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6 August 2021

Tracy Livingston

By email: fyi-request-14927-f0e10a34@requests.fyi.org.nz Ref: H202106580

Dear Tracy

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 27 May 2021. In response to your earlier request (H202102975 refers), you asked for:

"I requested the latrogenic reports from 2019 and 2020, (#14927) which were denied because I asked for the 'unscrubbed' data. I am sorry that I may have requested wrongly. What I mean was, the data without personal information but that included all the iatrogenic deaths reported (and obviously the medicines involved) and none missed out or deleted."

On 18 June 2021, the Ministry extended the timeline to respond to your request under section 15A of the Act until 20 August 2021 due to the need for further collation, research and consultation.

Please find attached the information requested. The data for deaths in 2019 is an excerpt from a report to the Medicines Adverse Reactions Committee and some information has been withheld under section 9(2)(a) of the Act to protect the privacy of natural persons. The data for deaths in 2020 has specifically prepared by the New Zealand Centre for Adverse Reactions Monitoring (CARM) at the University of Otago to respond to your request. CARM undertakes pharmacovigilance in New Zealand under contract to the Ministry. The report is released to you in full.

Accompanying the information for 2020 is a statement from the Director of the New Zealand Pharmacovigilance Centre at CARM that outlines important caveats that must be considered when interpreting the data. Similar caveats should be applied to the information provided for 2019. It is also important to note that while anyone – doctors, nurses, pharmacists, pharmaceutical companies, government agencies or a member of the public – can report an adverse reaction to CARM, reporting is voluntary. There is more information about adverse reaction reporting at: https://nzphyc.otago.ac.nz/reporting/

I also noted in your original request an interest in CARM reports related to Sudden Infant Death Syndrome (SUDI). SUDI cases are often investigated by coroners as sudden or unexplained deaths and many coronial findings are published on the New Zealand Legal Information Institute website at: <u>www.nzlii.org/nz/cases/NZCorC/</u> (search on SUDI or "cot death"). The Chief Coroner has also issued a *Recommendations Recap* that specifically examines SUDI deaths at: <u>www.coronialservices.justice.govt.nz/assets/Documents/Publications/issue-14-recommendationsrecap2.pdf</u> I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: <u>www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</u>.

Yours sincerely

Chris James Group Manager Medsafe



CAVEAT DOCUMENT

Accompanying statement to data released from the

NEW ZEALAND CENTRE FOR ADVERSE REACTIONS MONITORING

The Centre for Adverse Reactions Monitoring (CARM) has only limited details about each suspected adverse reaction contained in its Database. It is important that the limitations and qualifications which apply to the information and its use are understood.

The data made available represent the collection of spontaneous reports in the CARM database associated with therapeutic products/vaccines granted regulatory approval for use in New Zealand.

Reports have been submitted to the Centre since April 1965 and in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. This level of reporting is due to CARM encouraging reporters to report events they suspect may be associated with a pharmaceutical product/vaccine irrespective of whether or not they believe it was the cause. CARM accepts all reports and proof of causality is not required when submitting a report to CARM. Coincidental events that may be unrelated to pharmaceutical product/vaccine exposure may be reported. This is particularly possible when the product has widespread use, or is used in targeted strategies such as vaccination campaigns.

In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event in the Database. Reports vary in quality, completeness and detail and may include detail that is incorrect. Consequently, a report in the CARM database of an event does not confirm that the pharmaceutical product/vaccine caused the event.

The volume of reports for a particular product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time and from product to product. It is generally accepted internationally that systems such as CARM are subject to underreporting which may result in scant reports for events perceived by the reporter to be minor or well recognised, whilst more serious or unexpected events are possibly more likely to be reported, even if they are coincidental. Moreover, no information is provided on the number of patients exposed to the product.

The data contained in these tables are further subject to ongoing internal quality controls, review and updating and therefore may be subject to change, particularly if follow-up information is received.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. Any use of this information must take into account at least the above. Although this information is now released, it is strongly recommended that prior to any use of such information, CARM is contacted for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

- (i) of the source of the information
- (ii) that the information is not homogenous at least with respect to origin or likelihood that the pharmaceutical product/vaccine caused the adverse reaction,
- (iii) that the information does not represent the opinion of the NZPhvC or CARM.

Director New Zealand Pharmacovigilance



Fatal Cases reported to CARM from 01January to 31 December 2020

This listing covers the cases reported in 2020 which resulted in a fatal outcome regardless of causality. There were 107 reports, identifying 129 suspect medicines. An * (asterisk) beside the medicine name indicates a suspect medicine. Some cases involved more than one suspect medicine.

Report No	Date	Gender	Age	Me	edicines/Vaccine	Reactions
135633	JAN2020	Female	42	* *	AMPHOTERICIN, LIPOSOMAL GABAPENTIN METHADONE PIPERACILLIN/TAZOBACTAM MULTIVITAMINS	HYPERKALAEMIA CARDIAC ARREST
135703	JAN2020	Female	53	*	INFLIXIMAB	RENAL FAILURE ACUTE
135764	JAN2020	Male	82	*	ELTROMBOPAG FELODIPINE CANDESARTAN METFORMIN CITALOPRAM	MYOCARDIAL INFARCTION THROMBOCYTOSIS ARM PAIN CHEST PAIN
135869	JAN2020	Male	55	*	CLOZAPINE	MYOCARDIAL ISCHAEMIA
135870	JAN2020	Male	29	*	CLOZAPINE DIAZEPAM OMEPRAZOLE MYLANTA	SUICIDE
135871	JAN2020	Male	50	*	CLOZAPINE MORPHINE SULPHATE PREDNISONE	PNEUMONIA CHRONIC OBSTRUCT AIRWAYS DISEASE
135872	JAN2020	Male	84	\bigcirc	CLOZAPINE	PNEUMONIA
135873	JAN2020	Male	68	*	CLOZAPINE LEVODOPA/CARBIDOPA (100/25) CODEINE FLUDROCORTISONE LORAZEPAM	PARKINSONISM ASPIRATION PNEUMONITIS
135874	JAN2020	Female	68		CLOZAPINE MIDAZOLAM ACETYLSALICYLIC ACID MADOPAR ROPINIROLE	ARRHYTHMIA PARKINSONISM DEMENTIA TRANSIENT ISCHAEMIC ATTACK SYNCOPE
135875	JAN2020	Male	81	*	CLOZAPINE	DEMENTIA
135876	JAN2020	Female	67	*	CLOZAPINE	MYOCARDIAL ISCHAEMIA CORONARY ARTERY DISORDER
135877	JAN2020	Male	58	*	CLOZAPINE	Parkinsonism Myocardial Infarction Pneumonia
135878	JAN2020	Female	68	*	OCTREOTIDE LAR	COLLAPSE CIRCULATORY HEART DISORDER



Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
135879	JAN2020	Male	61	* VIEKIRA PAK-RBV SALBUTAMOL	CHOLELITHIASIS DYSPNOEA FATIGUE MYOCARDIAL ISCHAEMIA CORONARY ARTERY DISORDER
135906	JAN2020	Male	43	* CLOZAPINE	CARDIAC ARREST
135907	JAN2020	Male	77	* CLOZAPINE LORATADINE TERAZOSIN LAXSOL	APPENDICITIS ASPIRATION
135908	JAN2020	Male	54	* CLOZAPINE	MEGACOLON ACQUIRED STROKE
135909	JAN2020	Male	38	* CLOZAPINE	SUDDEN DEATH
135910	JAN2020	Male	40	* CLOZAPINE LEVOMEPROMAZINE DIAZEPAM HYOSCINE TOPICAL VALPROATE SODIUM	ASPIRATION PNEUMONITIS BOWEL MOTILITY DISORDER
135911	JAN2020	Male	66	* CLOZAPINE	PNEUMONIA
135912	JAN2020	Female	64	* CLOZAPINE	MELANOMA MALIGNANT
135913	JAN2020	Male	56	CLOZAPINE DIAZEPAM LORAZEPAM PAROXETINE PROPRANOLOL	CONSTIPATION RECTAL ULCER INTESTINAL PERFORATION PERITONITIS
135914	JAN2020	Male	48	* CLOZAPINE	INTENTIONAL OVERDOSE
135915	JAN2020	Male	67	* CLOZAPINE	ASPIRATION INTESTINAL OBSTRUCTION RESPIRATORY ARREST RENAL FAILURE AGGRAVATED
135916	JAN2020	Female	64	* CLOZAPINE	HYPERTENSION HEART DISORDER LIVER FATTY HEPATIC CIRRHOSIS
135917	JAN2020	Male	58	* CLOZAPINE	CARDIAC ARREST
135918	JAN2020	Female	75	* CLOZAPINE	CARDIAC FAILURE DIABETES MELLITUS
135982	FEB2020	Male	43	* CLOZAPINE	MEGACOLON ACQUIRED SEPSIS SECONDARY COLITIS



Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
136017	FEB2020	Female	91	* RIVAROXABAN ACE INHIBITOR (NOS) THYROXINE PARACETAMOL UNCLASSIFIED AGENT	CEREBRAL HAEMORRHAGE THROMBOSIS CEREBRAL
136027	FEB2020	Female	64	* ATEZOLIZUMAB	LYMPHANGITIS PULMONARY INFILTRATION
136028	FEB2020	Male	29	* ATEZOLIZUMAB * COBIMETINIB	FEVER FATIGUE PROGRESSION OF DISEASE
136172	FEB2020	Male	50	* PEMBROLIZUMAB	PROGRESSION OF DISEASE
136174	FEB2020	Male	67	* VALSARTAN/SACUBITRIL	SUDDEN DEATH
136250	MAR2020	Female	83	* FLUCLOXACILLIN RIVAROXABAN BETAMETHASONE PARACETAMOL METOPROLOL	HEPATITIS CHOLESTATIC
136300	MAR2020	Male	63	* DAUNORUBICIN * ANTHRACYCLINE NOS * DAUNORUBICIN	CARDIOMYOPATHY
136332	MAR2020	Female	35	LAMOTRIGINE LEVETIRACETAM	CONVULSIONS THERAPEUTIC RESPONSE DECREASED
136365	MAR2020	Female	69	* POMALIDOMIDE	PROGRESSION OF DISEASE
136416	MAR2020	Female	54	 * MIDAZOLAM * MORPHINE SULPHATE * MORPHINE SULPHATE DEXAMETHASONE 	RESPIRATORY DEPRESSION CARDIAC ARREST AGITATION
136512	MAR2020	Female	67	* INFLUENZA - QUADRIVALENT	CHRONIC OBSTRUCT AIRWAYS DISEASE
136520	MAR2020	Female	53	* PALIPERIDONE	SUICIDE
136521	APR2020	Male	67	* INFLUENZA - QUADRIVALENT ATORVASTATIN BENDROFLUAZIDE FELODIPINE ACETYLSALICYLIC ACID	SUDDEN DEATH
136522	APR2020	Female	71	* INFLUENZA - QUADRIVALENT ATENOLOL ENALAPRIL FRUSEMIDE	SUDDEN DEATH
136687	MAY2020	Female	80	* AMOXICILLIN	DRESS SYNDROME NEPHRITIS INTERSTITIAL



Report No	Date	Gender	Age	Mec	licines/Vaccine	Reactions
136929	MAY2020	Female	70		CHLORAMPHENICOL PREDNISONE	ANAEMIA APLASTIC
137053	MAY2020	Male	71	[LENALIDOMIDE DEXAMETHASONE CYCLOPHOSPHAMIDE	PROGRESSION OF DISEASE
137118	MAY2020	Female	54	* 1	FRASTUZUMAB	PROGRESSION OF DISEASE
137180	JUN2020	Male	69	* (PEMBROLIZUMAB CARBOPLATIN GEMCITABINE	PROGRESSION OF DISEASE MEDICINE INEFFECTIVE
137186	JUN2020	Female	79	* 4	ALIROCUMAB	ABDOMINAL PAIN ANOREXIA BLOATING MELAENA
137280	JUN2020	Male	58		CETUXIMAB ANTINEOPLASTIC AGENT(S) NOS	INTESTINAL PERFORATION
137377	JUN2020	Female	55	* (CLOZAPINE	PNEUMONIA
137378	JUN2020	Male	55	* (CLOZAPINE	SUDDEN DEATH DRUG TOXICITY
137379	JUN2020	Male	55	* (CLOZAPINE	MYOCARDIAL INFARCTION
137380	JUN2020	Female	79	* (CLOZAPINE	ARRHYTHMIA
137381	JUN2020	Male	49	F II <i>F</i>	CLOZAPINE PANTOPRAZOLE MIPRAMINE AMISULPRIDE SALBUTAMOL	THROMBOSIS CORONARY
137382	JUN2020	Male	47	* (CLOZAPINE	THROMBOSIS CORONARY
137383	JUN2020	Male	17	N	CLOZAPINE METFORMIN AXSOL ARIPIPRAZOLE	SUDDEN DEATH
137384	JUN2020	Male	59	* (QUETIAPINE	SUICIDE BLOOD DISORDER
137385	JUN2020	Male	43	N E F	CLOZAPINE METFORMIN BENZTROPINE MESYLATE PROPRANOLOL RISPERIDONE	SUDDEN DEATH
137416	JUN2020	Female	73	F	HUMAN SERUM ALBUMIN PARACETAMOL ACETYLSALICYLIC ACID	CHILLS



Report No	Date	Gender	Age	Medicines/Vaccine	Reactions				
137420	JUN2020	Male	20	* VELIPARIB TEMOZOLOMIDE	PROGRESSION OF DISEASE				
137451	JUN2020	Male	78	* CLOZAPINE MIDODRINE ACETYLSALICYLIC ACID DOCUSATE + SENNOSIDES FLUDROCORTISONE	ASPIRATION PNEUMONITIS PNEUMONIA				
137452	JUN2020	Male	61	* CLOZAPINE	MYOCARDIAL INFARCTION RESPIRATORY DISORDER				
137453	JUN2020	Male	76	* CLOZAPINE LEVOMEPROMAZINE	STROKE DEMENTIA				
137454	JUN2020	Male	54	* CLOZAPINE MOCLOBEMIDE ATORVASTATIN METFORMIN CHOLECALCIFEROL	CARCINOMA				
137455	JUN2020	Male	78	* CLOZAPINE	PNEUMONIA				
137486	JUN2020	Female	70	* PEMBROLIZUMAB	PROGRESSION OF DISEASE				
137487	JUN2020	Male	78	* LENALIDOMIDE	PROGRESSION OF DISEASE				
137495	JUN2020	Male		COBIMETINIB VEMURAFENIB	PROGRESSION OF DISEASE				
137514	JUL2020	Male	4m	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10	SUDDEN DEATH				
137578	JUL2020	Female	78	* M&P VITAL ALL-IN-ONE	FEELING UNWELL SUDDEN DEATH				
137603	JUL2020	Male	79	* HEPARIN-LMW - ENOXAPAR	IN HAEMORRHAGE RETROPERITONEAL				
137611	JUL2020	Male	85	* INFLUENZA - QUADRIVALEN	IT UNCONSCIOUSNESS FIXED PUPILS				
137623	JUL2020	Male		* COBIMETINIB * VEMURAFENIB	CONVULSIONS DYSPHAGIA				
137668	JUL2020	Male	45	* VENLAFAXINE BISOPROLOL	THERAPEUTIC RESPONSE DECREASED				
137732	JUL2020	Female	85	* RIVAROXABAN	HAEMORRHAGE INTRACRANIAL FALL FRACTURE				
137735	JUL2020	Male	76	* DABIGATRAN * IDARUCIZUMAB	INTESTINAL NECROSIS				



Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
137738	JUL2020	Female	58	 * IMMUNOGLOBULIN NORMAL MORPHINE SULPHATE * PLATELETS LAXSOL FAMOTIDINE 	HYPOTENSION BACK PAIN VOMITING RECTAL BLEEDING INFUSION REACTION
137761	JUL2020	Female	22	* LAMOTRIGINE	SUDDEN DEATH
137860	AUG2020	Male	45	* Olanzapine * Morphine Sulphate Methamphetamine	QT PROLONGED FIBRILLATION VENTRICULAR CARDIAC ARREST MULTIPLE ORGAN FAILURE CONVULSIONS
137875	AUG2020	Female	62	* CODEINE	RESPIRATORY ARREST CARDIAC ARREST INTENTIONAL OVERDOSE
137879	AUG2020	Male	69	* LEVODOPA/CARBIDOPA (NOS) LORAZEPAM QUETIAPINE GABAPENTIN DOMPERIDONE	ASPIRATION PNEUMONITIS RIGORS MEDICATION ERROR NEUTROPENIA HYPERKALAEMIA
137885	AUG2020	Male	63	* PEMBROLIZUMAB	PNEUMONIA
137890	AUG2020	Male	6w	* ROTA VIRUS VACCINE * DTaP-Hexa PNEUMOCOCCAL VACC - 10 CHOLECALCIFEROL FERROUS SULPHATE	SUDDEN DEATH
137895	AUG2020	Female	71	* OESTRIOL	UTERINE CARCINOMA
137934	AUG2020	Female	74	* DABIGATRAN	PULMONARY HAEMORRHAGE
138095	AUG2020	Female	74	* ALECTINIB DABIGATRAN FELODIPINE CHOLECALCIFEROL SALBUTAMOL	MYALGIA PNEUMONITIS PROGRESSION OF DISEASE
138123	AUG2020	Male	71	* INTRAGAM P DOXYCYCLINE VALACICLOVIR METOPROLOL TIOTROPIUM /OLODATEROL	CONGESTIVE HEART FAILURE HYPOXIA HYPOTENSION RENAL IMPAIRMENT HYPERKALAEMIA
138219	SEP2020	Male	6m	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10	SUDDEN INFANT DEATH SYNDROME
138323	SEP2020	Male	62	* PEMBROLIZUMAB PEMETREXED CARBOPLATIN	RASH RHINITIS LACRIMATION INCREASED PROGRESSION OF DISEASE



Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
138444	SEP2020	Female	64	* RITUXIMAB * BENDAMUSTINE FLUDARABINE MITOXANTRONE	LEUKOENCEPHALOPATHY PROGRESSION OF DISEASE IMMUNE (IRIS) SYNDROME PNEUMONIA RESPIRATORY ARREST
138645	OCT2020	Male	19	* LAMOTRIGINE TOPIRAMATE MIDAZOLAM	SUDDEN DEATH
138728	OCT2020	Male	81	* ADALIMUMAB	CARCINOMA COLON METASTASES NOS
138733	OCT2020	Male		* CHLORPROMAZINE * PARALDEHYDE	NEOPLASM MALIGNANT
138843	NOV2020	Male	73	* CLOZAPINE	PNEUMONIA NEOPLASM MALIGNANT PROGRESSION OF DISEASE
138844	NOV2020	Male	70	* CLOZAPINE OLANZAPINE	PNEUMONIA ATRIAL FIBRILLATION TACHYCARDIA VENTRICULAR CARDIAC ARREST
138845	NOV2020	Male	67	* CLOZAPINE * OMEPRAZOLE NICOTINE BUDESONIDE/EFORMOTER AMISULPRIDE	PNEUMONIA SEPSIS BRONCHIECTASIS 20L
138846	NOV2020	Female	73	* CLOZAPINE APOMORPHINE LEVODOPA AMANTADINE MIRTAZAPINE	PARKINSONISM
138847	NOV2020	Male	64	* CLOZAPINE ATENOLOL FRUSEMIDE LAXSOL OMEPRAZOLE	SUDDEN DEATH
138848	NOV2020	Male	67	* CLOZAPINE BENZTROPINE MESYLATE ATORVASTATIN	SUDDEN DEATH MYOCARDIAL INFARCTION
138849	NOV2020	Male	91	* CLOZAPINE ALENDRONATE + CHOLECA DONEPEZIL ESCITALOPRAM FLUDROCORTISONE	ASPIRATION PNEUMONITIS ALCIFEROL CONFUSION SOMNOLENCE FALL
138850	NOV2020	Male	52	* CLOZAPINE	METASTASES NOS NEOPLASM MALIGNANT NEUTROPHILIA LEUKOCYTOSIS



	Date	Gender	Age	Medicines/Vaccine	Reactions
138851	NOV2020	Male	72	* CLOZAPINE	DEMENTIA HEAD INJURY
138852	NOV2020	Female	72	* CLOZAPINE DONEPEZIL DOCUSATE + SENNOSIDES LORAZEPAM VENLAFAXINE	DEMENTIA
138952	NOV2020	Female	67	* PEMBROLIZUMAB	CONVULSIONS AGGRAVATED
139041	NOV2020	Female	80	* CLOZAPINE ESCITALOPRAM OMEPRAZOLE FLUTICASONE/SALMETEROL DORZOLAMIDE/TIMOLOL	PNEUMONIA
139042	NOV2020	Male	71	* ATEZOLIZUMAB * BEVACIZUMAB	PROGRESSION OF DISEASE
139195	DEC2020	Female		* TRASTUZUMAB	PROGRESSION OF DISEASE
				FFICI	
EAS	DUN	DER		officit	

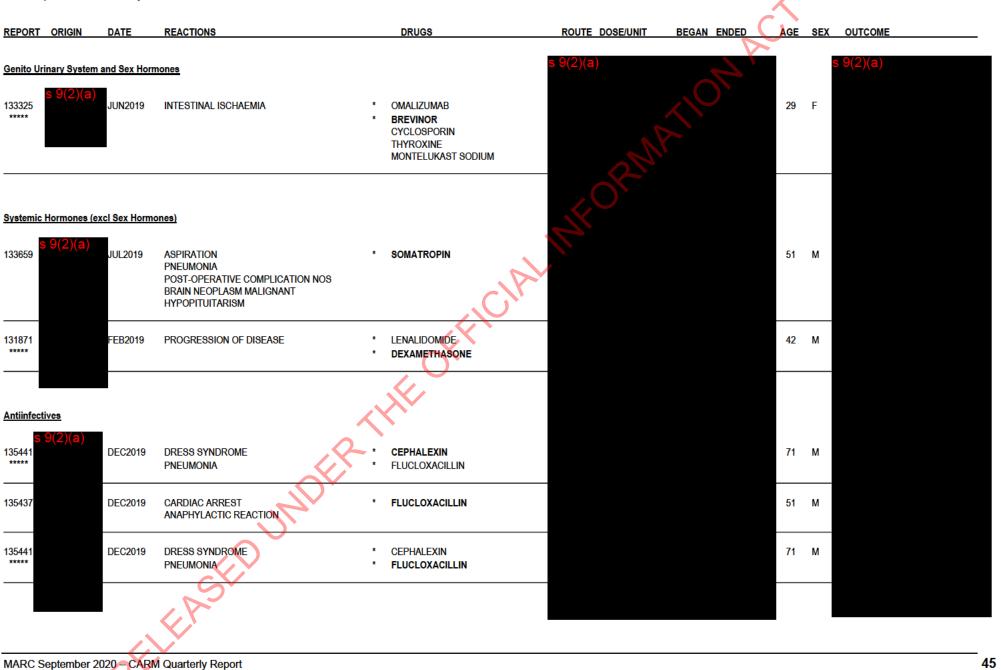
Reports are grouped according to the ATC classification of the suspect agent(s). Cases where there is more than one suspect agent are listed once in each relevant ATC classification and those cases appearing in more than one ATC classification are identified with ***** below the Report Number. This listing covers the 121 reports, identifying 146 suspect medicines, which resulted in a fatal outcome regardless of causality.

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	OUTCOME
imentary 2615 ****	2 s 9(2)(a)	APR2019	SUDDEN DEATH	 TRAMADOL LITHIUM CARBONATE METFORMIN ALCOHOL (ETHYL) GARCINIA 	s 9(2)(a)		47	М	s 9(2)(a)
ood and	l Blood formi	ng organs			AFC -				
31737 <mark>S</mark>	9(2)(a)	FEB2019	PNEUMONIA CARDIAC FAILURE	* APIXABAN	~		81	F	
31869		FEB2019	GI HAEMORRHAGE	* DABIGATRAN * WARFARIN			93	М	
32037		MAR2019	HAEMORRHAGE INTRACRANIAL	* DABIGATRAN			78	М	
33015		MAY2019	HAEMORRHAGE NOS	ABIGATRAN ATORVASTATIN FRUSEMIDE METOPROLOL CILAZAPRIL			79	F	
33051		MAY2019	CEREBRAL HAEMORRHAGE DEATH	* DABIGATRAN			70	F	
33201		MAY2019	HAEMORRHAGE INTRACRANIAL MEDICATION ERROR	* HEPARIN - UNFRACTIONATED			77	М	
			M Quarterly Report						

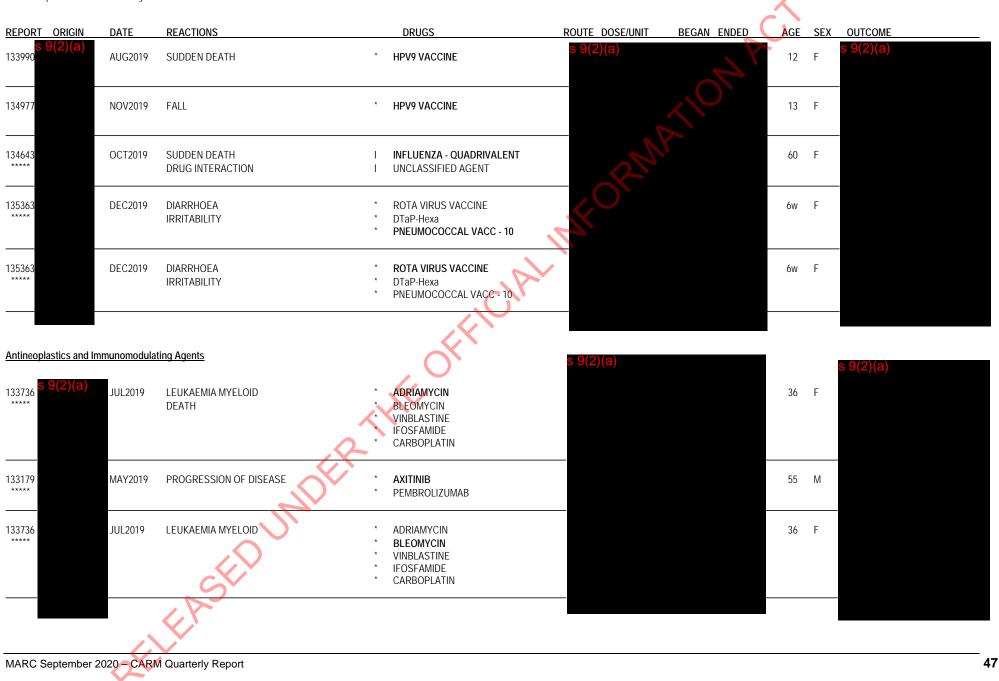
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ORT ORIGIN	DATE	REACTIONS	DRUGS		BEGAN ENDED	AGE	SEX	OUTCOME
1	SEP2019	HAEMORRHAGE NOS PROCEDURE ERROR	* HEPARIN - UNFRACTIONATED * PROTAMINE	s 9(2)(a)		78	F	s 9(2)(a)
n	MAY2019	HAEMORRHAGE INTRACRANIAL	* ILOPROST TROMETAMOL ACETYLSALICYLIC ACID TICAGRELOR			72	м	
2	NOV2019	STOMATITIS ORAL PAIN	* ILOPROST TROMETAMOL	R.M.		64	F	
8	MAY2019	HAEMORRHAGE STROKE	* RIVAROXABAN	, AF		70	F	
;9 *	FEB2019	GI HAEMORRHAGE	* DABIGATRAN * WARFARIN			93	М	
2	MAY2019	HAEMORRHAGE INTRACRANIAL INR INCREASED	* WARFARIN			70	F	
7	SEP2019	HAEMORRHAGE INTRAABDOMINAL CEREBRAL HAEMORRHAGE THROMBOSIS CEREBRAL OVARIAN CYST	* PROTHROMBINEX-VF WARFARIN VITAMIN K ANALOGUE			40	F	
ovascular		R						
60	JUL2019	INFECTION VIRAL MYOCARDIAL INFARCTION PAIN ANXIETY	* VALSARTAN/SACUBITRIL MORPHINE SULPHATE TICAGRELOR ACETYLSALICYLIC ACID BISOPROLOL			70	М	



Annual Rep	oort Fatal Cas	es January to	December 2019					<	09	52
EPORT	ORIGIN	DATE	REACTIONS		DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE		OUTCOME
34055		AUG2019	PNEUMONITIS DEATH	*	Nitrofurantoin Gabapentin P-Amino-Hippurate Baclofen	s 9(2)(a)		66	М	s 9(2)(a)
31702		FEB2019	HYPERKALAEMIA	*	AMPHOTERICIN, LIPOSOMAL PROPOFOL VANCOMYCIN CIPROFLOXACIN VECURONIUM	RIN		22	Μ	
34756		OCT2019	SEPSIS SECONDARY CHOLANGITIS RENAL IMPAIRMENT ACIDOSIS METABOLIC SHOCK CIRCULATORY	*	GLECAPREVIR+PIBRENTASVIR SOFOSBUVIR+LEDIPASVIR RIBAVIRIN	MF		68	М	
35286		NOV2019	SUICIDE NUMBNESS LOCALISED GAIT ABNORMAL INFECTION VIRAL	*	GLECAPREVIR+PIBRENTASVIR			44	м	
31974		MAR2019	RESPIRATORY DISORDER PNEUMONIA VIRAL RESPIRATORY INSUFFICIENCY WEIGHT DECREASE	•	VIEKIRA PAK DIAZEPAM CITALOPRAM METHADONE			59	F	
34138		AUG2019	RASH NAUSEA DIZZINESS PRURITUS	*	Immunoglobulin Normal Gabapentin Felodipine Citalopram Insulin			43	Μ	
35363 *****		DEC2019	DIARRHOEA IRRITABILITY	* * *	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 10			6w	F	
33945		AUG2019	CEREBRAL HAEMORRHAGE	•	HPV9 VACCINE			13	F	



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Annual Report Fatal Ca							~		
REPORT ORIGIN	DATE	REACTIONS		DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	
133695 S 9(2)(a)	JUL2019	NEOPLASM MALIGNANT	*	BORTEZOMIB CYCLOPHOSPHAMIDE	s 9(2)(a)		89	F	s 9(2)(a)
132015	MAR2019	HEADACHE VISION BLURRED CARDIAC FAILURE LEFT	*	CAPECITABINE	~		56	Μ	
133736 *****	JUL2019	LEUKAEMIA MYELOID DEATH	* * * *	Adriamycin Bleomycin Vinblastine Ifosfamide Carboplatin	JF PPM		36	F	
131442	JAN2019	PROGRESSION OF DISEASE	*	CARFILZOMIB CYCLOPHOSPHAMIDE DEXAMETHASONE			73	М	
135291	NOV2019	EMBOLISM PULMONARY	*	СЕТИХІМАВ			56	F	
133695 *****	JUL2019	NEOPLASM MALIGNANT	*	BORTEZOMIB CYCLOPHOSPHAMIDE			89	F	
134057	AUG2019	RESPIRATORY DISTRESS SYNDROME	*	CYTOSINE ARABINOSIDE			43	F	
134088	AUG2019	DIARRHOEA RENAL FAILURE ACUTE	*	Erlotinib Candesartan Frusemide			79	F	
134067	AUG2019	DEHYDRATION NAUSEA VOMITING CARDIAC ARREST	*	FLUOROURACIL			47	Μ	
		EAST							
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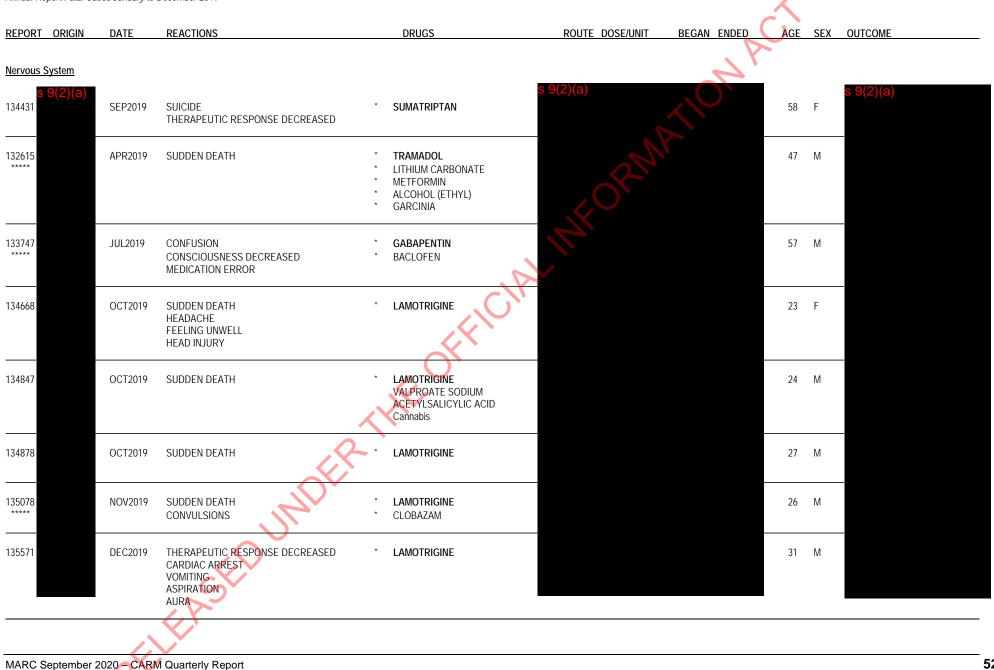
EPORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT BEGAN ENDED	AGE SEX	OUTCOME
<mark>s 9(2)(a)</mark> *****	JUL2019	LEUKAEMIA MYELOID	 * ADRIAMYCIN * BLEOMYCIN * VINBLASTINE * IFOSFAMIDE * CARBOPLATIN 	s 9(2)(a)	36 F	s 9(2)(a)
4082	AUG2019	INFECTION PNEUMONITIS RESPIRATORY FAILURE	* NINTEDANIB OMEPRAZOLE DABIGATRAN AZITHROMYCIN SOTALOL	CRMA.	67 F	
1436	JAN2019	PNEUMONITIS	* PEMBROLIZUMAB		60 M	
2549	APR2019	DEMYELINATION PROGRESSION OF DISEASE	* PEMBROLIZUMAB		63 M	
2550	APR2019	PROGRESSION OF DISEASE APLASIA, PURE RED CELL THROMBOCYTOPENIA HEPATIC ENZYMES INCREASED	* PEMBROLIZUMAB DEXAMETHASONE		85 M	
3179	MAY2019	PROGRESSION OF DISEASE	* AXITINIB * PEMBROLIZUMAB		55 M	
5292	NOV2019	PROGRESSION OF DISEASE	* PEMBROLIZUMAB ANTINEOPLASTIC AGENT(S) NOS		59 F	
3755	JUL2019	PULMONARY FIBROSIS INTERSTITIAL LUNG DISEASE	* RITUXIMAB		69 M	
2402	APR2019	MEDICINE INEFFECTIVE	* VENETOCLAX VALACICLOVIR COTRIMOXAZOLE - BACTRIM GROUP TRANEXAMIC ACID		62 M	

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PORT ORIGIN	DATE	December 2019 REACTIONS		DRUGS	Route Dose/Unit	BEGAN ENDED	AGE	SEX	OUTCOME
₅₈₈ <mark>s 9(2)(a</mark>	JUL2019	T-CELL LYMPHOMA HISTIOCYTOSIS HAEMATOPHAGIC (HLH)	*	VENETOCLAX MULTIVITAMINS	s 9(2)(a)	DEGAN ENDED		M	5 9(2)(a)
736	JUL2019	LEUKAEMIA MYELOID	* * * *	ADRIAMYCIN BLEOMYCIN VINBLASTINE IFOSFAMIDE CARBOPLATIN	N		36	F	
016	AUG2019	NEOPLASM MALIGNANT	*	ADALIMUMAB	.cor		56	М	
5472	DEC2019	STROKE PACKAGING CHANGE	*	ADALIMUMAB ISONIAZID PYRIDOXINE METFORMIN CILAZAPRIL			72	М	
532	JUN2019	THROMBOSIS VENOUS DEEP FRACTURE PNEUMONIA RESPIRATORY FAILURE RENAL FAILURE CHRONIC	*	INFLIXIMAB CILAZAPRIL TAMOXIFEN MESALAZINE AZATHIOPRINE			74	F	
058	AUG2019	PANCYTOPENIA MULTIPLE ORGAN FAILURE MACROPHAGE ACTIVATION SYNDROME		LEFLUNOMIDE			59	F	
871	FEB2019	PROGRESSION OF DISEASE	*	LENALIDOMIDE DEXAMETHASONE			42	М	
979	MAR2019	CARCINOMA SQUAMOUS	*	LENALIDOMIDE			76	Μ	
2941	MAY2019	MEDICINE INEFFECTIVE PROGRESSION OF DISEASE	*	LENALIDOMIDE			66	F	

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nnual Report Fatal C	ases January to	December 2019					5	09	
EPORT ORIGIN	DATE	REACTIONS		DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	OUTCOME
2942	MAY2019	PROGRESSION OF DISEASE	*	LENALIDOMIDE	s 9(2)(a)		80	Μ	s 9(2)(a)
31621	JAN2019	PROGRESSION OF DISEASE	*	POMALIDOMIDE	6		72	F	
31872	FEB2019	MYELOMATOSIS MULTIPLE	*	POMALIDOMIDE	201		77	Μ	
31873	FEB2019	PROGRESSION OF DISEASE	*	POMALIDOMIDE DEXAMETHASONE			80	F	
33887	- JUL2019	PROGRESSION OF DISEASE	*	POMALIDOMIDE			82	Μ	
34133	AUG2019	PROGRESSION OF DISEASE	*	POMALIDOMIDE			72	F	
lusculoskeletal 33270	JUN2019	GASTRIC ULCER PERFORATED		DICLOFENAC			62	М	
55270	50112017	RENAL FAILURE ACUTE PERITONITIS MULTIPLE ORGAN FAILURE	*	DICLOFENAC			02		
33747	JUL2019	CONFUSION CONSCIOUSNESS DECREASED MEDICATION ERROR	*	GABAPENTIN BACLOFEN			57	Μ	
32344	MAR2019	MEDICATION ERROR DYSPHAGIA	*	BOTULINUM TOXIN FELODIPINE GABAPENTIN BACLOFEN THYROXINE			63	F	



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₆₂₁ s 9(2				ROUTE DOSE/UNIT	BEGAN ENDED AGE	SEX OUTCOME
***	DEC2019	THROMBOCYTOPENIA NEUTROPENIA SUBDURAL HAEMATOMA	 VALPROATE SODIUM LEVETIRACETAM OMEPRAZOLE 	s 9(2)(a)	58	s 9(2)(a) M
621	DEC2019	THROMBOCYTOPENIA NEUTROPENIA SUBDURAL HAEMATOMA	* VALPROATE SODIUM * LEVETIRACETAM OMEPRAZOLE	NP	58	М
2417	APR2019	PROGRESSION OF DISEASE PNEUMONIA INFECTION VIRAL	* ROTIGOTINE LEVODOPA	KOPN	80	F
3382	JUN2019	CARDIOMYOPATHY CARDIAC ARREST	* Clozapine * Amisulpride		44	F
5078 ****	NOV2019	SUDDEN DEATH CONVULSIONS	* LAMOTRIGINE * CLOBAZAM		26	Μ
31769	FEB2019	PNEUMONIA	* CLOZAPINE		69	М
1770	FEB2019	PNEUMONIA	· CLOZAPINE		75	М
1771	FEB2019	PNEUMOTHORAX LOWER RESP TRACT INFECTION MEGACOLON ACQUIRED ATRIAL FIBRILLATION MEDICATION ERROR	* CLOZAPINE DILTIAZEM LAXSOL OMEPRAZOLE CLONAZEPAM		64	Μ
31772	FEB2019	PARKINSONISM	* CLOZAPINE		69	F

RT ORIGIN 5 S 9(2)(a)	DATE FEB2019	REACTIONS NEUTROPHILIA LEUKOCYTOSIS RENAL FAILURE ACUTE URINARY TRACT INFECTION	*	DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	GE	SEX	
s 9(2)(a)		NEUTROPHILIA LEUKOCYTOSIS RENAL FAILURE ACUTE	*					JLA	OUTCOME
		URINARY INCONTINENCE		CLOZAPINE	s 9(2)(a)	X101X		Μ	s 9(2)(a)
	FEB2019	DIABETES INSIPIDUS NEPHROGENIC RENAL FAILURE ACUTE NEUTROPHILIA LEUKOCYTOSIS PNEUMONIA		CLOZAPINE LITHIUM CARBONATE	ORM		82	Μ	
7	FEB2019	ARRHYTHMIA VENTRICULAR	*	CLOZAPINE	N		77	F	
3	FEB2019	BRAIN METASTASES	*	CLOZAPINE			55	F	
)	FEB2019	NEOPLASM MALIGNANT BRAIN METASTASES	*	CLOZAPINE			57	F	
)	FEB2019	ASPIRATION PNEUMONITIS	*	CLOZAPINE			79	М	
	FEB2019	ASPIRATION PNEUMONITIS GI HAEMORRHAGE NEUTROPHILIA		CLOZAPINE			73	М	
2	FEB2019	THROMBOEMBOLISM MYOCARDIAL ISCHAEMIA DEMENTIA BIPOLAR AFFECTIVE DISORDER FRACTURE	*	CLOZAPINE			95	F	
3	FEB2019 C	INTESTINAL OBSTRUCTION SEPTICAEMIA URINARY TRACT INFECTION RENAL FAILURE CHRONIC CHRONIC OBSTRUCT AIRWAYS DISEASE		CLOZAPINE OLANZAPINE CIPROFLOXACIN METRONIDAZOLE			76	F	

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PORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	OUTCOME
<mark>s 9(2)(a)</mark>	FEB2019	PNEUMONIA PULMONARY CARCINOMA	CLOZAPINE	s 9(2)(a)	2 A	72	F	9(2)(a)
795	FEB2019	OSTEOMYELITIS SEPSIS PERIPHERAL ISCHAEMIA	CLOZAPINE MORPHINE SULPHATE LORAZEPAM VENLAFAXINE MIRTAZAPINE	and and a second		65	Μ	
796	FEB2019	PULMONARY CARCINOMA METASTASES NOS CHRONIC OBSTRUCT AIRWAYS DISEASE	CLOZAPINE	140K		60	Μ	
797	FEB2019	CARDIAC ARREST	CLOZAPINE VALPROATE SODIUM FLUDROCORTISONE LAXSOL FRUSEMIDE			73	Μ	
798	FEB2019	INTESTINAL OBSTRUCTION	CLOZAPINE LAXSOL FRUSEMIDE PANTOPRAZOLE BUMETANIDE			73	F	
799	FEB2019	PULMONARY CARCINOMA BONE METASTASES PLEURAL EFFUSION MELANOMA MALIGNANT LYMPHANGITIS	CLOZAPINE PREDNISONE AMOXICILLIN/CLAVULANIC ACID ZOPICLONE MORPHINE SULPHATE			67	Μ	
1800	FEB2019	DEMENTIA VOMITING SYNCOPE CONFUSION AGGRAVATED	^T CLOZAPINE LAXSOL OMEPRAZOLE MIDAZOLAM MORPHINE SULPHATE			59	F	

PORT	ORIGIN	DATE	REACTIONS		DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	OUTCOME
33097	s 9(2)(a)	MAY2019	METASTASES NOS LEUKOCYTOSIS NEUTROPENIA NEUTROPHILIA CONSTIPATION	*	CLOZAPINE AMISULPRIDE PAROXETINE MOLAXOLE OMEPRAZOLE	s 9(2)(a) ∡	KION A	57	Μ	s 9(2)(a)
3382		JUN2019	CARDIOMYOPATHY CARDIAC ARREST	*	CLOZAPINE AMISULPRIDE	NR	~	44	F	
33383		JUN2019	LEUKOCYTOSIS NEUTROPHILIA	*	CLOZAPINE	KOK.		64	Μ	
33888		JUL2019	NEOPLASM MALIGNANT	*	CLOZAPINE	N.		64	F	
33889		JUL2019	ASPIRATION PNEUMONITIS PSYCHOSIS AGGRAVATED	*	CLOZAPINE LAMOTRIGINE THYROXINE CHOLECALCIFEROL LAXSOL			84	F	
3890		JUL2019	ASPIRATION PNEUMONITIS	*	CLOZAPINE THYROXINE LAXSOL			93	F	
3891		JUL2019	CARDIOVASCULAR DISORDERS GASTRO-INTESTINAL DISORDER NOS CHRONIC OBSTRUCT AIRWAYS DISEASE	*	CLOZAPINE			70	F	
3892		JUL2019	PARKINSONISM CHRONIC OBSTRUCT AIRWAYS DISEASE	*	CLOZAPINE			69	Μ	
33893		JUL2019	PULMONARY CARCINOMA METASTASES NOS	*	CLOZAPINE	_		64	М	

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ORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT BEGAN ENDED	AGE S	
s 9(2)(a)	JUL2019	PNEUMONIA NEUTROPHILIA PARKINSONISM MYOCARDIAL ISCHAEMIA	* CLOZAPINE MADOPAR METOPROLOL LEVODOPA/CARBIDOPA (100/25) QUETIAPINE	s 9(2)(a)	82 1	s 9(2)(a) M
	JUL2019	PNEUMONIA PARKINSONISM	* CLOZAPINE	MA.	74 M ther	M
6	JUL2019	RESPIRATORY FAILURE LOWER RESP TRACT INFECTION PARKINSONISM	* CLOZAPINE	KOK	90 1	M
7	JUL2019	PNEUMONIA SEPTIC ARTHRITIS	* CLOZAPINE SELEGILINE LEVODOPA/CARBIDOPA (100/25) DONEPEZIL FLUCLOXACILLIN		74 1	M
8	JUL2019	PNEUMONIA	* CLOZAPINE		87 F	F
	JUL2019	MYOCARDIAL INFARCTION CORONARY ARTERY DISORDER	* CLOZAPINE		68 F	F
	AUG2019	NEUTROPHILIA LEUKOCYTOSIS	* CLOZAPINE		38 1	M
5	OCT2019	BLADDER CARCINOMA ASPIRATION PNEUMONITIS	* CLOZAPINE		61 F	F
6	OCT2019	PNEUMONIA INTESTINAL OBSTRUCTION MULTIPLE ORGAN FAILURE INFLUENZA-LIKE SYMPTOMS	* CLOZAPINE		58 1	M

PORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT BEGA	N ENDED AGE	SEX	OUTCOME
s 9(2)(a)	OCT2019	CARCINOMA COLON	* CLOZAPINE	s 9(2)(a)	51	Μ	s 9(2)(a)
818	OCT2019	RESPIRATORY FAILURE CHRONIC OBSTRUCT AIRWAYS DISEASE CARDIAC FAILURE HYPOVENTILATION OBESITY	* CLOZAPINE BUDESONIDE/EFORMOTEROL AMISULPRIDE TIOTROPIUM BROMIDE MOLAXOLE	MATI	50	М	
819	OCT2019	SEPSIS ASPIRATION PNEUMONITIS AORTIC STENOSIS	* CLOZAPINE	KOK	67	F	
820	OCT2019	RESPIRATORY FAILURE CHRONIC OBSTRUCT AIRWAYS DISEASE PNEUMONIA	* CLOZAPINE TIOTROPIUM /OLODATEROL FLUTICASONE CLONAZEPAM METFORMIN		65	Μ	
821	OCT2019	MYOCARDIAL INFARCTION	* CLOZAPINE		65	Μ	
822	OCT2019		* CLOZAPINE LORAZEPAM TRAMADOL TEMAZEPAM LITHIUM CARBONATE		76	F	
823	OCT2019	RESPIRATORY ARREST COR PULMONALE CHRONIC OBSTRUCT AIRWAYS DISEASE OBESITY CONSTIPATION	* CLOZAPINE AMISULPRIDE ATORVASTATIN DOCUSATE + SENNOSIDES INSULIN ASPART		50	Μ	
1824	OCT2019	MYOCARDIAL INFARCTION RESPIRATORY ARREST	* CLOZAPINE		70	М	

EPORT OR	RIGIN DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX OUTCOME
31786 S S	9(2)(a) _{FEB2019}	DIABETES INSIPIDUS NEPHROGENIC RENAL FAILURE ACUTE NEUTROPHILIA LEUKOCYTOSIS PNEUMONIA	* CLOZAPINE * LITHIUM CARBONATE	9(2)(a)	XION AND	82	s 9(2)(a)
2615	APR2019	SUDDEN DEATH	 * TRAMADOL * LITHIUM CARBONATE * METFORMIN * ALCOHOL (ETHYL) * GARCINIA 			47	Μ
34109	AUG2019	LITHIUM TOXICITY ENCEPHALOPATHY ACIDOSIS DIABETES INSIPIDUS NEPHROGENIC	* LITHIUM CARBONATE	1 Mr		60	F
1741	FEB2019	ARRHYTHMIA	* PALIPERIDONE				М
2131	MAR2019	SUICIDE	* PALIPERIDONE			26	М
<u>spiratory</u>							
S 9(32411	(Z)(A) APR2019	CHEST PAIN SUDDEN DEATH	* MEPOLIZUMAB ATORVASTATIN MONTELUKAST SODIUM UMECLIDINIUM BROMIDE PREDNISONE			54	M
33325 *****	JUN2019	INTESTINAL ISCHAEMIA	 * OMALIZUMAB * BREVINOR CYCLOSPORIN THYROXINE 			29	F

