUS DEMENTIA	* CLOZAPINE	77	F
117675	AUG2015	PNEUMONIA ASPIRATION PARKINSONISM COLECTOMY	* CLOZAPINE	61	M
117676	AUG2015	RESPIRATORY FAILURE CARDIAC FAILURE MYOCARDIAL ISCHAEMIA DEMENTIA DIABETES MELLITUS NIDDM	* CLOZAPINE	68	M
117677	AUG2015	PNEUMONIA STROKE DIABETES MELLITUS NIDDM RENAL IMPAIRMENT	* CLOZAPINE SIMVASTATIN ACETYLSALICYLIC ACID METFORMIN METOPROLOL	74	M
117678	AUG2015	SEPSIS CHOLECYSTITIS PARKINSONISM SALIVA INCREASED PROSTATE CANCER	* CLOZAPINE ROPINIROLE AMANTADINE LEVODOPA ORPHENADRINE CITRATE	62	M
117885	SEP2015	SALIVA INCREASED BRAIN NEOPLASM MALIGNANT	* CLOZAPINE	60	F
117886	SEP2015	MULTIPLE ORGAN FAILURE STROKE DEMENTIA DYSPHAGIA URINARY TRACT INFECTION	* CLOZAPINE LAXSOL CITALOPRAM VALPROATE SODIUM OMEPRAZOLE	77	M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117887	SEP2015	RENAL FAILURE CHRONIC PROGRESSION OF DISEASE	* CLOZAPINE	60	M
117888	SEP2015	PNEUMONIA PULMONARY CARCINOMA	CLOZAPINE	58	M
117889	SEP2015	MYOCARDIAL INFARCTION DIABETES MELLITUS APPETITE INCREASED WEIGHT INCREASE NOCTURNAL ENURESIS	* CLOZAPINE ARIPRAZOLE OXYBUTYRIN METFORMIN SIMVASTATIN	61	F
117890	SEP2015	INTESTINAL ISCHAEMIA MYOCARDIAL ISCHAEMIA HYPERTENSION	* CLOZAPINE	84	F
117891	SEP2015	PULMONARY CARCINOMA PNEUMONIA MYOCARDIAL INFARCTION CHRONIC OBSTRUCT AIRWAYS DISEASE DRUG LEVEL INCREASED	* CLOZAPINE	70	M
117892 ****	SEP2015	LYMPHOMA MALIGNANT RENAL FAILURE CHRONIC	* CLOZAPINE * DICLOFENAC	62	M
117893	SEP2015	RENAL CARCINOMA	* CLOZAPINE	49	F
117894	SEP2015	BRONCHOPNEUMONIA CHRONIC OBSTRUCT AIRWAYS DISEASE RENAL FAILURE CHRONIC DIABETES MELLITUS HYPERTENSION	* CLOZAPINE	50	F
117895	SEP2015	PULMONARY CARCINOMA DIABETES MELLITUS NIDDM	* CLOZAPINE	56	M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
117896	SEP2015	STROKE PNEUMONIA	* CLOZAPINE	64	M
117897	SEP2015	EMBOLISM PULMONARY	* CLOZAPINE	80	F
117898	SEP2015	CARDIAC FAILURE CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE	60	M
117899	SEP2015	RESPIRATORY ARREST CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE	71	F
117900	SEP2015	STROKE MYOCARDIAL ISCHAEMIA CEREBRAL ISCHAEMIA	* CLOZAPINE	92	F
117979	SEP2015	MEGACOLON ACQUIRED DEATH ILEUS PARALYTIC	* CLOZAPINE OLANZAPINE	38	M
118028	SEP2015	ASPIRATION PNEUMONITIS	* CLOZAPINE QUETIAPINE CITALOPRAM MADOPAR TOLCAPONE	68	M
118029	SEP2015	CEREBRAL HAEMORRHAGE ASPIRATION PNEUMONITIS PNEUMONIA	* CLOZAPINE ROPINIROLE MADOPAR SELEGILINE ACETYSALICYLIC ACID	68	M
118030	SEP2015	ASPIRATION PNEUMONITIS SEPSIS RESPIRATORY FAILURE MULTIPLE ORGAN FAILURE	* CLOZAPINE	75	F

