

15 AUG 2017

Ref: H201702874

Dear [REDACTED]

### Response to your request for official information

Thank you for your request of 18 July 2017 under the Official Information Act 1982 (the Act) for

“Can I have a copy of 4.1.5 Special Reports: Annual Review of Fatalities (January 2016 – December 2016).”

This report is in respect to the 170<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. Please note there is a typo on page 20 of the document; 2016 has been inadvertently written as 2017.

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>“Can I have a copy of 4.1.5 Special Reports: Annual Review of Fatalities (January 2016 – December 2016).”</i>	Attached is: <i>1. A copy of the report presented to the MARC (item 4.1.5 of the 170<sup>th</sup> MARC meeting).</i>

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

[REDACTED]  
Group Manager  
Medsafe

## Section 5: Special Reports

### Annual Review of Fatalities (January 2016 – December 2016)

#### *Overview*

There were 77 reports of death submitted to CARM in the context of medicine use involving 120 medication administrations (i.e. more than one medication may be implicated in each report). In 66% of cases (n=51) a causal relationship to the medicine(s) identified was assessed as either unrelated (22%) or the cause of death was unclassifiable (44%). In 34% of reports (n=26), the medicine was assessed as potentially contributing to the death (n=12) or resulted in an adverse reaction(s) that likely caused the death (n=14) (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 in recent years.

The most frequent ATC group of medicines represented by the 120 medicines in the 77 reports was "Blood and Blood forming organs" (n=38) followed by similar numbers of medicines in each of the "Antineoplastics and Immunomodulating Agents" (n=24), "Nervous System" (n=21) and "Anti-infectives" (n=17) and a smaller contribution by "Cardiovascular" (n=11). The remaining ATC groups involved 6 medicines collectively with a single medicine in each class, (Tables 2 & 3). In the Blood and Blood forming organs ATC group 10 of the 38 reports are for NOAC's with warfarin and Heparin accounting for a further 13. With the exception of 9 of the 21 reports in the Nervous System ATC that involve clozapine (all from the MAH), in the other ATC groups only single, or occasionally up to 3 reports per medicine are noted.

Table 4 illustrates the age distribution of all fatal reports to CARM irrespective of causality. In 95% of the reports where the age was known, the over 65 year age group accounted for 70% of reports and 20% were older than 80 years. There were more males (58%) compared to females (42%), a similar pattern to last year. There were 4 reports in patients under the age of 19 years. Three of these were under 2 years reporting sudden death/Sudden Unexpected Death in Infancy in the context of routine childhood immunization schedule. One occurred the day following vaccination, another 21 days after vaccination and the third one month after vaccination. One report was for a 15 year old who had a history of intractable seizures since very early childhood managed at some point with Sativex and had had seizures prior to death. There were insufficient details in the MAH report to determine the cause of death or whether Sativex may have been in use at the time of death.

Table 5 lists the 77 reports of fatalities to CARM grouped by ATC group. In 66% of these reports the cause of death was assessed as unrelated or unclassifiable and in the remaining 34% 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 34% (contributed/likely causal), the reactions reported most frequently were bleeding episodes with anticoagulants accounting for 57% (n=8/14) of reports where death was considered due to the drug and 50% (n=6/12) of reports where the drug may have been contributory. The remainder were 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	14	18.2
Died – drug may be contributory	12	15.6
Died – unrelated to the drug	17	22.1
Died – cause unclassifiable	34	44.2
<b>Total Reports</b>	<b>77</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	1	0.8
Blood and Blood forming organs	38	21.7
Cardiovascular	11	9.2
Dermatological	1	0.8
Genito Urinary System and Sex Hormones	0	
Systemic Hormones (excl Sex Hormones)	1	0.8
Anti-infectives	17	14.2
Antineoplastics and Immunomodulating Agents	24	20.0
Musculoskeletal	3	2.5
Nervous System	21	17.5
Antiparasitic Products, Insecticides and Repellents	1	0.8
Respiratory System	1	0.8
Sensory Organs	0	
Miscellaneous	1	0.8
<b>Total Suspect Medicines</b>	<b>120</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>1</b>
A10	Saxagliptin	1	
<b>B</b>	<b>Blood and Blood forming organs</b>		<b>38</b>
B01	Acetylsalicylic acid	6	
	Apixaban	1	
	Clopidogrel	2	
	Dabigatran	9	
	Heparin – unfractionated	2	
	Heparin LMW – Enoxaparin	4	
	Ticagrelor	6	
	Warfarin	7	
B02	Eltrombopag	1	
<b>C</b>	<b>Cardiovascular</b>		<b>11</b>
C01	Amiodarone	1	
C07	Beta Blocker NOS	1	
	Metoprolol	1	
C09	ACE Inhibitor NOS	1	
	Candesartan	1	
	Cilazapril	1	
	Cilazapril/Hydrochlorothiazide	1	
C10	Atorvastatin	2	
	Rosuvastatin	1	
	Simvastatin	1	
<b>D</b>	<b>Genito Urinary System and Sex Hormones</b>		<b>1</b>
D06	Imiquimod	1	
<b>H</b>	<b>Systemic Hormones (excl Sex Hormones)</b>		<b>1</b>
H02	Prednisone	1	
<b>J</b>	<b>Anti-infectives</b>		<b>17</b>
J01	Amoxicillin/Clavulanic Acid	1	
	Cefaclor	1	
	Ceftriaxone	1	
	Cephazolin	1	
	Clindamycin	1	
	Flucloxacillin	1	
J05	Sofosbuvir + Ledipasvir	1	
J07	DTaP-Hexa Vaccine	2	
	Haemophilus B Vaccine	1	
	Influenza – Trivalent	1	
	Measles Mumps Rubella Vaccine	1	
	Pneumococcal 13	3	
	Rota Virus Vaccine	2	
<b>L</b>	<b>Antineoplastics and Immunomodulating Agents</b>		<b>24</b>
L01	Capecitabine	1	
	Cyclophosphamide	1	
	Dabrafenib	2	
	Epirubicin	1	
	Fludarabine	1	
	Ibrutinib	3	
	Methotrexate	1	
	Oxaliplatin	1	
	Paclitaxel	1	
	Rituximab	1	
	Trametinib	2	



	ATC Group	No. of Medicines	Total
L02	Abiraterone	2	
	Leuprorelin	1	
L04	Adalimumab	1	
	Lenalidomide	2	
	Pomalidomide	1	
	Tacrolimus	1	
	Thalidomide	1	
<b>M</b>	<b>Musculoskeletal</b>		<b>3</b>
M01	Diclofenac	1	
	NSAID unclassified	1	
M05	Zoledronate	1	
<b>N</b>	<b>Nervous System</b>		<b>21</b>
N01	General Anaesthetics unclassified	1	
N02	Morphine sulphate	1	
	Sativex	1	
N03	Carbamazepine	1	
N04	Rotigotine	1	
N05	Clozapine	9	
	Lithium carbonate	1	
	Olanzapine	2	
	Paliperidone	1	
	Quetiapine	1	
N06	Citalopram	1	
N07	Varenicline	1	
<b>P</b>	<b>Antiparasitic Products, Insecticides &amp; Repellents</b>		<b>1</b>
P02	Ivermectin	1	
<b>R</b>	<b>Respiratory</b>		<b>1</b>
R03	Tiotropium bromide	1	
<b>Z</b>	<b>Miscellaneous</b>		<b>1</b>
	Cannabis	1	
	<b>Total Medicines</b>		<b>120</b>

Table 4: Age group and Gender Overview

Age Group	Female	Male	Unknown	Total
Under 2	0	3		3
02 – 09				
10 – 19		1		1
20 – 29		1		1
30 – 39				
40 – 49	2	1		3
50 – 59	3	4		7
60 – 69	5	11		16
70 – 79	17	10		27
80 plus	5	10		15
Unknown		4		4
<b>Total</b>	<b>32</b>	<b>45</b>		<b>77</b>
	42%	58%		

**Table 5: Annual Report Fatal Cases January to December 2017**

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 77 reports, identifying 120 suspect medicines, which resulted in a fatal outcome regardless of causality.

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
<u>Alimentary</u>					
121741 *****	AUG2016	CEREBRAL HAEMORRHAGE	* SAXAGLIPTIN * CLOPIDOGREL * ACETYLSALICYLIC ACID CILAZAPRIL METOPROLOL	62	M
<u>Blood and Blood forming organs</u>					
119981	MAR2016	DISSECTING AORTIC ANEURYSM RENAL FAILURE ACUTE PERICARDIAL EFFUSION COLLAPSE CIRCULATORY PERIPHERAL ISCHAEMIA	* APIXABAN BISOPROLOL PRAVASTATIN LOSARTAN	73	F
121741 *****	AUG2016	CEREBRAL HAEMORRHAGE	* SAXAGLIPTIN * CLOPIDOGREL * ACETYLSALICYLIC ACID CILAZAPRIL METOPROLOL	62	M
119548	FEB2016	PANCREAS NEOPLASM MALIGNANT METASTASES NOS	* DABIGATRAN	78	F
119549	FEB2016	HEPATIC NEOPLASM MALIGNANT BILIARY TRACT DISORDER SEPSIS MULTIPLE ORGAN FAILURE ASPIRATION PNEUMONITIS	* DABIGATRAN	77	F
120234	APR2016	HAEMORRHAGE STROKE DEATH	* DABIGATRAN IDARUCIZUMAB	67	M

Blood and Blood forming organs

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
120613	MAY2016	RASH PRURITUS SUDDEN DEATH	DABIGATRAN FRUSEMIDE DIGOXIN ALLOPURINOL	92	M
120614	MAY2016	HAEMATOMA COLLAPSE CIRCULATORY SEPSIS	DABIGATRAN		M
121252	JUN2016	STROKE	* DABIGATRAN	71	M
122175 ****	SEP2016	ATRIAL FIBRILLATION CONGESTIVE HEART FAILURE BRONCHOPNEUMONIA RENAL IMPAIRMENT GI HAEMORRHAGE	* IBRUTINIB * DABIGATRAN FRUSEMIDE AMOXICILLIN/CLAVULANIC ACID CLARITHROMYCIN	75	F
122453	OCT2016	HAEMORRHAGE INTRACRANIAL DEATH	* DABIGATRAN SIMVASTATIN ALLOPURINOL QUINAPRIL PANTOPRAZOLE	79	F
122688	NOV2016	PULMONARY HAEMORRHAGE INTERSTITIAL LUNG DISEASE RESPIRATORY FAILURE	* DABIGATRAN METOPROLOL SIMVASTATIN FLUOXETINE ACETYLSALICYLIC ACID	71	F
121508	JUL2016	ANTIBODIES DRUG SPECIFIC	* HEPARIN - UNFRACTIONATED	83	F
122153	SEP2016	ANTIBODIES DRUG SPECIFIC THROMBUS INTRACARDIAC VENOUS THROMBOSIS DEATH	* HEPARIN - UNFRACTIONATED AMIODARONE	69	F



Blood and Blood forming organs

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119364	JAN2016	HAEMORRHAGE INTRACRANIAL DEATH	ACETYLSALICYLIC ACID TICAGRELOR HEPARIN-LMW-ENOXAPARIN	59	F
121687	AUG2016	CEREBRAL HAEMORRHAGE DEATH	HEPARIN-LMW-ENOXAPARIN	89	M
122157	SEP2016	HAEMORRHAGE INTRACRANIAL DEATH	HEPARIN-LMW-ENOXAPARIN CLOPIDOGREL ACETYLSALICYLIC ACID CILAZAPRIL IBUPROFEN	63	F
122687	NOV2016	HAEMATOMA HAEMORRHAGE RETROPERITONEAL MULTIPLE ORGAN FAILURE	TICAGRELOR HEPARIN-LMW-ENOXAPARIN ACETYLSALICYLIC ACID	72	F
119547	FEB2016	AORTIC ANEURYSM RUPTURE	TICAGRELOR	73	M
120610	MAY2016	HAEMORRHAGE INTRACRANIAL	TICAGRELOR		M
121347 ****	JUL2016	PNEUMONITIS	TICAGRELOR ACETYLSALICYLIC ACID METOPROLOL QUINAPRIL ATORVASTATIN	71	F
122856 ****	NOV2016	SHOCK CIRCULATORY THROMBOSIS CORONARY HAEMORRHAGE NOS	CANDESARTAN METOPROLOL TICAGRELOR	72	F
119159	JAN2016	SUBARACHNOID HAEMORRHAGE INR INCREASED DEATH	WARFARIN	67	F
119531	FEB2016	CEREBRAL HAEMORRHAGE DEATH	WARFARIN	72	M



Blood and Blood forming organs

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119534	FEB2016	HAEMORRHAGE SUBDURAL	* ACETYLSALICYLIC ACID WARFARIN DOXAZOSIN	65	M
119726	FEB2016	SKIN NECROSIS CALCINOSIS	WARFARIN ERYTHROPOIETIN CANDESARTAN CHOLECALCIFEROL CIPROFLOXACIN	79	F
120014	MAR2016	CEREBRAL HAEMORRHAGE	* WARFARIN * ACETYLSALICYLIC ACID	75	M
121157	JUN2016	PNEUMONIA HAEMORRHAGE SUBDURAL	* WARFARIN	73	F
122009	SEP2016	HAEMORRHAGE RETROPERITONEAL DEATH	* WARFARIN	69	M
122539	OCT2016	THROMBOCYTOPENIA THERAPEUTIC RESPONSE DECREASED NEPHROPATHY NOS	* ELTROMBOPAG	92	M
<u>Cardiovascular</u>					
122712	NOV2016	HEPATIC CIRRHOSIS DEATH	* AMIODARONE METOPROLOL ATORVASTATIN	86	M
122856 ****	NOV2016	SHOCK CIRCULATORY THROMBOSIS CORONARY HAEMORRHAGE NOS	* CANDESARTAN * METOPROLOL * TICAGRELOR	72	F
120891 ****	MAY2016	RESPIRATORY DEPRESSION ASPIRATION PNEUMONITIS DEATH MULTIPLE ORGAN FAILURE DISORIENTATION	* MORPHINE SULPHATE * BETA BLOCKER NOS * ACE INHIBITOR (NOS)	57	M

Cardiovascular

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
121571 ****	JUL2016	MEDICATION ERROR LITHIUM TOXICITY DEATH	LITHIUM CARBONATE NSAID UNCLASSIFIED CILAZAPRIL	72	F
119564 ****	FEB2016	SUDDEN DEATH	IVERMECTIN PREDNISON CILAZAPRIL/HYDROCHLOROTHIAZIDE ATORVASTATIN DICLOFENAC	78	M
121347 ****	JUL2016	PNEUMONITIS	TICAGRELOR ACETYLSALICYLIC ACID METOPROLOL QUINAPRIL ATORVASTATIN	71	F
120535	APR2016	MYOCARDIAL INFARCTION	ROSUVASTATIN		M
120704	MAY2016	MYOSITIS	TAMOXIFEN SIMVASTATIN QUETIAPINE	50	F
120088 ****	MAR2016	STEVENS JOHNSON SYNDROME	FLUCLOXACILLIN IMIQUIMOD	90	F
119564 ****	FEB2016	SUDDEN DEATH	IVERMECTIN PREDNISON CILAZAPRIL/HYDROCHLOROTHIAZIDE ATORVASTATIN DICLOFENAC	78	M

Systemic Hormones (excl Sex Hormones)

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119564 ****	FEB2016	SUDDEN DEATH	IVERMECTIN PREDNISON CILAZAPRIL/HYDROCHLOROTHIAZIDE ATORVASTATIN DICLOFENAC	78	M



Antimicrobials

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
122498	OCT2016	DYSPNOEA UNCONSCIOUSNESS	AMOXICILLIN/CLAVULANIC ACID	89	M
121569	JUL2016	COLITIS PSEUDOMEMBRANOUS DIARRHOEA, CLOSTRIDIUM DIFFICILE DEATH	CLINDAMYCIN CEPHAZOLIN CEFTRIAXONE CEFAZOLIN	71	M
120088 ****	MAR2016	STEVENS JOHNSON SYNDROME	FLUCLOXACILLIN IMIQIMOD	90	F
119170	JAN2016	PROGRESSION OF DISEASE SUDDEN DEATH	SOFOSBUVIR + LEDIPASVIR	60	M
120924	MAY2016	VASCULITIS MYOCARDIAL INFARCTION	INFLUENZA - TRIVALENT	54	M
120274	APR2016	SUDDEN DEATH	MEASLES-MUMPS-RUBELLA VACCINE HAEMOPHILUS B (ACT-HIB) PNEUMOCOCCAL VACC - 13	916	M
121228	JUN2016	SUDDEN DEATH	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	905	M
121297	JUN2016	SUDDEN DEATH	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	902	M
121322	JUL2016	PROGRESSION OF DISEASE	DABRAFENIB TRAMETINIB	63	M
121323	JUL2016	SEPSIS	DABRAFENIB TRAMETINIB	67	M

Antineoplastics and Immunomodulating Agents

Antineoplastics and Immunomodulating Agents

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119363	JAN2016	NEUTROPENIA ENTEROCOLITIS THROMBOCYTOPENIA	EPIDRIBICIN OXALIPLATIN CAPECITABINE	70	F
122175 ****	SEP2016	ATRIAL FIBRILLATION CONGESTIVE HEART FAILURE BRONCHOPNEUMONIA RENAL IMPAIRMENT GI HAEMORRHAGE	IBRUTINIB DABIGATRAN FRUSEMIDE AMOXICILLIN/CLAVULANIC ACID CLARITHROMYCIN	75	F
122540	OCT2016	LOWER RESP TRACT INFECTION PROGRESSION OF DISEASE	* IBRUTINIB VINCISTINE DOXORUBICIN/HYDROCHLORIDE PREDNISONE RITUXIMAB	82	M
122854	NOV2016	RENAL FAILURE ACUTE LOWER RESP TRACT INFECTION	* IBRUTINIB OMEPRAZOLE FLUOXETINE FLUTICASONE/SALMETEROL SALBUTAMOL	75	F
122534	OCT2016	SEPSIS INFECTION FUNGAL	* METHOTREXATE * CYCLOPHOSPHAMIDE * FLUDARABINE * FLUCONAZOLE * ACICLOVIR	54	F
121321	JUL2016	PROGRESSION OF DISEASE	* PACLITAXEL HALOPERIDOL OXYCODONE PROPRANOLOL AMOXICILLIN/CLAVULANIC ACID	66	M
120008	MAR2016	IMMUNOGLOBULINS DECREASED RENAL FAILURE CHRONIC	* RITUXIMAB FENTANYL	51	M

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Antineoplastics and Immunomodulating Agents

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119924	MAR2016	OEDEMA PERIPHERAL HEPATIC ENZYMES INCREASED DYSPNOEA NASAL DRYNESS DEATH	* ABRATERONE PREDNISON	73	M
122485	OCT2016	CARDIAC FAILURE	* ABRATERONE	84	M
120470	APR2016	HERPES ZOSTER SUDDEN DEATH	* LEUPRORELIN	90	M
122483	OCT2016	HEPATIC NEOPLASM MALIGNANT METASTASES NOS	* ADALIMUMAB	77	F
119802	MAR2016	PROGRESSION OF DISEASE	* LENALIDOMIDE	78	F
122912	DEC2016	PROGRESSION OF DISEASE	* LENALIDOMIDE	65	M
121395	JUL2016	PROGRESSION OF DISEASE	* POMALIDOMIDE	82	F
120156 ****	APR2016	CEREBRAL INFARCTION ENCEPHALOPATHY HYPERTENSIVE ENCEPHALOPATHY ANOXIC	* TACROLIMUS * GEN ANAESTHETICS UNCLASSIFIED	23	M
119602	FEB2016	HAEMORRHAGE STROKE	* THALIDOMIDE	80	M
<u>Musculoskeletal</u>					
119564 ****	FEB2016	SUDDEN DEATH	* IVERMECTIN * PREDNISON * CILZAPRIL/HYDROCHLOROTHIAZIDE * ATORVASTATIN * DICLOFENAC	78	M

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Musculoskeletal

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
121571 *****	JUL2016	MEDICATION ERROR LITHIUM TOXICITY DEATH	* LITHIUM CARBONATE * NSAID UNCLASSIFIED * CILAZAPRIL * RISPERIDONE * TRANYLCYPROMINE	72	F
119765	MAR2016	CARDIAC ARREST	* ZOLEDRONATE	89	F
<u>Nervous System</u>					
120156 *****	APR2016	CEREBRAL INFARCTION ENCEPHALOPATHY HYPERTENSIVE ENCEPHALOPATHY ANOXIC	* TACROLIMUS * GEN ANAESTHETICS UNCLASSIFIED	23	M
120891 *****	MAY2016	RESPIRATORY DEPRESSION ASPIRATION PNEUMONITIS DEATH MULTIPLE ORGAN FAILURE DISORIENTATION	* MORPHINE SULPHATE * BETA BLOCKER NOS * ACE INHIBITOR (NOS)	57	M
122920	DEC2016	CONVULSIONS	* SATIVEX	15	M
119237	JAN2016	CARDIAC FAILURE FRACTURE PATHOLOGICAL	* ROTIGOTINE FENTANYL LEVODOPA/CARBIDOPA (NOS)		M
119605	FEB2016	PULMONARY CARCINOMA	* CLOZAPINE	77	F
119606	FEB2016	BRONCHOPNEUMONIA	* CLOZAPINE ANTIBIOTICS UNCLASSIFIED PARACETAMOL	81	F
119607	FEB2016	BRONCHOPNEUMONIA	* CLOZAPINE	69	M
119608	FEB2016	PNEUMONIA	* CLOZAPINE	82	M



Nervous System

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
119984	MAR2016	NEUTROPHILIA LEUKOCYTOSIS PULMONARY CARCINOMA THROMBOCYTOSIS PROGRESSION OF DISEASE	* CLOZAPINE	67	F
120051	MAR2016	ASPIRATION PNEUMONITIS PARKINSONISM STROKE THYROTOXICOSIS HEPATITIS B	* CLOZAPINE	62	M
121203	JUN2016	LYMPHOMA MALIGNANT METASTASES NOS PANCYTOPENIA DRUG LEVEL INCREASED	* CLOZAPINE LORAZEPAM	50	M
121542	JUL2016	MYOCARDIAL INFARCTION DEATH ATHEROSCLEROSIS	* CLOZAPINE LAXSOL OMEPRAZOLE ARIPIRAZOLE QUETIAPINE	66	F
122352	OCT2016	PNEUMONIA	* CLOZAPINE	70	M
121571 ****	JUL2016	MEDICATION ERROR LITHIUM TOXICITY DEATH	* LITHIUM CARBONATE NSAID UNCLASSIFIED * CILAZAPRIL * RISPERIDONE * TRANYLCYPROMINE	72	F
122497	OCT2016	INTENTIONAL OVERDOSE DEATH	* OLANZAPINE IBUPROFEN	42	M
119925	MAR2016	CARDIAC ARREST	* PALIPERIDONE * OLANZAPINE * CARBAMAZEPINE * QUETIAPINE	40	F

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Nervous System

REPORT [REDACTED] DATE REACTIONS [REDACTED] AGE SEX [REDACTED]

119506 [REDACTED] FEB2016 CEREBRAL HAEMORRHAGE [REDACTED] 74 M [REDACTED]

\* VARENICLINE [REDACTED]

Antiparasitic Products, Insecticides & Repellents

119564 [REDACTED] FEB2016 SUDDEN DEATH [REDACTED] 78 M [REDACTED]

\* IVERMECTIN [REDACTED]  
\* PREDNISON [REDACTED]  
\* OLANZAPRIL/HYDROCHLOROTHIAZIDE [REDACTED]  
\* AYORVASTATIN [REDACTED]  
\* DICLOFENAC [REDACTED]

Respiratory

121562 [REDACTED] JUL2016 MYOCARDIAL INFARCTION DEATH [REDACTED] 71 M [REDACTED]

\* TIOTROPIUM BROMIDE [REDACTED]

Miscellaneous

120231 [REDACTED] APR2016 SUDDEN DEATH [REDACTED] 45 F [REDACTED]

\* CITALOPRAM [REDACTED]  
\* Cannabis [REDACTED]  
\* PARACETAMOL [REDACTED]

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**Table 6:** [REDACTED]

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
119159	JAN2016	SUBARACHNOID HAEMORRHAGE INR INCREASED	* WARFARIN	67	F
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
119364	JAN2016	HAEMORRHAGE INTRACRANIAL	* ACETYLSALICYLIC ACID * TICAGRELOR * HEPARIN/LMW-ENOXAPARIN	59	F
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
119531	FEB2016	CEREBRAL HAEMORRHAGE	* WARFARIN	72	M
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
120234	APR2016	HAEMORRHAGE STROKE DEATH	* DABIGATRAN IDARUCIZUMAB	67	M
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
120891	MAY2016	RESPIRATORY DEPRESSION ASPIRATION PNEUMONITIS DEATH MULTIPLE ORGAN FAILURE DISORIENTATION	* MORPHINE SULPHATE * BETA BLOCKER NOS * ACE INHIBITOR (NOS)	57	M
121569	JUL2016	COLITIS PSEUDOMEMBRANOUS DIARRHOEA, CLOSTRIDIUM DIFFICILE DEATH	* CLINDAMYCIN * CEPHAZOLIN * CEFTRIAXONE * CEFACLOR	71	M
121571	JUL2016	MEDICATION ERROR LITHIUM TOXICITY DEATH	* LITHIUM CARBONATE * NSAID UNCLASSIFIED * CILAZAPRIL * RISPERIDONE * TRANYLCPROMINE	72	F



REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
121687	AUG2016	CEREBRAL HAEMORRHAGE DEATH	* HEPARIN-LMW - ENOXAPARIN * HEPARIN-LMW - ENOXAPARIN * HEPARIN-LMW - ENOXAPARIN	89	M
122009	SEP2016	HAEMORRHAGE RETROPERITONEAL DEATH	* WARFARIN	69	M
122153	SEP2016	ANTIBODIES DRUG SPECIFIC THROMBUS INTRACARDIAC VENOUS THROMBOSIS DEATH	* HEPARIN - UNFRACTIONATED AMIODARONE	69	F
122157	SEP2016	HAEMORRHAGE INTRACRANIAL	* HEPARIN-LMW - ENOXAPARIN * CLOPIDOGREL * ACETYLSALICYLIC ACID CILAZAPRIL IBUPROFEN	63	F

REPORT	DATE	REACTIONS	DRUGS	AGE	SEX
122463	OCT2016	HAEMORRHAGE INTRACRANIAL DEATH	* DABIGATRAN SIMVASTATIN ALLOPURINOL QUINAPRIL PANTOPRAZOLE	79	F
122497	OCT2016	INTENTIONAL OVERDOSE DEATH	* OLANZAPINE IBUPROFEN	42	M
122712	NOV2016	HEPATIC CIRRHOSIS DEATH	* AMIODARONE METOPROLOL ATORVASTATIN	86	M

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