AU-TGA-0000516823

Case details:

Original received date: 18/01/2021

Creation date: 26/07/2023

Date sent to WHO: 27/07/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: No

Sender details:

s.22

Sender type: Health Professional

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 41 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group:

Ethnicity:

Reporter details:

Phone:

Case narrative:

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Serotonin syndrome			Recovered/resolved

Drug information:

Product name	Role characterisation	Action taken
TN007121 Sertraline Hydrochloride - Tradename not specified	Interacting	Drug withdrawn

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Reported Indication/s

PTSD

Product name	Role characterisation	Action taken
TN008727 Tradename not specified - Tradename not specified	Interacting	

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000516823

Sender details

Are you a health professional	Yes
Profession	Medical Practitioner (Other)
Business name	[redacted]
Business type	Clinic/practice
Title	s.22 [redacted]
First name	
Last name	
Email	
Telephone	
Address 1	
Address 2	
Town/City	
State	
Post code	

Patient details

Patient	[redacted]
Date of birth	
Age at time of adverse event	41 (Number) Year/s (Unit)
Sex	Male
Body Weight (Kg)	
Ethnicity	
Ethnic sub-group	
In which Australian state did the adverse event begin	

Medicine details

1) Product role in adverse event Suspected
Trade/Brand name Setraline
AUST L/R number
Action taken with medicine Stopped dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date
Unknown				

Reason for use

Reason for use
PTSD

Report generated 18/01/2021 09:58:13

Reaction(s)

Reaction description	Start date	End date	Outcome
Sertonin syndrome: unwell, seizure, worsened mood			Recovered/resolved

Further information

Adverse event narrative [redacted]

Have you reported this adverse event to someone else Yes

Name of individual/business [redacted]

Date 15-Jan-2021

Supporting documentation

Title	Type

AU-TGA-0000744955

Case details:

Original received date: 7/07/2022

Creation date: 23/10/2023

Date sent to WHO: 24/10/2023

Modified on: 31/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

Masked Masked

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 17 (Year)

Date of birth:

Pregnancy status: N/A

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Physician

Phone:

Literature Reference:

Anderson LL, Arnold JC, McGregor IS, Nation TR. A Potential Drug-Gene-Drug Interaction Between Cannabidiol, CYP2D6*4, and Fluoxetine: A Case Report. J-Clin-Psychopharmacol 2022;:no pagination.

Case narrative:

Anderson LL, Arnold JC, McGregor IS, Nation TR. A Potential Drug-Gene-Drug Interaction Between Cannabidiol, CYP2D6*4, and Fluoxetine: A Case Report. J-Clin-Psychopharmacol 2022;:no pagination.

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Agitation			Recovered/resolved
Akathisia			Recovered/resolved
Condition aggravated			Recovered/resolved
Drug interaction			Unknown
Drug-genetic interaction			Recovered/resolved
Insomnia			Recovered/resolved
Mydriasis			Recovered/resolved
Obsessive-compulsive disorder			Recovered/resolved
Psychomotor hyperactivity			Recovered/resolved

Drug information:

Product name	Role characterisation	Action taken
TN004367 Loratadine - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
10.000000 Milligram			Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN002730 Fluoxetine Hydrochloride - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
20.000000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN006591 Risperidone - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
1.000000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Oral			

Reported Indication/s

Autism spectrum disorder

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
36.000000 Milligram	1 Day		Oral			

Product name	Role characterisation	Action taken
TN001886 Clonidine Hydrochloride - Tradename not specified	Interacting	Unknown

Active Ingredient/s

clonidine hydrochloride ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.100000 Milligram			Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

AU-TGA-0000746908

Case details:

Original received date: 6/07/2022

Creation date: 23/10/2023

Date sent to WHO: 24/10/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

s.22

Sender type:

Sender's ICSR identifier:

Patient details:

Patient initials: Privacy

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 17 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group:

Ethnicity:

Reporter details:

Physician

Phone:

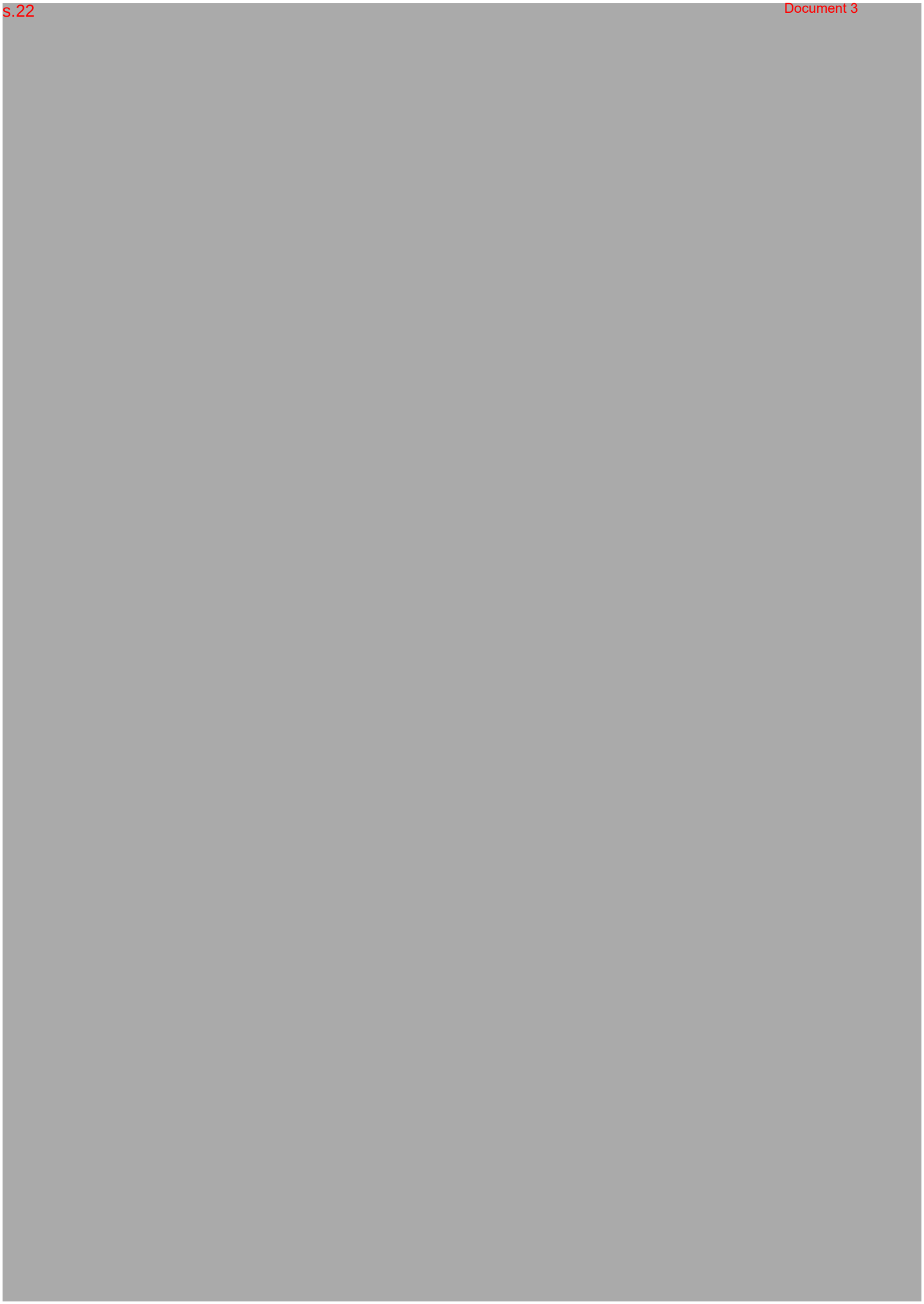
Literature Reference:

Anderson LL, Arnold JC, McGregor IS, Nation TR..A Potential Drug-Gene-Drug Interaction Between Cannabidiol, CYP2D6 4, and Fluoxetine: A Case Report..A Case Report. Journal of clinical psychopharmacology. 2022;42(4):.DOI:DOI: 10.1097/JCP.0000000000001568

Case narrative:

This case was detected in the medical literature by the EMA MLM Service from Anderson LL, Arnold JC, McGregor IS, Nation TR. A Potential Drug-Gene-Drug Interaction Between Cannabidiol, CYP2D6 4, and Fluoxetine: A Case Report. Journal of clinical psychopharmacology. 2022:42(4) on 14 Jun 2022.

s.22



Reactions:

Preferred term	Onset date	End date	Outcome
Agitation			Recovered/resolved
Akathisia			Recovered/resolved
Condition aggravated			Recovered/resolved
Drug interaction			Recovered/resolved
Drug-genetic interaction			Recovered/resolved
Insomnia			Recovered/resolved
Mydriasis			Recovered/resolved
Obsessive-compulsive disorder			Recovered/resolved
Psychomotor hyperactivity			Recovered/resolved
Screaming			Recovered/resolved

Drug information:

Product name	Role characterisation	Action taken
TN002730 Fluoxetine Hydrochloride - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
20.000000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s
Product used for unknown indication

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
18.000000 Milligram			Oral			

Reported Indication/s
Autism spectrum disorder

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Oral			

Product name	Role characterisation	Action taken
TN006591 Risperidone - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
1.000000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN004367 Loratadine - Tradename not specified	Interacting	Unknown

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
10.000000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN001886 Clonidine Hydrochloride - Tradename not specified	Interacting	Unknown

Active Ingredient/s

clonidine hydrochloride ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
0.100000 Milligram	1 Day		Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

Test name	Test date	Normal range
R2 to R3 transformation		-

Test result

Comments

s.22

AU-TGA-0000785155

Case details:

Original received date: 12/03/2014

Creation date: 31/10/2023

Date sent to WHO: 2/11/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

Masked Masked

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Female

Another term:

Gender:

Different Term:

Weight:

Age: 30 (Year)

Date of birth:

Pregnancy status:

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Other health professional

Phone:

Literature Reference:

Pilgrim JL, Gerostamoulos D, Drummer OH.. The prevalence of duloxetine in medico-legal death investigations in Victoria, Australia (2009-2012).. Forensic Science International.. 2014;234:165-73

Case narrative:

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Drug interaction			Fatal
Toxicity to various agents			Fatal

Drug information:

Product name	Role characterisation	Action taken
TN002212 Tradename not specified - Tradename not specified	Interacting	Not applicable

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Product name	Role characterisation	Action taken
TN002536 Diazepam - Tradename not specified	Interacting	Not applicable

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Product name	Role characterisation	Action taken
TN004249 Methadone Hydrochloride - Tradename not specified	Interacting	Not applicable

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Product name	Role characterisation	Action taken
TN006126 Paracetamol - Tradename not specified	Interacting	Not applicable

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Product name	Role characterisation	Action taken
TN006463 Quetiapine - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

quetiapine fumarate ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Product name	Role characterisation	Action taken
TN009522 Tradename not specified - Tradename not specified	Interacting	Not applicable

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch

Reported Indication/s

Drug use for unknown indication

Additional information

DELTA-9 TETRAHYDROCANNABINOL

Tests and procedures:

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result: Unknown

Comments

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result: Unknown

Comments

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result:0.01 Unit:mg/L

Comments

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result: [redacted] Unit:mg/L

Comments

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result: [redacted] Unit:mg/L

Comments

Test name | **Test date** | **Normal range**

[redacted] | | -

Test result

Test Result: [redacted] Unit:mg/L

Comments

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result: [redacted] Unit:mg/L

Comments

Test name	Test date	Normal range
R2 to R3 transformation		-

Test result

Comments

s.22 [redacted]

AU-TGA-0000786239

Case details:

Original received date: 4/09/2023

Creation date: 12/09/2023

Date sent to WHO: 14/09/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

Masked Masked

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 23 (Year)

Date of birth:

Pregnancy status:

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Other health professional

Phone:

Literature Reference:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

Case narrative:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Drug interaction			Fatal
Toxicity to various agents			Fatal

Drug information:

Product name	Role characterisation	Action taken
TN007422 Tilray - THC/CBD 1:1 Ratio 10mg/mL - Tilray - THC/CBD 1:1 Ratio 10mg/mL	Interacting	Not applicable

Active Ingredient/s

cannabidiol ( )

DRONABINOL ( )

dronabinol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN000407 Alprazolam - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

ALPRAZOLAM ( )

alprazolam ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008655 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

COCAINE ( )

Illicit Product ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result: Unknown

Comments

Test name	Test date	Normal range
R2 to R3 transformation		-

Test result

Comments

[redacted]

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result: Unknown

Comments

AU-TGA-0000786353

Case details:

Original received date: 4/09/2023

Creation date: 13/09/2023

Date sent to WHO: 15/09/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

Masked Masked

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 39 (Year)

Date of birth:

Pregnancy status:

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Other health professional

Phone:

Literature Reference:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

Case narrative:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

s.22

[redacted]

Reactions:

Preferred term	Onset date	End date	Outcome
Condition aggravated			Fatal
Drug interaction			Fatal
Myocardial ischaemia			Fatal
Myocarditis			Fatal
Serotonin syndrome			Fatal

Drug information:

Product name	Role characterisation	Action taken
TN007428 Tilray CBD - Tilray CBD	Interacting	Not applicable

Active Ingredient/s

cannabidiol ( )

DRONABINOL ( )

dronabinol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN002033 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

CITALOPRAM ( )

citalopram hydrobromide ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN006126 Paracetamol - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

PARACETAMOL ( )

paracetamol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008655 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

COCAINE ( )

Illicit Product ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN002071 Codeine - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

CODEINE ( )

codeine ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

Test name **Test date** **Normal range**

-

Test result

Test Result: Unknown

Comments

Test name **Test date** **Normal range**

R2 to R3 transformation -

Test result

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result: Unknown

Comments

AU-TGA-0000786356

Case details:

Original received date: 4/09/2023

Creation date: 13/09/2023

Date sent to WHO: 15/09/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

Masked Masked

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 52 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group:

Ethnicity:

Reporter details:

Other health professional

Phone:

Literature Reference:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

Case narrative:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic-Sci-Int 2013;227:52-59.

s.22

[redacted]

Reactions:

Preferred term	Onset date	End date	Outcome
Arteriosclerosis coronary artery			Fatal
Condition aggravated			Fatal
Drug interaction			Fatal

Drug information:

Product name	Role characterisation	Action taken
TN007422 Tilray - THC/CBD 1:1 Ratio 10mg/mL - Tilray - THC/CBD 1:1 Ratio 10mg/mL	Interacting	Not applicable

Active Ingredient/s

cannabidiol ( )

DRONABINOL ( )

dronabinol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN006126 Paracetamol - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

PARACETAMOL ( )

paracetamol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008655 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

COCAINE ( )

Illicit Product ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
		Unknown	Information Not Provided By Sponsor			

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result: Unknown

Comments

Test name	Test date	Normal range
R2 to R3 transformation		-

Test result

Comments

[redacted]

Test name	Test date	Normal range
Toxicologic test		-

Test result

Test Result: Unknown

Comments

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result: Unknown

Comments

AU-TGA-0000786442

Case details:

Original received date: 4/09/2023

Creation date: 14/09/2023

Date sent to WHO: 19/09/2023

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

s.22

Sender type: Pharmaceutical Company

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 54 (Year)

Date of birth:

Pregnancy status:

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Other health professional

Phone:

Literature Reference:

Pilgrim JL, Woodford N, Drummer OH. Cocaine in sudden and unexpected death: A review of 49 post-mortem cases. Forensic Science International. 2013;227:52-59

Case narrative:

Individual case safety report reference number 2023-07766 received on 04-SEP-2023 is a literature report received from Australia. This case pertains to a 54-years-old, male patient (case 18 from table 1) who died due to combined drug

[redacted]

Reactions:

Preferred term	Onset date	End date	Outcome
Drug interaction			Fatal
Toxicity to various agents			Fatal

Drug information:

Product name	Role characterisation	Action taken
TN005243 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

MORPHINE SULFATE ( )

MORPHINE SULFATE PENTAHYDRATE ( )

morphine sulfate pentahydrate ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Information Not Provided By Sponsor			Unknown

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008655 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

COCAINE ( )

Illicit Product ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Information Not Provided By Sponsor			Unknown

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN009522 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

DELTA(9)-TETRAHYDROCANNABINOLIC ACID ( )

tetrahydrocannabinol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Information Not Provided By Sponsor			Unknown

Reported Indication/s

Drug use for unknown indication

Product name	Role characterisation	Action taken
TN008655 Tradename not specified - Tradename not specified	Interacting	Not applicable

Active Ingredient/s

DIAMORPHINE ( )

Illicit Product ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Information Not Provided By Sponsor			Unknown

Reported Indication/s

Drug use for unknown indication

Tests and procedures:

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:less than [redacted] Unit:milligram per litre

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:[redacted] Unit:milligram per litre

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:[redacted] Unit:milligram per litre

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:less than [redacted] Unit:milligram per litre

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:[redacted] Unit:milligram per litre

Comments

Test name **Test date** **Normal range**

Toxicologic test -

Test result

Test Result:[redacted] Unit:milligram per litre

Comments

Test name	Test date	Normal range
[redacted]		-

Test result

Test Result:Detected [redacted]

Comments

AU-TGA-0000790311

Case details:

Original received date: 21/11/2023

Creation date: 22/11/2023

Date sent to WHO: 23/11/2023

Modified on: 31/01/2026

Decision Reason: Causality possible

Serious ICSR: No

Sender details:

s.22

Sender type: Health Professional

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 53 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group:

Ethnicity:

Reporter details:

Phone:

Case narrative:

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Drug interaction			Recovered/resolved with sequelae

Drug information:

Product name	Role characterisation	Action taken
TN009522 Tradename not specified - Tradename not specified	Interacting	Dose not changed

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Inhalation			

Reported Indication/s

Chronic pain

Product name	Role characterisation	Action taken
TN001344 Carbamazepine - Tradename not specified	Interacting	

Product name	Role characterisation	Action taken
TN000331 Amitriptyline - Tradename not specified	Interacting	

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000790311

Sender details

Are you a health professional	Yes
Profession	Nurse
Business name	s.22
Business type	
Title	
First name	
Last name	
Email	
Telephone	
Address 1	
Address 2	
Town/City	
State	
Post code	

Patient details

Patient	
Date of birth	
Age at time of adverse event	53 (Number) Year/s (Unit)
Sex	Male
Body Weight (Kg)	
Ethnicity	
Ethnic sub-group	
In which Australian state did the adverse event begin	

Vaccine details

Did the patient receive a vaccine? No

Additional information for immunisation

Was the vaccinated person pregnant at the time of vaccination?
Has the vaccinated person had previous reactions to vaccinations?
Has the vaccinated person ever been diagnosed with COVID-19?
Medical history

Vaccination Provider

Where given	Organisation name	State

Report generated 21/11/2023 17:56:30

Medicine details

1) Product role in adverse event Interaction
Trade/Brand name THC
AUST L/R number
Action taken with medicine Continued at same dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date
0.25 grams	Inhalation			

Reason for use

Reason for use
Chronic pain

Reaction(s)

Reaction description	Start date	End date	Outcome
Possible drug interaction			Recovered/resolved with sequelae

Further information

Adverse event narrative s.22 [redacted]

Have you reported this adverse event to someone else No
Name of individual/business
Date

Supporting documentation

Title	Type

AU-TGA-0000807086

Case details:

Original received date: 15/04/2024

Creation date: 15/04/2024

Date sent to WHO: 27/04/2024

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: No

Sender details:

s.22

Unknown

Sender type: Health Professional

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 71 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group: Australian

Ethnicity: Australian Peoples

Reporter details:

Phone:

Case narrative:

Reactions:

Preferred term	Onset date	End date	Outcome
Condition aggravated	[redacted]		Unknown
Insomnia			Recovering/resolving

Drug information:

Product name	Role characterisation	Action taken
TN010751 Althea THC20 : CBD1 - Althea THC20 : CBD1	Interacting	Dose not changed

Active Ingredient/s

cannabidiol ( )

tetrahydrocannabinol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
				[redacted]		1132321

Reported Indication/s

Insomnia

Osteoarthritis

Product name	Role characterisation	Action taken
TN009768 OZEMPIC - OZEMPIC	Interacting	Drug withdrawn

Active Ingredient/s

Semaglutide ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
				[redacted]		NP5K306

Reported Indication/s

Type 2 Diabetes

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000807086

Sender details

Are you a health professional	Yes
Profession	Pharmacist
Business name	
Business type	Other
Title	
First name	s.22
Last name	
Email	
Telephone	
Address 1	
Address 2	
Town/City	
State	
Post code	

Patient details

Patient	
Date of birth	
Age at time of adverse event	71 (Number) Year/s (Unit)
Sex	Male
Body Weight (Kg)	
Ethnicity	Australian Peoples
Ethnic sub-group	Australian
In which Australian state did the adverse event begin	

Vaccine details

Did the patient receive a vaccine? No

Additional information for immunisation

Was the vaccinated person pregnant at the time of vaccination?
Has the vaccinated person had previous reactions to vaccinations?
Has the vaccinated person ever been diagnosed with COVID-19?
Medical history

Vaccination Provider

Where given	Organisation name	State

Report generated 15/04/2024 11:27:14

Medicine details

1) Product role in adverse event Interaction
Trade/Brand name Althea TCH 20: CBD1
AUST L/R number 344013
Action taken with medicine Continued at same dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

2) Product role in adverse event Interaction
Trade/Brand name Ozempic
AUST L/R number 315107
Action taken with medicine Stopped dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date
0.25mg (18 clicks) weekly		NP5K306	[redacted]	

Reason for use

Reason for use
Type 2 Diabetes

Reaction(s)

Reaction description	Start date	End date	Outcome
increased insomnia	[redacted]		Recovering/resolving

Further information

Adverse event narrative BACKGROUND: s.22 [redacted]

MEDICAL HISTORY: [redacted]

Report generated 15/04/2024 11:27:14

s.22 [redacted]

Have you reported this adverse event to someone else No
Name of individual/business
Date

Supporting documentation

Title	Type

AU-TGA-0000807847

Case details:

Original received date: 24/04/2024

Creation date: 24/04/2024

Date sent to WHO: 7/05/2024

Modified on: 31/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

s.22

Unknown

Sender type: Patient/Consumer

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Female

Another term:

Gender:

Different Term:

Weight:

Age: 34 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group: Australian

Ethnicity: Australian Peoples

Reporter details:

Phone:

Literature Reference:

Case narrative:

s.22

[redacted]

Reactions:

Preferred term	Onset date	End date	Outcome
Hyperthyroidism	[redacted]		Recovering/resolving
Nausea			Recovering/resolving
Thyroxine free increased			Unknown

Drug information:

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn

Active Ingredient/s

cannabidiol ( )

Dosage/s

Dose	Interval	Dose form	Route of admin	Start date	End date	Batch
			Oral			

Reported Indication/s

Chronic back pain

Complex PTSD

Product name	Role characterisation	Action taken
TN004284 Tradename not specified - Tradename not specified	Interacting	

Active Ingredient/s

levothyroxine sodium ( )

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000807847

Sender details

Are you a health professional No
Profession
Business name
Business type
Title s.22
First name
Last name
Email
Telephone
Address 1
Address 2
Town/City
State
Post code

Patient details

Patient
Date of birth
Age at time of adverse event 34 (Number) Year/s (Unit)
Sex Female
Body Weight (Kg)
Ethnicity Australian Peoples
Ethnic sub-group Australian
In which Australian state did the adverse event begin

Vaccine details

Did the patient receive a vaccine? No

Additional information for immunisation

Was the vaccinated person pregnant at the time of vaccination?
Has the vaccinated person had previous reactions to vaccinations?
Has the vaccinated person ever been diagnosed with COVID-19?
Medical history

Vaccination Provider

Where given	Organisation name	State

Report generated 24/04/2024 12:22:47

Medicine details

1) Product role in adverse event Interaction
Trade/Brand name CBD Oil 100
AUST L/R number
Action taken with medicine Stopped dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date
Titrated dose that started at 0.25ml BID and reached 1.75ml BID	Oral		[redacted]	

Reason for use

Reason for use
Chronic back pain
Complex PTSD

Reaction(s)

Reaction description	Start date	End date	Outcome
Caused hyperthyroidism	[redacted]		Recovering/resolving

Further information

Adverse event narrative

s.22 [redacted]

s.22

[redacted]

Supporting documentation

Title	Type
March 2023	Other
October 2023	Other
February 2024	Other
Preclinical Science and Clinical Studies – Review Article	Literature Article

AU-TGA-0000818986

Case details:

Original received date: 28/08/2024

Creation date: 28/08/2024

Date sent to WHO: 30/08/2024

Modified on: 31/01/2026

Decision Reason: Causality possible

Serious ICSR: Yes

Sender details:

s.22

Unknown

Sender type: Patient/Consumer

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 51 (Year)

Date of birth:

Pregnancy status:

State:

Ethnicity sub-group: Australian

Ethnicity: Australian Peoples

Reporter details:

Phone:

Case narrative:

Reactions:

Preferred term	Onset date	End date	Outcome
Psychotic disorder			Recovering/resolving

Drug information:

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn
Active Ingredient/s		
cannabidiol ( )		

Product name	Role characterisation	Action taken
TN005063 Modafinil - Tradename not specified	Interacting	Drug withdrawn
Active Ingredient/s		
modafinil ( )		

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000818986

Sender details

Are you a health professional No
Profession
Business name
Business type
Title s.22
First name
Last name
Email
Telephone
Address 1
Address 2
Town/City
State
Post code

Patient details

Patient
Date of birth
Age at time of adverse event 51 (Number) Year/s (Unit)
Sex Male
Body Weight (Kg)
Ethnicity Australian Peoples
Ethnic sub-group Australian
In which Australian state did the adverse event begin

Vaccine details

Did the patient receive a vaccine? No

Additional information for immunisation

Was the vaccinated person pregnant at the time of vaccination?
Has the vaccinated person had previous reactions to vaccinations?
Has the vaccinated person ever been diagnosed with COVID-19?
Medical history

Vaccination Provider

Where given	Organisation name	State

Report generated 28/08/2024 14:49:34

Medicine details

1) Product role in adverse event Suspected
Trade/Brand name Cannabis
AUST L/R number
Action taken with medicine Continued at same dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

Reaction(s)

Reaction description	Start date	End date	Outcome
Psychotic episode	[redacted]	[redacted]	Recovering/resolving

Further information

Adverse event narrative

s.22 [redacted]

Have you reported this adverse event to someone else No
Name of individual/business
Date

Supporting documentation

Title	Type
Discharge summary	Clinical Record
Discharge summary 3	Clinical Record
Discharge summary 2.1	Hospital Record
Discharge summary 3	Hospital Record
Discharge summary 4	Hospital Record
Discharge summary 5	Hospital Record

Report generated 28/08/2024 14:49:34

Discharge summary 6	Hospital Record
Discharge summary 7	Hospital Record

AU-TGA-0000823049

Case details:

Original received date: 22/10/2024

Creation date: 22/10/2024

Date sent to WHO: 23/10/2024

Modified on: 30/01/2026

Decision Reason: Causality possible

Serious ICSR: No

Sender details:

s.22

Unknown

Sender type: Health Professional

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age:

Date of birth:

Pregnancy status: Unknown

State: UNK

Ethnicity sub-group:

Ethnicity:

Reporter details:

Phone:

Case narrative:

s.22

Reactions:

Preferred term	Onset date	End date	Outcome
Agitation			Recovered/resolved
Anger			Recovered/resolved
Anxiety			Recovered/resolved
Paranoia			Recovered/resolved

Drug information:

Product name	Role characterisation	Action taken
TN013176 Dispensed Black Mountain dried cannabis flower - Dispensed Black Mountain dried cannabis flower	Interacting	Dose not changed
Active Ingredient/s		
cannabidiol ( )		
tetrahydrocannabinol ( )		

Product name	Role characterisation	Action taken
TN006042 Phenergan - Phenergan	Interacting	
Active Ingredient/s		
promethazine hydrochloride ( )		

Product name	Role characterisation	Action taken
TN002504 Dymista - Dymista	Concomitant	
Active Ingredient/s		
azelastine hydrochloride ( )		
fluticasone propionate ( )		

Product name	Role characterisation	Action taken
TN006354 Promethazine Hydrochloride - Tradename not specified	Concomitant	
Active Ingredient/s		
promethazine hydrochloride ( )		

Product name	Role characterisation	Action taken
TN005218 Montelukast - Tradename not specified	Concomitant	
Active Ingredient/s		
montelukast sodium ( )		

Tests and procedures:

TGA eBusiness Services Adverse Event Report for a Medicine or Vaccine

Your identifier:
TGA identifier: AU-TGA-0000823049

Sender details

Are you a health professional	Yes
Profession	Pharmacist
Business name	
Business type	Community pharmacy
Title	s.22
First name	
Last name	
Email	
Telephone	
Address 1	
Address 2	
Town/City	
State	
Post code	