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
118031	SEP2015	FALL PROGRESSION OF DISEASE	* CLOZAPINE	76	M
118625	NOV2015	ARRHYTHMIA CARDIOMYOPATHY (FIBROSIS)	* CLOZAPINE	47	F
118626	NOV2015	HYPERTENSION MYOCARDIAL INFARCTION	* CLOZAPINE	65	F
118627	NOV2015	SALIVA INCREASED HYPOTHERMIA	* CLOZAPINE TERAZOSIN	60	M
118628 ****	NOV2015	SELF INJURY	* CLOZAPINE * PAROXETINE	38	M
118629 ****	NOV2015	FALL HEART DISORDER HYPERTENSION	* CLOZAPINE * BENZTROPINE MESYLATE	54	F
118630	NOV2015	SUDDEN DEATH HYPERCHOLESTEROLAEMIA	* CLOZAPINE	69	F
117552 ****	AUG2015	DEAFNESS PROGRESSION OF DISEASE BONE METASTASES	* ABIRATERONE * ZOLEDRONATE * FENTANYL * HALOPERIDOL * SERTRALINE	78	M
117160	JUL2015	ASPIRATION LIVER FATTY DRUG LEVEL INCREASED MEDICATION ERROR	* OLANZAPINE OLANZAPINE	42	M
118095	SEP2015	SUICIDE	* OLANZAPINE		M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT



Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
115416	MAR2015	SUICIDE	* QUETIAPINE	39	M
118411	OCT2015	MEDICATION ERROR CONSCIOUSNESS DECREASED FALL RESTLESS APPETITE DECREASED	* RISPERIDONE * LORAZEPAM * CLONAZEPAM	77	F
115253 *****	FEB2015	PROGRESSION OF DISEASE DRUG INTERACTION THERAPEUTIC RESPONSE DECREASED	TAMOXIFEN   FLUOXETINE	39	F
117946 *****	SEP2015	SUICIDE	* LAMOTRIGINE * CLONAZEPAM * PAROXETINE	29	M
118628 *****	NOV2015	SELF INJURY	* CLOZAPINE * PAROXETINE	38	M
117552 *****	AUG2015	DEAFNESS PROGRESSION OF DISEASE BONE METASTASES	* ABIRATERONE * ZOLEDRONATE * FENTANYL * HALOPERIDOL * SERTRALINE	78	M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

**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	DATE	REACTIONS	DRUGS	AGE	SEX
114877	JAN2015	RENAL FAILURE AGGRAVATED MEDICATION ERROR DEATH	* GENTAMICIN	87	M
115140	FEB2015	GI HAEMORRHAGE RENAL FAILURE ACUTE DEATH	* DABIGATRAN * IBUPROFEN BACLOFEN METOPROLOL DIGOXIN	61	M
117076	JUL2015	TOXIC EPIDERMAL NECROLYSIS MEDICATION ERROR DEATH	* TRIMETHOPRIM	80	F

REPORT DATE REACTIONS DRUGS AGE SEX

117107 JUL2015 PULMONARY HAEMORRHAGE VASCULITIS RENAL FAILURE ACUTE DEATH DABIGATRAN DIGOXIN DILTIAZEM METOPROLOL 78 F

117339 JUL2015 CEREBRAL HAEMORRHAGE DEATH \* DABIGATRAN 80 F

117737 SEP2015 ANAPHYLACTIC SHOCK DEATH \* ROCURONIUM \* CILAZAPRIL PROPOFOL FENTANYL MIDAZOLAM 69 F

117979 SEP2015 MEGACOLON ACQUIRED DEATH ILEUS PARALYTIC \* CLOZAPINE OLANZAPINE 38 M

OFFICIAL INFORMATION ACT  
RELEASED UNDER THE

OFFICIAL INFORMATION ACT  
 RELEASED UNDER THE

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
118018	SEP2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN * BISOPROLOL * CILAZAPRIL * OMEPRAZOLE * SIMVASTATIN	85	M

118019	SEP2015	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN * ACETYLSALICYLIC ACID * ATORVASTATIN * BISOPROLOL * IBUPROFEN	77	F
--------	---------	-------------------------------	---	----	---

118417	OCT2015	HEPATIC FAILURE RENAL TUBULAR NECROSIS DEATH	* FLUCLOXACILLIN	78	M
--------	---------	--	------------------	----	---

118523	NOV2015	HAEMORRHAGE INTRAABDOMINAL	* TICAGRELOR * HEPARIN-LMW - ENOXAPARIN * WARFARIN * ACETYLSALICYLIC ACID * DILTIAZEM	67	F
--------	---------	----------------------------	---	----	---

REPORT \_\_\_\_\_

DRUGS \_\_\_\_\_

DATE \_\_\_\_\_

REACTIONS \_\_\_\_\_

AGE \_\_\_\_\_

SEX \_\_\_\_\_

118819

NOV/2015

GI HAEMORRHAGE  
DUODENAL ULCER HAEMORRHAGIC  
MEDICATION ERROR  
DEATH

DICLOFENAC

73 F

118821

NOV/2015

HAEMORRHAGE RETROPERITONEAL  
DEATH

\* HEPARIN-LMW-ENOXAPARIN  
\* ACETYLSALICYLIC ACID

68 M

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Notes:

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT