



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 Centre

Table 6: Annual Report Fatal Cases January to December 2020

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 107 reports, identifying 129 suspect medicines, which resulted in a fatal outcome regardless of causality.

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE/UNIT	BEGAN ENDED	AGE	SEX	OUTCOME
Alimentary									
138845 *****	s 9(2)(a)	NOV2020	PNEUMONIA SEPSIS BRONCHIECTASIS	* CLOZAPINE * OMEPRAZOLE NICOTINE BUDESONIDE/EFORMOTEROL AMISULPRIDE		s 9(2)(a)	67	M	s 9(2)(a)
Blood and Blood forming organs									
137735 *****	s 9(2)(a)	JUL2020	INTESTINAL NECROSIS	* DABIGATRAN * IDARUCIZUMAB			76	M	
137934		AUG2020	PULMONARY HAEMORRHAGE	* DABIGATRAN			74	F	
137603		JUL2020	HAEMORRHAGE RETROPERITONEAL	* HEPARIN-LMW - ENOXAPARIN			79	M	
136017		FEB2020	CEREBRAL HAEMORRHAGE THROMBOSIS CEREBRAL	* RIVAROXABAN ACE INHIBITOR (NOS) THYROXINE PARACETAMOL UNCLASSIFIED AGENT			91	F	
137732		JUL2020	HAEMORRHAGE INTRACRANIAL FALL FRACTURE	* RIVAROXABAN			85	F	
135764		JAN2020	MYOCARDIAL INFARCTION THROMBOCYTOSIS ARM PAIN CHEST PAIN	* ELTROMBOPAG FELODIPINE CANDESARTAN METFORMIN CITALOPRAM			82	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137416	s 9(2)(a)	JUN2020	CHILLS	* HUMAN SERUM ALBUMIN PARACETAMOL ACETYLSALICYLIC ACID	s 9(2)(a)				73	F	s 9(2)(a)
137738 *****		JUL2020	HYPOTENSION BACK PAIN VOMITING RECTAL BLEEDING INFUSION REACTION	* IMMUNOGLOBULIN NORMAL MORPHINE SULPHATE * PLATELETS LAXSOL FAMOTIDINE					58	F	
Cardiovascular											
136174	s 9(2)(a)	FEB2020	SUDDEN DEATH	* VALSARTAN/SACUBITRIL					67	M	
137186		JUN2020	ABDOMINAL PAIN ANOREXIA BLOATING MELAENA	* ALIROCUMAB					79	F	
Genito Urinary System and Sex Hormones											
137895	s 9(2)(a)	AUG2020	UTERINE CARCINOMA	* OESTRIOL					71	F	
Systemic Hormones (excl Sex Hormones)											
135878	s 9(2)(a)	JAN2020	COLLAPSE CIRCULATORY HEART DISORDER	* OCTREOTIDE LAR					68	F	

Antiinfectives

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
136687	s 9(2)(a)	MAY2020	DRESS SYNDROME NEPHRITIS INTERSTITIAL	* AMOXICILLIN	s 9(2)(a)				80	F	s 9(2)(a)
136929		MAY2020	ANAEMIA APLASTIC	* CHLORAMPHENICOL PREDNISONE					70	F	
136250		MAR2020	JAUNDICE HEPATITIS CHOLESTATIC DEATH	* FLUCLOXACILLIN RIVAROXABAN BETAMETHASONE PARACETAMOL METOPROLOL					83	F	
135633 *****		JAN2020	HYPERKALAEMIA CARDIAC ARREST	* AMPHOTERICIN, LIPOSOMAL * GABAPENTIN * METHADONE PIPERACILLIN/TAZOBACTAM MULTIVITAMINS					42	F	
138123		AUG2020	CONGESTIVE HEART FAILURE HYPOXIA HYPOTENSION RENAL IMPAIRMENT HYPERKALAEMIA	* INTRAGAM P DOXYCYCLINE VALACICLOVIR METOPROLOL TIOTROPIUM /OLODATEROL					71	M	
135879		JAN2020	CHOLELITHIASIS DYSPNOEA FATIGUE MYOCARDIAL ISCHAEMIA CORONARY ARTERY DISORDER	* VIEKIRA PAK-RBV SALBUTAMOL					61	M	
137738 *****		JUL2020	HYPOTENSION BACK PAIN VOMITING RECTAL BLEEDING INFUSION REACTION	* IMMUNOGLOBULIN NORMAL MORPHINE SULPHATE * PLATELETS LAXSOL FAMOTIDINE					58	F	
137514		JUL2020	SUDDEN DEATH	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10					4m	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137890	s 9(2)(a)	AUG2020	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 10 CHOLECALCIFEROL FERROUS SULPHATE	s 9(2)(a)				1m	M	s 9(2)(a)
138219		SEP2020	SUDDEN INFANT DEATH SYNDROME	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10					6m	M	
136512		MAR2020	CHRONIC OBSTRUCT AIRWAYS DISEASE	* INFLUENZA - QUADRIVALENT					67	F	
136521		APR2020	SUDDEN DEATH	* INFLUENZA - QUADRIVALENT ATORVASTATIN BENDROFLUAZIDE FELODIPINE ACETYLSALICYLIC ACID					67	M	
136522		APR2020	SUDDEN DEATH	* INFLUENZA - QUADRIVALENT ATENOLOL ENALAPRIL FRUSEMIDE					71	F	
137611		JUL2020	UNCONSCIOUSNESS FIXED PUPILS	* INFLUENZA - QUADRIVALENT					85	M	
137514		JUL2020	SUDDEN DEATH	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10					4m	M	
137890		AUG2020	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 10 CHOLECALCIFEROL FERROUS SULPHATE					1m	M	
138219		SEP2020	SUDDEN INFANT DEATH SYNDROME	* DTaP-Hexa * PNEUMOCOCCAL VACC - 10					6m	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137890	s 9(2)(a)	AUG2020	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 10 * CHOLECALCIFEROL * FERROUS SULPHATE	s 9(2)(a)				1m	M	s 9(2)(a)
<u>Antineoplastics and Immunomodulating Agents</u>											
138095	s 9(2)(a)	AUG2020	MYALGIA PNEUMONITIS PROGRESSION OF DISEASE	* ALECTINIB * DABIGATRAN * FELODIPINE * CHOLECALCIFEROL * SALBUTAMOL	s 9(2)(a)				74	F	s 9(2)(a)
136300	s 9(2)(a)	MAR2020	CARDIOMYOPATHY DEATH	* DAUNORUBICIN * ANTHRACYCLINE NOS * DAUNORUBICIN	s 9(2)(a)				63	M	s 9(2)(a)
136027	s 9(2)(a)	FEB2020	LYMPHANGITIS PULMONARY INFILTRATION	* ATEZOLIZUMAB	s 9(2)(a)				64	F	s 9(2)(a)
136028	s 9(2)(a)	FEB2020	FEVER FATIGUE PROGRESSION OF DISEASE	* ATEZOLIZUMAB * COBIMETINIB	s 9(2)(a)				29	M	s 9(2)(a)
139042	s 9(2)(a)	NOV2020	PROGRESSION OF DISEASE	* ATEZOLIZUMAB * BEVACIZUMAB	s 9(2)(a)				71	M	s 9(2)(a)
138444	s 9(2)(a)	SEP2020	LEUKOENCEPHALOPATHY PROGRESSION OF DISEASE IMMUNE (IRIS) SYNDROME PNEUMONIA RESPIRATORY ARREST	* RITUXIMAB * BENDAMUSTINE * FLUDARABINE * MITOXANTRONE	s 9(2)(a)				64	F	s 9(2)(a)
139042	s 9(2)(a)	NOV2020	PROGRESSION OF DISEASE	* ATEZOLIZUMAB * BEVACIZUMAB	s 9(2)(a)				71	M	s 9(2)(a)

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137180	s 9(2)(a)	JUN2020	PROGRESSION OF DISEASE MEDICINE INEFFECTIVE	* PEMBROLIZUMAB * CARBOPLATIN * GEMCITABINE	s 9(2)(a)				69	M	s 9(2)(a)
137280		JUN2020	INTESTINAL PERFORATION	* CETUXIMAB ANTINEOPLASTIC AGENT(S) NOS					58	M	
136028		FEB2020	FEVER FATIGUE PROGRESSION OF DISEASE	* ATEZOLIZUMAB * COBIMETINIB					29	M	
137495		JUN2020	PROGRESSION OF DISEASE	* COBIMETINIB * VEMURAFENIB						M	
137623		JUL2020	CONVULSIONS DYSPHAGIA	* COBIMETINIB * VEMURAFENIB						M	
136300		MAR2020	CARDIOMYOPATHY DEATH	* DAUNORUBICIN * ANTHRACYCLINE NOS * DAUNORUBICIN					63	M	
136300		MAR2020	CARDIOMYOPATHY DEATH	* DAUNORUBICIN * ANTHRACYCLINE NOS * DAUNORUBICIN					63	M	
137180		JUN2020	PROGRESSION OF DISEASE MEDICINE INEFFECTIVE	* PEMBROLIZUMAB * CARBOPLATIN * GEMCITABINE					69	M	
136172		FEB2020	PROGRESSION OF DISEASE	* PEMBROLIZUMAB					50	M	
137180		JUN2020	PROGRESSION OF DISEASE MEDICINE INEFFECTIVE	* PEMBROLIZUMAB * CARBOPLATIN * GEMCITABINE					69	M	
137486		JUN2020	PROGRESSION OF DISEASE	* PEMBROLIZUMAB					70	F	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137885	s 9(2)(a)	AUG2020	PNEUMONIA	* PEMBROLIZUMAB	s 9(2)(a)				63	M	s 9(2)(a)
138323		SEP2020	RASH RHINITIS LACRIMATION INCREASED PROGRESSION OF DISEASE	* PEMBROLIZUMAB PEMETREXED CARBOPLATIN					62	M	
138952		NOV2020	CONVULSIONS AGGRAVATED	* PEMBROLIZUMAB					67	F	
138444		SEP2020	LEUKOENCEPHALOPATHY PROGRESSION OF DISEASE IMMUNE (IRIS) SYNDROME PNEUMONIA RESPIRATORY ARREST	* RITUXIMAB * BENDAMUSTINE FLUDARABINE MITOXANTRONE					64	F	
137118		MAY2020	PROGRESSION OF DISEASE	* TRASTUZUMAB					54	F	
139195		DEC2020	PROGRESSION OF DISEASE	* TRASTUZUMAB						F	
137420		JUN2020	PROGRESSION OF DISEASE	* VELIPARIB TEMOZOLOMIDE					20	M	
137495		JUN2020	PROGRESSION OF DISEASE	* COBIMETINIB * VEMURAFENIB						M	
137623		JUL2020	CONVULSIONS DYSPHAGIA	* COBIMETINIB * VEMURAFENIB						M	
138728		OCT2020	CARCINOMA COLON METASTASES NOS	* ADALIMUMAB					81	M	
135703		JAN2020	RENAL FAILURE ACUTE	* INFlixIMAB					53	F	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137053	s 9(2)(a)	MAY2020	PROGRESSION OF DISEASE	* LENALIDOMIDE DEXAMETHASONE CYCLOPHOSPHAMIDE	s 9(2)(a)				71	M	s 9(2)(a)
137487		JUN2020	PROGRESSION OF DISEASE	* LENALIDOMIDE					78	M	
136365		MAR2020	PROGRESSION OF DISEASE	* POMALIDOMIDE					69	F	
<u>Nervous System</u>											
137875	s 9(2)(a)	AUG2020	RESPIRATORY ARREST CARDIAC ARREST INTENTIONAL OVERDOSE	* CODEINE					62	F	
135633 ****		JAN2020	HYPERKALAEMIA CARDIAC ARREST	* AMPHOTERICIN, LIPOSOMAL * GABAPENTIN * METHADONE PIPERACILLIN/TAZOBACTAM MULTIVITAMINS					42	F	
136416		MAR2020	RESPIRATORY DEPRESSION CARDIAC ARREST AGITATION	* MIDAZOLAM * MORPHINE SULPHATE * MORPHINE SULPHATE DEXAMETHASONE					54	F	
136416		MAR2020	RESPIRATORY DEPRESSION CARDIAC ARREST AGITATION	* MIDAZOLAM * MORPHINE SULPHATE * MORPHINE SULPHATE DEXAMETHASONE					54	F	
137860		AUG2020	QT PROLONGED FIBRILLATION VENTRICULAR CARDIAC ARREST MULTIPLE ORGAN FAILURE CONVULSIONS	* OLANZAPINE * MORPHINE SULPHATE METHAMPHETAMINE					45	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
135633 ****	s 9(2)(a)	JAN2020	HYPERKALAEMIA CARDIAC ARREST	* AMPHOTERICIN, LIPOSOMAL * GABAPENTIN * METHADONE PIPERACILLIN/TAZOBACTAM MULTIVITAMINS	s 9(2)(a)				42	F	s 9(2)(a)
136332		MAR2020	CONVULSIONS THERAPEUTIC RESPONSE DECREASED	* LAMOTRIGINE LEVETIRACETAM					35	F	
137761		JUL2020	SUDDEN DEATH	* LAMOTRIGINE					22	F	
138645		OCT2020	SUDDEN DEATH	* LAMOTRIGINE TOPIRAMATE MIDAZOLAM					19	M	
137879		AUG2020	ASPIRATION PNEUMONITIS RIGORS NEUTROPENIA HYPERKALAEMIA	* LEVODOPA/CARBIDOPA (NOS) LORAZEPAM QUETIAPINE GABAPENTIN DOMPERIDONE					69	M	
138733		OCT2020	NEOPLASM MALIGNANT	* CHLORPROMAZINE * PARALDEHYDE						M	
135869		JAN2020	MYOCARDIAL ISCHAEMIA	* CLOZAPINE					55	M	
135870		JAN2020	SUICIDE	* CLOZAPINE DIAZEPAM OMEPRAZOLE MYLANTA					29	M	
135871		JAN2020	PNEUMONIA CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE MORPHINE SULPHATE PREDNISONE					50	M	
135872		JAN2020	PNEUMONIA	* CLOZAPINE					84	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
135873	s 9(2)(a)	JAN2020	PARKINSONISM ASPIRATION PNEUMONITIS	* CLOZAPINE LEVODOPA/CARBIDOPA (100/25) CODEINE FLUDROCORTISONE LORAZEPAM	s 9(2)(a)				68	M	s 9(2)(a)
135874		JAN2020	ARRHYTHMIA PARKINSONISM DEMENTIA TRANSIENT ISCHAEMIC ATTACK SYNCOPE	* CLOZAPINE MIDAZOLAM ACETYLSALICYLIC ACID MADOPAR ROPINIROLE					68	F	
135875		JAN2020	DEMENTIA	* CLOZAPINE					81	M	
135876		JAN2020	MYOCARDIAL ISCHAEMIA CORONARY ARTERY DISORDER	* CLOZAPINE					67	F	
135877		JAN2020	PARKINSONISM MYOCARDIAL INFARCTION PNEUMONIA	* CLOZAPINE					58	M	
135906		JAN2020	CARDIAC ARREST	* CLOZAPINE					43	M	
135907		JAN2020	APPENDICITIS ASPIRATION	* CLOZAPINE LORATADINE TERAZOSIN LAXSOL					77	M	
135908		JAN2020	MEGACOLON ACQUIRED STROKE	* CLOZAPINE					54	M	
135909		JAN2020	SUDDEN DEATH	* CLOZAPINE					38	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
135910	s 9(2)(a)	JAN2020	ASPIRATION PNEUMONITIS BOWEL MOTILITY DISORDER	* CLOZAPINE LEVOMEPRMAZINE DIAZEPAM HYOSCINE TOPICAL VALPROATE SODIUM	s 9(2)(a)				40	M	s 9(2)(a)
135911		JAN2020	PNEUMONIA	* CLOZAPINE					66	M	
135912		JAN2020	MELANOMA MALIGNANT	* CLOZAPINE					64	F	
135913		JAN2020	CONSTIPATION RECTAL ULCER INTESTINAL PERFORATION PERITONITIS	* CLOZAPINE DIAZEPAM LORAZEPAM PAROXETINE PROPRANOLOL					56	M	
135914		JAN2020	INTENTIONAL OVERDOSE	* CLOZAPINE					48	M	
135915		JAN2020	ASPIRATION INTESTINAL OBSTRUCTION RESPIRATORY ARREST RENAL FAILURE AGGRAVATED	* CLOZAPINE					67	M	
135916		JAN2020	HYPERTENSION HEART DISORDER LIVER FATTY HEPATIC CIRRHOSIS	* CLOZAPINE					64	F	
135917		JAN2020	CARDIAC ARREST	* CLOZAPINE					58	M	
135918		JAN2020	CARDIAC FAILURE DIABETES MELLITUS	* CLOZAPINE					75	F	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
135982	s 9(2)(a)	FEB2020	MEGACOLON ACQUIRED SEPSIS SECONDARY COLITIS DEATH	* CLOZAPINE	s 9(2)(a)				43	M	s 9(2)(a)
137377		JUN2020	PNEUMONIA	* CLOZAPINE					55	F	
137378		JUN2020	SUDDEN DEATH DRUG TOXICITY	* CLOZAPINE					55	M	
137379		JUN2020	MYOCARDIAL INFARCTION	* CLOZAPINE					55	M	
137380		JUN2020	ARRHYTHMIA	* CLOZAPINE					79	F	
137381		JUN2020	THROMBOSIS CORONARY	* CLOZAPINE PANTOPRAZOLE IMIPRAMINE AMISULPRIDE SALBUTAMOL					49	M	
137382		JUN2020	THROMBOSIS CORONARY	* CLOZAPINE					47	M	
137383		JUN2020	SUDDEN DEATH	* CLOZAPINE METFORMIN LAXSOL ARIPIPRAZOLE					17	M	
137385		JUN2020	SUDDEN DEATH	* CLOZAPINE METFORMIN BENZTROPINE MESYLATE PROPRANOLOL RISPERIDONE					43	M	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137451	s 9(2)(a)	JUN2020	ASPIRATION PNEUMONITIS PNEUMONIA	* CLOZAPINE MIDODRINE ACETYLSALICYLIC ACID DOCUSATE + SENNOSIDES FLUDROCORTISONE	s 9(2)(a)				78	M	s 9(2)(a)
137452		JUN2020	MYOCARDIAL INFARCTION RESPIRATORY DISORDER	* CLOZAPINE					61	M	
137453		JUN2020	STROKE DEMENTIA	* CLOZAPINE LEVOMEPRMAZINE					76	M	
137454		JUN2020	CARCINOMA	* CLOZAPINE MOCLOBEMIDE ATORVASTATIN METFORMIN CHOLECALCIFEROL					54	M	
137455		JUN2020	PNEUMONIA	* CLOZAPINE					78	M	
138843		NOV2020	PNEUMONIA NEOPLASM MALIGNANT PROGRESSION OF DISEASE	* CLOZAPINE					73	M	
138844		NOV2020	PNEUMONIA ATRIAL FIBRILLATION TACHYCARDIA VENTRICULAR CARDIAC ARREST	* CLOZAPINE OLANZAPINE					70	M	
138845 ****		NOV2020	PNEUMONIA SEPSIS BRONCHIECTASIS	* CLOZAPINE * OMEPRAZOLE NICOTINE BUDESONIDE/EFORMOTEROL AMISULPRIDE					67	M	
138846		NOV2020	PARKINSONISM	* CLOZAPINE APOMORPHINE LEVODOPA AMANTADINE MIRTAZAPINE					73	F	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
138847	s 9(2)(a)	NOV2020	SUDDEN DEATH	* CLOZAPINE ATENOLOL FRUSEMIDE LAXSOL OMEPRAZOLE	s 9(2)(a)				64	M	s 9(2)(a)
138848		NOV2020	SUDDEN DEATH MYOCARDIAL INFARCTION	* CLOZAPINE BENZTROPINE MESYLATE ATORVASTATIN					67	M	
138849		NOV2020	ASPIRATION PNEUMONITIS CONFUSION SOMNOLENCE FALL	* CLOZAPINE ALENDRONATE + CHOLECALCIFERO DONEPEZIL ESCITALOPRAM FLUDROCORTISONE					91	M	
138850		NOV2020	METASTASES NOS NEOPLASM MALIGNANT NEUTROPHILIA LEUKOCYTOSIS	* CLOZAPINE					52	M	
138851		NOV2020	DEMENTIA HEAD INJURY	* CLOZAPINE					72	M	
138852		NOV2020	DEMENTIA	* CLOZAPINE DONEPEZIL DOCUSATE + SENNOSIDES LORAZEPAM VENLAFAXINE					72	F	
139041		NOV2020	PNEUMONIA	* CLOZAPINE ESCITALOPRAM OMEPRAZOLE FLUTICASONE/SALMETEROL DORZOLAMIDE/TIMOLOL					80	F	
136416		MAR2020	RESPIRATORY DEPRESSION CARDIAC ARREST AGITATION	* MIDAZOLAM * MORPHINE SULPHATE * MORPHINE SULPHATE DEXAMETHASONE					54	F	

REPORT	ORIGIN	DATE	REACTIONS	DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
137860	s 9(2)(a)	AUG2020	QT PROLONGED FIBRILLATION VENTRICULAR CARDIAC ARREST MULTIPLE ORGAN FAILURE CONVULSIONS	* OLANZAPINE * MORPHINE SULPHATE * METHAMPHETAMINE	s 9(2)(a)				45	M	Died drug may be contributory Maori
136520		MAR2020	SUICIDE	* PALIPERIDONE					53	F	Died - cause unclassifiable Unknown
138733		OCT2020	NEOPLASM MALIGNANT	* CHLORPROMAZINE * PARALDEHYDE						M	Died - cause unclassifiable Unknown
137384		JUN2020	SUICIDE BLOOD DISORDER	* QUETIAPINE					59	M	Died - unrelated to drug Maori
137668		JUL2020	THERAPEUTIC RESPONSE DECREASED	* VENLAFAXINE * BISOPROLOL					45	M	Died - unrelated to drug European
Miscellaneous											
137735 *****	s 9(2)(a)	JUL2020	INTESTINAL NECROSIS	* DABIGATRAN * IDARUCIZUMAB					76	M	Died - cause unclassifiable Unknown
137578		JUL2020	FEELING UNWELL SUDDEN DEATH	* M&P VITAL ALL-IN-ONE					78	F	Died - cause unclassifiable European

Table 6: Annual Report Fatal Cases - 2021

REPORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE	BEGAN ENDED	AGE	SEX	OUTCOME/ETH
A Alimentary								
B Blood and Blood forming organs								
139677	s 9(2)(a)	FEB2021 HEPATOCELLULAR DAMAGE LOWER RESP TRACT INFECTION RASH	* ERLOTINIB * RIVAROXABAN DEXAMETHASONE MORPHINE SULPHATE FAMOTIDINE	s 9(2)(a)		71	Female	s 9(2)(a)
141782		AUG2021 CARDIAC ARREST	* IRON CARBOXYMALTOSE			76	Male	
141884		AUG2021 SUBARACHNOID HAEMORRHAGE HYDROCEPHALUS	* RIVAROXABAN DICLOFENAC LANSOPRAZOLE PARACETAMOL			65	Male	
142681		NOV2021 HAEMATEMESIS CEREBRAL HAEMORRHAGE	* ROMIPLOSTIM			64	Male	
142789		NOV2021 SUBARACHNOID HAEMORRHAGE HAEMORRHAGE SUBDURAL CEREBRAL HAEMORRHAGE	* DABIGATRAN ATORVASTATIN EMPAGLIFLOZIN METOPROLOL QUINAPRIL			54	Male	
C Cardiovascular								
D Dermatological								
G Genito Urinary System and Sex Hormones								
H Systemic Hormones (excl Sex Hormones)								
J Anti-infectives								
140732	s 9(2)(a)	MAY2021 PROGRESSION OF DISEASE	* INFLUENZA - QUADRIVALENT * PFIZER COVID-19 mRNA VACCINE ACETYLSALICYLIC ACID QUINAPRIL CITALOPRAM	s 9(2)(a)		83	Female	s 9(2)(a)

140863	s 9(2)(a)	MAY2021	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 10	0	Female	s 9(2)(a)
141456		JUN2021	EMBOLISM PULMONARY	* GSK RSV Vaccine Study 214488	62	Male	
142203		SEP2021	RESPIRATORY FAILURE PARALYSIS NEUROPATHY	* INFLUENZA - TRIVALENT	81	Female	
142238		SEP2021	FLUID OVERLOAD	* INTRAGAM P BISOPROLOL PIPERACILLIN/TAZOBACTAM ALLOPURINOL VALACICLOVIR	79	Female	

L Antineoplastics and Immunomodulating Agents

139644	s 9(2)(a)	JAN2021	BLADDER CARCINOMA	* ADALIMUMAB	61	Male	s 9(2)(a)
139677		FEB2021	HEPATOCELLULAR DAMAGE LOWER RESP TRACT INFECTION RASH	* ERLOTINIB * RIVAROXABAN DEXAMETHASONE MORPHINE SULPHATE FAMOTIDINE	71	Female	
141693		JUL2021	DUODENAL ULCER PERFORATED HAEMORRHAGE RETROPERITONEAL	* SECUKINUMAB	62	Male	
142282		SEP2021	RENAL FAILURE ACUTE	* BICALUTAMIDE	85	Male	
142328		OCT2021	BRAIN METASTASES PROGRESSION OF DISEASE	* ALECTINIB * LORLATINIB MORPHINE SULPHATE CELECOXIB	55	Male	
142335		OCT2021	SUDDEN DEATH	* BEVACIZUMAB	76	Female	
142342		OCT2021	SUDDEN DEATH	* POLATUZUMAB * RITUXIMAB		Male	

142588	s 9(2)(a)	NOV2021	NEUTROPENIA SEPSIS SHOCK-LIKE SYMPTOM THROMBOCYTOPENIA	* RITUXIMAB FOLIC ACID PREDNISON CILAZAPRIL NAPROXEN	s 9(2)(a)	53	Female	s 9(2)(a)
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M Musculoskeletal
N Nervous System

139400	s 9(2)(a)	JAN2021	DROWNING	* LAMOTRIGINE	s 9(2)(a)	36	Male	s 9(2)(a)
139556		JAN2021	LEUKOCYTOSIS NEOPLASM MALIGNANT NEUTROPHILIA	* CLOZAPINE MIDODRINE FERROUS FUMARATE		52	Femal	
139557		JAN2021	BRONCHIECTASIS	* CLOZAPINE LORATADINE LORAZEPAM TEMAZEPAM ALENDRONATE + CHOLECALCIFE		75	Femal	
139558		JAN2021	NEOPLASM MALIGNANT	* CLOZAPINE VALPROATE SODIUM ATENOLOL ATORVASTATIN BENZTROPINE MESYLATE		60	Male	
139559		JAN2021	NEOPLASM MALIGNANT	* CLOZAPINE		69	Male	
139842		FEB2021	LYMPHOCYTOSIS HAEMOGLOBIN DECREASED HAEMATOCRIT DECREASED MYOCARDIAL INFARCTION	* CLOZAPINE		88	Femal	
141207		JUN2021	MYOCARDIAL ISCHAEMIA OVERDOSE EFFECT	* NORTRIPTYLINE SERTRALINE TOPIRAMATE ZOPICLONE FLUTICASONE/SALMETEROL		40	Male	

141491 [REDACTED] JUL2021 HEPATIC ENZYMES INCREASED * PREGABALIN

[REDACTED] s 9(2)(a)

76 Female [REDACTED] s 9(2)(a)

- P** Antiparasitic Products, Insecticides and Repellents
- R** Respiratory System
- S** Sensory Organs
- V** Miscellaneous

Table 6: Annual Report Fatal Cases - 2022

REPORT ORIGIN	DATE	REACTIONS	DRUGS	ROUTE DOSE	BEGAN ENDED	AGE	SEX	OUTCOME/ETH	
A Alimentary									
145301	s 9(2)(a)	OCT2022	DRUG EXPOSURE IN PREGNANCY DEATH FOETAL FOETAL DISORDERS FOETAL DISTRESS POTTERS SYNDROME	* EMPAGLIFLOZIN * LOSARTAN	s 9(2)(a)		0	Female	s 9(2)(a)
B Blood and Blood forming organs									
143354	s 9(2)(a)	MAR2022	HAEMATOMA	* DABIGATRAN	s 9(2)(a)		83	Female	s 9(2)(a)
143526		APR2022	HAEMORRHAGE INTRAABDOMINAL SHOCK HAEMORRHAGIC RENAL FAILURE ACUTE	* HEPARIN-LMW - ENOXAPARIN			72	Female	
144398		JUL2022	EMBOLISM ARTERIAL PERIPHERAL ISCHAEMIA MULTIPLE ORGAN FAILURE	* DABIGATRAN			84	Female	
C Cardiovascular									
143014	s 9(2)(a)	JAN2022	INTERSTITIAL LUNG DISEASE	* AMIODARONE PIPERACILLIN/TAZOBACTAM	s 9(2)(a)		75	Male	s 9(2)(a)
143342		MAR2022	HEPATIC FAILURE HEPATORENAL SYNDROME ENCEPHALOPATHY	* TOLVAPTAN			73	Male	
144472		JUL2022	DYSPNOEA CHEST X-RAY ABNORMAL INTERSTITIAL LUNG DISEASE PLEURAL EFFUSION CARDIAC ARREST	* AMIODARONE FRUSEMIDE AMOXICILLIN/CLAVULANIC ACID DOXYCYCLINE			68	Male	
145301		OCT2022	DRUG EXPOSURE IN PREGNANCY DEATH FOETAL FOETAL DISORDERS FOETAL DISTRESS POTTERS SYNDROME	* EMPAGLIFLOZIN * LOSARTAN			0	Femal	

145977	s 9(2)(a)	DEC2022	ANGIOEDEMA	* QUINAPRIL ALLOPURINOL OMEPRAZOLE METOPROLOL PREDNISONE	s 9(2)(a)	62	Male	s 9(2)(a)
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D Dermatological
G Genito Urinary System and Sex Hormones
 section 9(2)(a)

H Systemic Hormones (excl Sex Hormones)

145254	s 9(2)(a)	OCT2022	SEPTICAEMIA	* TOFACITINIB * PREDNISONE CYCLOPHOSPHAMIDE CYCLOSPORIN IMMUNOGLOBULIN NORMAL	s 9(2)(a)	65	Female	s 9(2)(a)
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J Anti-infectives

143687	s 9(2)(a)	APR2022	ERYTHRODERMA PETECHIAE ORAL MUCOSA HAEMATURIA PROTEINURIA ANAEMIA	* CEFTRIAXONE * VANCOMYCIN AMLODIPINE DOXAZOSIN SPIRONOLACTONE	s 9(2)(a)	83	Male	s 9(2)(a)
143830		MAY2022	SUDDEN DEATH	* ROTA VIRUS VACCINE * DTaP-Hexa * PNEUMOCOCCAL VACC - 10 PARACETAMOL		0	Male	
143861		MAY2022	DIZZINESS NAUSEA VOMITING HAEMOGLOBIN DECREASED BLOOD IN VOMIT	* NIRMATRELVIR+RITONAVIR DOXAZOSIN RIVAROXABAN DEXAMETHASONE ANTINEOPLASTIC AGENT(S) NOS		70	Male	
143900		MAY2022	INTERSTITIAL LUNG DISEASE RENAL FAILURE ACUTE	* METHOTREXATE * COTRIMOXAZOLE - BACTRIM GROUP PREDNISONE		56	Femal	

Section 9 (2)(a)

L Antineoplastics and Immunomodulating Agents								
143421	s 9(2)(a)	MAR2022	DIARRHOEA COLITIS PANCYTOPENIA BONE MARROW DEPRESSION SEPTICAEMIA	* CAPECITABINE PARACETAMOL METOPROLOL QUETIAPINE ROSUVASTATIN	s 9(2)(a)	68	Female	s 9(2)(a)
143900		MAY2022	INTERSTITIAL LUNG DISEASE RENAL FAILURE ACUTE	* METHOTREXATE * COTRIMOXAZOLE - BACTRIM GROUP PREDNISONE		56	Female	
144199		JUN2022	SHAKING SHIVERING PNEUMONIA EYE PAIN THERAPEUTIC RESPONSE DECREASED	* ADALIMUMAB		73	Male	
145254		OCT2022	SEPTICAEMIA	* TOFACITINIB * PREDNISONE CYCLOPHOSPHAMIDE CYCLOSPORIN IMMUNOGLOBULIN NORMAL		65	Female	
M Musculoskeletal								

143028	s 9(2)(a)	JAN2022	DRESS SYNDROME STEVENS JOHNSON SYNDROME	* ALLOPURINOL	s 9(2)(a)	63	Male	s 9(2)(a)
146005		DEC2022	THROMBOCYTOPENIA	* IBUPROFEN TICAGRELOR		75	Female	

N Nervous System								
143785	s 9(2)(a)	MAY2022	HEPATOCELLULAR DAMAGE	* VALPROATE SODIUM	s 9(2)(a)	70	Male	s 9(2)(a)
145315		OCT2022	DEMENTIA MULTIPLE ORGAN FAILURE	* CLOZAPINE LEVODOPA/CARBIDOPA (NOS) ALENDRONATE SOLIFENACIN DOCUSATE SODIUM		84	Female	
145316		OCT2022	SUICIDE	* CLOZAPINE		48	Male	
145317		OCT2022	LYMPHOPENIA HAEMATOCRIT DECREASED DEMENTIA	* CLOZAPINE		76	Male	
145321		OCT2022	ASPIRATION PNEUMONITIS GI HAEMORRHAGE	* CLOZAPINE		89	Male	
145361		OCT2022	ASPIRATION PNEUMONITIS CONSTIPATION COLITIS CONVULSIONS HAEMOGLOBIN DECREASED	* CLOZAPINE MIDODRINE LEVODOPA/CARBIDOPA (NOS) ESCITALOPRAM ACETYLSALICYLIC ACID		82	Male	
145363		OCT2022	NEUTROPENIA PNEUMONIA SEPSIS MULTIPLE ORGAN FAILURE ERYTHROCYTOPENIA	* CLOZAPINE		71	Male	
145364		OCT2022	ASPIRATION PNEUMONITIS	* CLOZAPINE DOCUSATE + SENNOSIDES ALLOPURINOL MACROGOL 3350 MADOPAR		69	Male	

145365	s 9(2)(a)	OCT2022 SUICIDE	* CLOZAPINE LAXSOL CODEINE FLUOXETINE ZOPICLONE	s 9(2)(a)	23	Female	s 9(2)(a)
145367		OCT2022 DEMENTIA	* CLOZAPINE HYOSCINE BUTYLBROMIDE LEVODOPA/CARBIDOPA (NOS) HYDROXOCOBALAMIN LACTULOSE		80	Male	
145369		OCT2022 PNEUMONIA DRUG LEVEL INCREASED PULMONARY CARCINOMA POST-OPERATIVE COMPLICATION NOS	* CLOZAPINE		58	Male	
145415		OCT2022 METABOLIC SYNDROME	* CLOZAPINE		60	Female	
145416		OCT2022 LOWER RESP TRACT INFECTION RESPIRATORY FAILURE	* CLOZAPINE METFORMIN SIMVASTATIN OMEPRAZOLE ARIPIPRAZOLE		71	Male	
145420		OCT2022 CARCINOMA SQUAMOUS METASTASES NOS	* CLOZAPINE		76	Male	
145421		OCT2022 LYMPHOMA MALIGNANT	* CLOZAPINE		67	Female	
145423		OCT2022 CARDIAC ARREST	* CLOZAPINE		41	Male	
145459		OCT2022 DEMENTIA CACHEXIA	* CLOZAPINE MORPHINE SULPHATE CILAZAPRIL THYROXINE OMEPRAZOLE		78	Female	
145465		OCT2022 DEMENTIA	* CLOZAPINE MADOPAR CLONAZEPAM CELECOXIB RIVASTIGMINE		74	Male	

145467	s 9(2)(a)	OCT2022 ASPIRATION PNEUMONITIS	* CLOZAPINE	s 9(2)(a)	77	Female	s 9(2)(a)
145546		NOV2022 CARDIAC FAILURE	* CLOZAPINE RISPERIDONE GLICLAZIDE VALPROATE SODIUM VILDAGLIPTIN		55	Male	
145547		NOV2022 MYOCARDITIS CARDIOMYOPATHY CARDIAC FAILURE	* CLOZAPINE		74	Male	
145548		NOV2022 VOMITING ASPIRATION PNEUMONIA DROWSINESS	* CLOZAPINE LEVODOPA/CARBIDOPA (200/50) ENTACAPONE VENLAFAXINE GABAPENTIN		71	Male	
145549		NOV2022 PANCREAS NEOPLASM MALIGNANT CACHEXIA ANAEMIA	* CLOZAPINE CLONAZEPAM SIMVASTATIN LACTULOSE		50	Male	
145550		NOV2022 CARDIAC FAILURE	* CLOZAPINE INSULIN GLARGINE INSULIN ASPART		45	Male	
145838		DEC2022 CARCINOMA COLON	* CLOZAPINE LAXSOL VITAMIN D		63	Male	
145842		DEC2022 RENAL FAILURE CHRONIC	* CLOZAPINE		59	Male	
145900		DEC2022 UNCONSCIOUSNESS COLLAPSE CIRCULATORY HEART DISORDER	* CLOZAPINE		60	Male	
145902		DEC2022 MELANOMA MALIGNANT	* CLOZAPINE SERTRALINE LORAZEPAM LAXSOL		81	Male	

145904	s 9(2)(a)	DEC2022 NEUTROPHILIA PNEUMONIA	* CLOZAPINE BENZTROPINE MESYLATE HALOPERIDOL FLUOXETINE TETRABENAZINE	s 9(2)(a)	46	Male	s 9(2)(a)
145906		DEC2022 PNEUMONIA ASPIRATION ASTHENIA	* CLOZAPINE ATROPINE MADOPAR FLUDROCORTISONE POTASSIUM CHLORIDE		87	Female	
145907		DEC2022 SHOCK CIRCULATORY	* CLOZAPINE		51	Female	
145908		DEC2022 PNEUMONIA	* CLOZAPINE VENLAFAXINE CYCLIZINE MORPHINE SULPHATE		92	Female	
145909		DEC2022 HYPOXIA CHRONIC OBSTRUCT AIRWAYS DISEASE	* CLOZAPINE DIHYDROCODEINE METFORMIN EMPAGLIFLOZIN ATORVASTATIN		51	Male	
145911		DEC2022 DYSPNOEA COVID-19 VIRUS POSITIVE ASPIRATION	* CLOZAPINE		86	Male	
145912		DEC2022 PULMONARY OEDEMA INTESTINAL OBSTRUCTION MYOCARDIAL INFARCTION BRONCHOPNEUMONIA	* CLOZAPINE		61	Male	

P	Antiparasitic Products, Insecticides and Repellents
R	Respiratory System
S	Sensory Organs
V	Miscellaneous