Patient details

Patient	
Date of birth	
Age at time of adverse event	
Sex	Male
Body Weight (Kg)	
Ethnicity	
Ethnic sub-group	
In which Australian state did the adverse event begin	

Vaccine details

Did the patient receive a vaccine? No

Additional information for immunisation

Was the vaccinated person pregnant at the time of vaccination?
Has the vaccinated person had previous reactions to vaccinations?
Has the vaccinated person ever been diagnosed with COVID-19?
Medical history

Vaccination Provider

Where given	Organisation name	State

Report generated 22/10/2024 10:24:22

Medicine details

1) Product role in adverse event Suspected
Trade/Brand name Dispensed Black Mountain THC 32% Flower 10g
AUST L/R number
Action taken with medicine Continued at same dose

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

2) Product role in adverse event Not suspected (concomitant)
Trade/Brand name promethazine hydrochloride tablets
AUST L/R number
Action taken with medicine

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

3) Product role in adverse event Not suspected (concomitant)
Trade/Brand name Montelukast tablet
AUST L/R number
Action taken with medicine

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

4) Product role in adverse event Not suspected (concomitant)
Trade/Brand name Dymista azelastine (as hydrochloride) / fluticasone propionate 125 ug/50ug per spray
AUST L/R number

Action taken with medicine

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

Reaction(s)

Reaction description	Start date	End date	Outcome
Paranoid reaction			Recovered/resolved

Further information

Adverse event narrative

[redacted]

Have you reported this adverse event to someone else
Name of individual/business
Date

Supporting documentation

Title	Type

AU-TGA-0000863258

Case details:

Original received date: 11/02/2026

Creation date: 11/02/2026

Date sent to WHO: 13/02/2026

Modified on: 31/07/2026

Decision Reason: Causality possible

Serious ICSR: No

Sender details:

s.22

Unknown

Sender type: Patient/Consumer

Sender's ICSR identifier:

Patient details:

Patient initials:

Sex: Male

Another term:

Gender:

Different Term:

Weight:

Age: 46 (Year)

Date of birth:

Pregnancy status: No

State:

Ethnicity sub-group: Neither Aboriginal nor Torres Strait Islander

Ethnicity: Australian Peoples

Reporter details:

Phone:

Case narrative:

Reactions:

Preferred term	Onset date	End date	Outcome
Adverse event			Unknown

Drug information:

Product name	Role characterisation	Action taken
TN008483 Tradename not specified - Tradename not specified	Interacting	Drug withdrawn
Active Ingredient/s		
cannabidiol ( )		
cannabidiol ( )		
tetrahydrocannabinol ( )		

Product name	Role characterisation	Action taken
TN005606 Olanzapine - Tradename not specified	Interacting	
Active Ingredient/s		
olanzapine ( )		

Tests and procedures:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Adverse Event Report for a Medicine or Vaccine

Your case identifier [redacted]
TGA identifier AU-TGA-0000863258

Reporter details

Are you a health professional? No
Profession
Business name
Business type
Title s.22
First name
Last name
Email (Preferred)
Telephone

Patient details

Patient [redacted]
Date of birth [redacted]
Age at time of adverse event 46 (Number) Year/s (Unit)
Sex (Recorded at Birth) Male
Another term
Gender Man or Male
Different term
Was the patient pregnant when administered the vaccine/medicine? No
Gestation (Weeks)
Body Weight (Kg) [redacted]
Is the patient of Aboriginal or Torres Strait Islander origin? No
Ethnicity Australian Peoples
In which state was the vaccine/medicine administered? [redacted]

Vaccine details

Are you reporting an adverse event relating to a vaccine? No

Provider details

Where given	Organisation name	State
Clinic	[redacted]	[redacted]
Clinic	[redacted]	[redacted]

Medicine details

1) Product role in adverse event Suspected

Trade/Brand name Cannabis Flower, CBD, Gummies all
AUST L/R number
Action taken with medicine Not applicable

Dosage information

Dosage amount	Route of administration	Batch/lot number	Start date	End date

Reason for use

Reason for use

List reactions

Reaction/symptom	Start date	End date	Outcome
COUNTERACTIVE WITH PHARMA MEDS			Unknown

Reaction details

Describe the reaction/symptom

s.22

Provide medical background

No

Supporting documentation

Title	Type