

MINISTERIAL INFORMATION REQUEST

MB20-001710

Date Sent to MO: 28/05/20

MINISTER: Greg Hunt**Issue:** Adverse Events - Lyrica - Depression / Suicide - Senator Murray Watt
obo s22**Response:**

The Therapeutic Goods Administration (TGA) within the Department of Health is responsible for the regulation of medicines in Australia, including continued monitoring for safety, quality and efficacy once a product is available on the market.

s22

All medicines can have serious side effects. The potential benefits offered by a medicine and the potential risks associated with its use should always be balanced by the prescriber against other available treatment options, or no treatment.

The decision to prescribe a medicine should also be made in the setting of informed consent, including a discussion about possible side effects and monitoring.

Product Information (PI) documents and Consumer Medicine Information (CMI) documents are available to help health professionals and patients make informed choices about whether a particular medicine may be suitable: www.ebs.tga.gov.au.

Suicidal ideation is a known potential risk for Lyrica (pregabalin). The PI contains the following warning:

Suicidal Behaviour and Ideation: Antiepileptic drugs (AED), including LYRICA, increase the risk of suicidal thoughts or behaviour in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviour, and/or any unusual changes in mood or behaviour.

In addition, the CMI includes:

Tell your doctor immediately if you have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression. Some people taking medicines to treat convulsions, such as Lyrica, have had thoughts of harming themselves or taking their life. Patients and caregivers should be alert and monitor for these effects.

Patients and caregivers should be alert and monitor for these effects. Signs and symptoms of suicidal risk include:

- thoughts or talk of death or suicide.
- thoughts or talk of self-harm or harm to others.
- any recent attempts of self-harm.
- new or an increase in aggressive behaviour, irritability or agitation.
- new or worsening depression.

Mention of suicide or violence must be taken seriously. If you or someone you know is demonstrating these warning signs of suicide while taking Lyrica, contact your doctor or a mental health professional right away.

In 2014, the TGA published an article entitled 'Pregabalin and suicidality' that included a reminder to health professionals to 'Advise patients and caregivers of the risk of suicidality and educate them regarding the associated symptoms and the need to contact you if they experience any' (www.tga.gov.au/publication-issue/medicines-safety-update-volume-5-number-6-december-2014#pregabalin). We continue to closely monitor this issue.

While the TGA regulates therapeutic goods, we do not regulate health professionals or clinical practice. Complaints regarding clinical practice issues are matters for the Australian Health Practitioner Regulation Agency (AHPRA). Further information is available on the AHPRA website: www.ahpra.gov.au.

Minister Greg Hunt

PDR Number MB20-001710

Issue MIR: Lyrica (Sen Murray Watt obo **s22**)

Contact Officer Dr Grant Pegg
s22

Clearance Officer Adj Prof John Skerritt
(02) 6289 4200
0438 800 407

Division/Branch Medicines Regulation

Adviser/DLO Comments:

Return for
Redraft

From: [HPRG Parliamentary](#)
To: [s22](#) [@pmc.gov.au](#)
Cc: [OTB: s22](#) [HPRG Parliamentary](#)
Subject: FW: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]
Date: Tuesday, 27 November 2018 12:51:50 PM
Attachments: [image001.png](#)

Good afternoon [s22](#),

Please see below input as requested. This has been Deputy Secretary cleared by Adj Prof John Skerritt.

- *The TGA is finalising an investigation into the misuse of pregabalin in Australia, and will refer the issue to the Advisory Committee on Medicines, prior to implementing any regulatory action in Australia.*
- *As part of this investigation, the TGA has commissioned a study to explore pregabalin prescribing patterns in General Practice, which will help to inform any regulatory response.*
- *The Product Information (PI) for pregabalin currently includes precautions regarding the risks of substance misuse, abuse and dependence and suicidal behaviour/ideation.*
- *The TGA publishes adverse event reports we receive in the searchable Database of Adverse Event Notifications (DAEN) available online at:
<https://www.tga.gov.au/database-adverse-event-notifications-daen>*
- *The DAEN currently includes 7 cases coded with reaction term "suicide attempt" and 6 cases coded with reaction term "completed suicide".*
- *NB - The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. Adverse events are suspected of being related to a medicine, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors. There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was given.*

Prescription of a medicine for a condition other than which the medicine is approved is known as "off-label" use. Off-label use is not illegal and is a decision made by the prescriber and their patient based on the risks and benefits of use of the medicine in those individual circumstances. TGA does not regulate clinical practice

Kind regards,

[s22](#)

HPRG Regulatory Engagement Services

Ministerial Correspondence / Ministerial Submissions

Ministerial Briefs / QTBs

Reporting and Collaborative Services Section

Regulatory Engagement & Planning Branch

Health Products Regulation Group

Phone: [s22](#)

Mobile: [s22](#)

Email: [s22](#) [@health.gov.au](#)

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: s22 [mailto:s22@pmc.gov.au]
Sent: Tuesday, 27 November 2018 9:50 AM
To: ATODB Coordination
Cc: QTB; s22
Subject: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]

For Official Use Only

Good morning colleagues

There are reports in the media of increases in overdoses and suicides linked to Pregabalin:

<https://www.smh.com.au/national/popular-pain-drug-linked-to-rise-in-overdoses-suicides-20181125-p50i6n.html>

Can you please share any lines you have prepared in response to this, or a QTB if you have prepared one.

Thanks in advance

s22
Public Health and Primary Care | Health and Sport Branch
Social Policy Division | Department of the Prime Minister and Cabinet



The Department acknowledges the Traditional Custodians of Country throughout Australia and their continuing connection to land, waters and community. We pay our respect to their Cultures, Country and Elders both past and present.

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From: [HPRG Parliamentary](#)
To: s22
Cc: s22
Subject: RE: Request for input: MC20-029026 [SEC=OFFICIAL]
Date: Monday, 20 July 2020 3:53:31 PM
Attachments: [image001.png](#)

Good afternoon,

Please find below our cleared suggested content for your consideration:

Suicidal ideation is listed in the 'Special warnings and precautions for use' section of the Product Information (PI) for pregabalin (Lyrica). Warnings surrounding discontinuation of Lyrica are also listed in this section, and include symptoms such as: insomnia, headache, nausea, anxiety, excessive sweating and diarrhoea. In addition, consumer-targeted information regarding these adverse events are detailed in the Consumer Medicine Information (CMI). These documents are available on the TGA website:

www.ebs.tga.gov.au

The TGA conducted a review of the risk of suicide-related events with regard to off-label use of pregabalin in 2014. Given the serious nature of suicidal ideation and suicidal behaviour as adverse events, an outcome of this investigation was to remind prescribers of this potential risk. A Medicines Safety Update (MSU) article was published in Australian Prescriber in December 2014. This MSU (Volume 5, Number 6, December 2014, 'Pregabalin and suicidality') is available on the TGA website:

www.tga.gov.au/publication-issue/medicines-safety-update-volume-5-number-6-december-2014

Separate to the above issue, the TGA is currently conducting a review of hazardous and harmful use of pregabalin in Australia.

Please let us know if there is anything further we can assist with.

Regards,

s22

HPRG Regulatory Engagement Services

Reporting and Collaborative Services Section

Ministerial Correspondence | Ministerial Submissions | Ministerial Briefs | QTBs

s22

Regulatory Practice & Support Division | Health Products Regulation Group
 Regulatory Engagement, Education and Planning Branch
 Australian Government Department of Health

T: s22 | M: s22 | E: s22@health.gov.au

Location: Symonston, GE.32

From: s22@health.gov.au>

Sent: Thursday, 16 July 2020 2:36 PM

To: HPRG Parliamentary <s22@health.gov.au>

Cc: s22@health.gov.au>

Subject: Request for input: MC20-029026 [SEC=OFFICIAL]

Good afternoon,

We would be most grateful with your assistance to respond to the MinCorro below.

In particular, we would appreciate your input in relation to adverse events associated with Lyrica, and whether there may have been any further reviews undertaken by the TGA since the addition of warnings in 2008.

We would appreciate your input by **Friday 24 July 2020**.

Please feel free to contact me should you wish to discuss.

Kind regards

s22

Accreditation and Registration Policy Section

Health Workforce Division

Health Workforce Reforms Branch

Australian Government Department of Health

T: s22 | E: s22@health.gov.au

Location: Sirius Building 6.N.322

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: Minister Hunt <Minister.Hunt@health.gov.au>

Sent: Monday, 13 July 2020 11:12 PM

To: MPS s22@health.gov.au

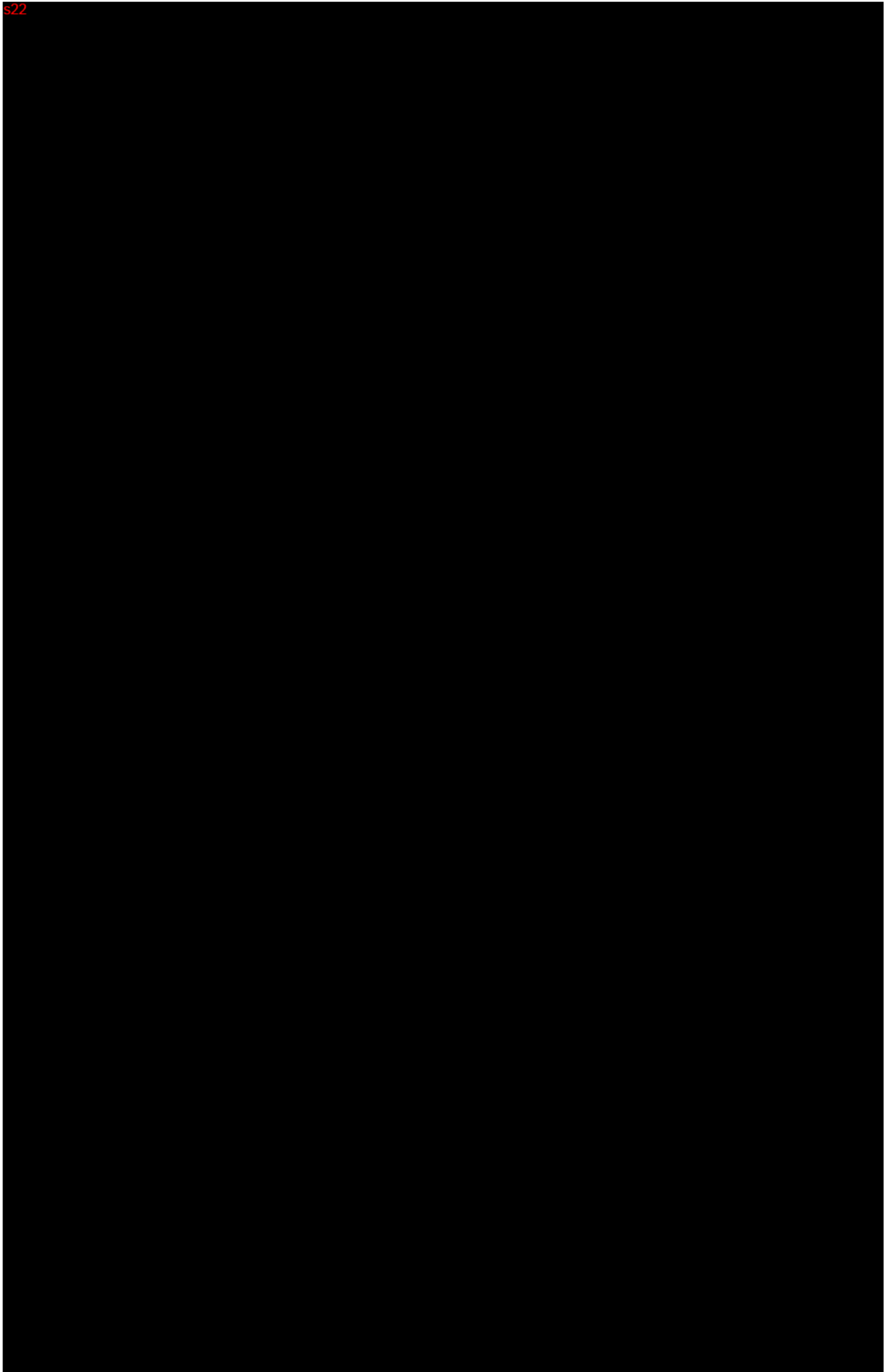
Subject: MC20-029026

MC20-029026

D response - HWD

s22





s22

From: [HPRG Parliamentary](#)
To: [SKERRITT, John](#)
Cc: s22 [HPRG Parliamentary](#)
Subject: CLEARANCE - Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]
Date: Tuesday, 27 November 2018 12:13:07 PM
Attachments: [image002.png](#)
[image003.png](#)

Hi John,

PM&C have requested some input or our QTB on Lyrica misuse (see below). While we don't have a QTB Jane has cleared the release of the below given it was a previously cleared media response. Grateful for your clearance please.

- *The TGA is finalising an investigation into the misuse of pregabalin in Australia, and will refer the issue to the Advisory Committee on Medicines, prior to implementing any regulatory action in Australia.*
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Kind regards,

s22

HPRG Regulatory Engagement Services

Ministerial Correspondence / Ministerial Submissions

Ministerial Briefs / QTBs

Reporting and Collaborative Services Section

Regulatory Engagement & Planning Branch

Health Products Regulation Group

Phone: s22

Mobile: s22

Email: s22 [@health.gov.au](#)

Therapeutic Goods Administration

Department of Health

PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: COOK, Jane
Sent: Tuesday, 27 November 2018 11:12 AM
To: s22; HPRG Parliamentary
Cc: s22; PEGG, Grant; s22
Subject: RE: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]
Hi s22

I think we can just send the response below. Noting that they did use the figures we provided in the article.

Jane

From: s22
Sent: Tuesday, 27 November 2018 11:08 AM
To: HPRG Parliamentary; COOK, Jane
Cc: s22; PEGG, Grant; s22
Subject: RE: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]
Dear Jane and s22,

We haven't prepared a QTB for pregabalin, however we have responded to a number of media enquiries on this issue.

Our most recent media response cleared by Jane was:

- *The TGA is finalising an investigation into the misuse of pregabalin in Australia, and will refer the issue to the Advisory Committee on Medicines, prior to implementing any regulatory action in Australia.*
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Jane – will that suffice for a response to PM&C, or would you like us to prepare a QTB (noting that this investigation sits with s22)?

Kind regards,

s22

Signal Investigation Unit
Pharmacovigilance and Special Access Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: HPRG Parliamentary

Sent: Tuesday, 27 November 2018 10:22 AM

To: PEGG, Grant

Cc: s22; HPRG Parliamentary

Subject: FW: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]

Good morning Grant,

Further to the emails below could you please provide AS cleared input to the below request for FAS clearance. PM&C have not provided a deadline but if you're able to provide something by COB today that would be great. Please let me know if this timeframe isn't able to be achieved and I will contact them and request more information.

Kind regards,

s22

HPRG Regulatory Engagement Services

Ministerial Correspondence / Ministerial Submissions

Ministerial Briefs / QTBs

Reporting and Collaborative Services Section

Regulatory Engagement & Planning Branch

Health Products Regulation Group

Phone: s22

Mobile: s22

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

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From: s22
Sent: Tuesday, 27 November 2018 10:11 AM
To: HPRG Parliamentary
Cc: QTB; PHSD Coords; s22
Subject: FW: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]

Hi Parli,

MRD will take carriage of this. This request sits best with PSAB.

Could you please send this response through to Grant Pegg, CCing s22 and s22 ?

Kind regards,

s22

Medicines Regulation Division

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: QTB
Sent: Tuesday, 27 November 2018 10:06 AM
To: PHSD Coords
Cc: QTB; s22
Subject: FW: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]
 Hi s22

This request seems to have been sent from PM&C to the Alcohol, Tobacco and Other Drugs Branch. However, I believe it should sit with Med Reg Division.

Could you please confirm that the ATODB does not own this request for input?

cheers

s22

QTB Team

Ministerial, Governance and Cabinet Branch | People, Communication & Parliamentary Division

T: s22 | M: s22 | E: s22@health.gov.au

I acknowledge the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. I pay my respects to them and to elders both past and present.

From: s22 [mailto:s22@pmc.gov.au]
Sent: Tuesday, 27 November 2018 9:50 AM
To: ATODB Coordination
Cc: QTB; s22
Subject: Pregabalin (Lyrica) misuse [DLM=For-Official-Use-Only]

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Can you please share any lines you have prepared in response to this, or a QTB if you have prepared

one.

Thanks in advance

s22

Public Health and Primary Care | Health and Sport Branch
Social Policy Division | Department of the Prime Minister and Cabinet

p. s22



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